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NARRATIVE MATTERS



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A Black Alzheimer's Patient Wants To Be Part Of The Cure

A daughter gets her mother into a clinical trial for an Alzheimer's drug, with few other black patients enrolled.

BY KATTI GRAY

At her thirty-third appearance as Subject 16019 in a clinical trial of an experimental drug she hoped would fix “this little problem with my memory,” Sandra Brannon sank into a medical exam room’s recliner and waited.

“What’s the date again?” Sandra asked me. I had escorted her to a wing at Bellevue Hospital Center, in Manhattan, where NYU Langone Medical Center was conducting the trial—one of 210

institutions worldwide doing so. As a family friend, I was standing in for Sandra’s only child and chief caregiver, Monica Montgomery. Thirty-five-year-old Monica was a globetrotter and had business elsewhere that morning.

“November eighteenth,” I answered.

I’d responded to the same question from Sandra four times during our twenty-seven-minute ride from a Brooklyn Bridge subway station to Bellevue.

“Right. Got it.” Sandra scribbled my reply on her cheat sheet as a nurse

bounded through the door to prep her for her monthly intravenous infusion of the experimental drug solanezumab, which Eli Lilly developed to target mild cognitive impairment caused by Alzheimer’s.

“How was your commute here?” the nurse began.

Sandra had been diagnosed with Alzheimer’s in 2011, at the age of sixty-four. She was sixty-nine on that day at Bellevue. Sandra’s mother had died of the incurable degenerative disease in March 2004 at the age of eighty-three, about seven years after her diagnosis.

“Any changes in your health since the last time we saw you?” the nurse continued, probing Sandra. “You know what today is?”

Sandra cheerfully wiggled and snapped her fingers. She let out a blip of laughter and grinned.

“The third of May?” She hesitated, looked at the nurse’s raised eyebrows, and realized she’d gotten it wrong. “No. Ummm—oh, yes, it’s November eighteenth, Friday.”

“You looked at your pad, huh?” the nurse said, smiling and gently patting Sandra’s hand. She pushed two plastic water-cooler cups toward her: “You’re dehydrated, and we can’t get the needle into your vein easily when you’re dehydrated. Drink this.”

That cheat sheet of scribbled notes and details had become Sandra’s brace and comfort during visits to that special NYU Langone wing at Bellevue. It was ground zero in her quest for something—anything—to slow her dementia. As a black woman, she played a critical role in the trial, and not just because of her own plight: Blacks and Latinos are diagnosed with Alzheimer’s more often than whites. Yet during those many visits to that wing, Sandra seemed to be the only black patient present. Ever.

“From the beginning of this,” Monica told me, “I’d see lots of little white ladies lovingly leading their girlfriends into the office and asking questions: ‘I hear you have a clinical trial for Alzheimer’s? We want to get in that.’ But hardly

ever—if ever—did I see others of us, black people, there signing up for the same thing.”

When Eli Lilly reported preliminary results of the trial in December 2016, the data told a similar story: 90.8 percent of the trial participants who reported their race were white, 1.7 percent black.

Getting Into The Trial

Sandra grew up in Washington, D.C., the child of a schoolteacher and a preacher, and moved to New York straight out of high school to study art at the Pratt Institute. I'd met her and Monica more than twenty years earlier at Emmanuel Baptist Church in Brooklyn. At the time, Monica was active in the church's Teen Canteen group, Sandra was a trustee, and I did double duty as a choir member and newsletter editor.

At the start of our surrogate kinship, Sandra was assistant principal at a high school. She'd gone into education after being a graphic designer at the *New York Times* and CBS News. She switched careers as computer-made illustrations were supplanting the pen-and-pencil renderings that she preferred. Plus, an educator's work hours were more suited to raising a child during a rocky marriage. She and her husband, a college professor, divorced when Monica was a teenager.

Time was when Sandra, voluble and vibrant, commanded a room, weighing in on any discussion and perhaps, to liven things up, peppering the conversation with cuss words.

Monica was living in D.C. when she first noticed Sandra's lapses. Sandra had driven there to visit her, but on her way back to New York, she called Monica to ask what highway she was supposed to take.

Over time, Sandra started repeating herself and misplacing things. “She was having these small accidents,” Monica says. “Bumping a street sign with her car. Losing her keys, wallet. It was scary, nerve-racking.

“And I instantly knew what it was.”

Years earlier, Monica had been involved, hands-on, in her grandmother's twenty-four-hour care at the end of her life. Eventually, home health aides were hired as well.

“I knew this thing ran in families,”



Monica says. “I felt this disappointment and dread, and rugged resignation.”

Monica is an arts activist and museum curator who has lectured internationally and been an adjunct professor at Harvard University. Like her mom, she is charismatic, whip-smart, and a life-of-the-party type. Like her mom, she can be no-nonsense and resolute. Her resolve would serve her well after her mom was diagnosed.

An internist in a private practice, who was also black, had diagnosed Sandra but offered little in the way of treatment options. Instead, the physician recommended that Sandra do crossword puzzles and that the family hope for the best. After Monica's repeated requests, the doctor finally prescribed Aricept, a treatment for mild-to-moderate Alzheimer's symptoms.

Monica was living in Philadelphia then. She emptied her rental and moved back to her mom's Brooklyn apartment.

Monica researched Alzheimer's and searched for physicians lauded for their work on the disease. She conferred with a dear friend, a geriatric social worker, about how to move forward. In the fall of 2013, Monica chose a neurologist at the NYU Medical Center's Center for Cognitive Neurology to treat her mother, and began discussing how to enroll her in a clinical trial.

“Actually getting her into the trial was an uphill battle,” Monica says.

They needed a letter from Sandra's diagnosing physician, but she ignored Monica's pleas for assistance.

“At a certain point I just rolled in there and, without causing a scene, said ‘My mom is deteriorating,’” Monica re-

members.

She also wrote a pointed letter to the Center for Cognitive Neurology. She was frustrated after too many delays and *we'll see's*.

In the fall of 2014 Sandra joined what ultimately were the 2,129 patients in Eli Lilly's trial of solanezumab at those 210 sites in the United States, Canada, Australia, Japan, and Europe. Sandra was notified in fall 2015 that she was being infused with solanezumab, not the trial's placebo drug.

Sandra's optimism spiked.

Minorities In Clinical Trials

In 1994 the National Institutes of Health (NIH) mandated that participants' enrollment in NIH-approved clinical trials reflect the nation's racial makeup and gender breakdown.

Whites accounted for 61.6 percent of the US population in July 2015, according to the most recent census data. Census analysts project that the share will dip to 44 percent by 2060, if current trends hold. And in 2020 more than half of the nation's children up to age eighteen are projected to be people of color, the Census Bureau says.

According to a 2013 NIH report, minorities accounted for 36.5 percent of the 17.6 million participants in NIH-registered clinical trials of drugs and other medical interventions in fiscal year 2012.

But researchers in the EMPaCT Consortium, which provides training to medical professionals and community organizations on the mechanics of clinical trials in a bid to increase minority participation in trials, estimate the share of minority participants in NIH-registered clinical trials to be less than 10 percent. Depending on the disease targeted by a trial, that rate could be even lower. A study published in *Cancer* in April 2014 concluded that fewer than 2 percent of National Cancer Institute clinical trials focused primarily on any minority population.

The percentage of minorities in clinical trials conducted by drug manufacturers—which now carry out the vast majority of drug trials—is more difficult to pin down. According to Nathaniel Stinson, a medical doctor who heads the Division of Scientific Pro-

Policy Checklist

The issue: More than two decades after a federal mandate that clinical trial enrollees reflect the nation's racial makeup, experts say that progress in achieving diversity in clinical trials has been nominal.

Resource:

Enhancing Minority Participation in Clinical Trials (EMPaCT) Consortium, <http://empactconsortium.com/>

Related reading:

Durant RW, Wenzel JA, Scarinci IC, Paterniti DA, Fouad MN, Hurd TC, et al. Perspectives on barriers and facilitators to minority recruitment for clinical trials among cancer center leaders, investigators, research staff, and referring clinicians: Enhancing Minority Participation in Clinical Trials (EMPaCT). *Cancer*. 2014;120(Suppl 7):1097–105.

Supplement: Enhancing Minority Participation in Clinical Trials (EMPaCT): laying the groundwork for improving minority clinical trial accrual. *Cancer*; 2014;120(Issue Supp. S7): 1087–1130. Available from: <http://onlinelibrary.wiley.com/doi/10.1002/cncr.v120.S7.issue-toc>

Hamburg MA. Clinical trials: enhancing data quality, encouraging participation, and improving recruitment. *FDA Voice* [blog on the Internet]. 2014 Aug 20 [cited 2017 Apr 28]. Available from: <http://blogs.fda.gov/fdavoices/index.php/2014/08/clinical-trials-enhancing-data-quality-encouraging-participation-and-improving-transparency/>

tunities at the moment when they deliver a dire medical diagnosis. That might be the least opportune time to raise the possibility of joining a trial.

Thus far, some of the more than fifty graduates of the intensive four-month-long training program have gone on to sit on clinical trial Institutional Review Boards in Mississippi and to win grants for public health initiatives.

Still, as more minorities express interest in enrolling in clinical trials, there are some looming questions and challenges: How can medical science and the culture surrounding trials be demystified? Should clinical trials continue to exclude, as they generally do, patients with comorbidities—especially given the disproportionate percentage of minorities with more than one illness?

“That’s the million-dollar question,” says Michelle Martin, a preventive medicine professor and researcher who was hired by the University of Tennessee Health Science Center in 2016 to help shape its research programs.

“It probably does matter in some cases,” Martin tells me. “But there has been a movement toward more pragmatic trials where the inclusion-exclusion criteria are a little broader.”

Whether trials accommodate the everyday circumstances of participants is another key concern. What of the added costs of taking time away from a job to keep a spate of clinical trial appointments? What of a participant’s child care or elder care needs? Who’ll put gas in the tank or cover public transit costs so participants can get to trial sites?

Too often patients and caregivers are solving those problems on their own, and doing all the legwork needed to get into clinical trials they hope will benefit their health, says Jennifer Wenzel, a professor at the Johns Hopkins University School of Nursing and School of Medicine and an EMPaCT researcher and advocate. It’s an unfair burden, she says.

Some patient navigators specializing in clinical trials have helped trial participants of color stick with their experimental treatments. The navigators function as patient advocates. They serve as liaisons between patients and their physicians and trial researchers. They whisk away tears. They explain things. They cheer on participants and have

grams at the National Institute on Minority Health and Health Disparities, companies often don’t disclose much—if any—information about the race of participants or other aspects of their trials until the trials are over.

“At that point, everything, regrettably, is after the fact,” he says.

Increasing Minority Enrollment

Given the nation’s changing demographics, it’s neither good health policy nor good business to be developing drugs and possible cures that are tested in only a subset of the population, says Willie Deese, who retired in June 2016 as executive vice president at Merck. Months after retiring, he earmarked part of a \$1 million gift to the North Carolina Agricultural and Technical State University in Greensboro—a historically black college and Deese’s alma mater—for its groundbreaking Center for Outreach in Alzheimer’s, Aging and Community Health. In addition to collecting and studying the DNA of black patients with Alzheimer’s, the center provides support services for such patients and their caregivers and educates blacks about scientific research.

Deese, whose mother has Alzheimer’s, says there’s a growing recog-

nition within the black community that its members can’t be absent from clinical trials and expect medicine to work as well for them as it does for other populations.

“We have to be included,” he says. “Enlightened companies are ensuring that that’s taking place today.”

Raegan Durant, an internist and professor at the University of Alabama at Birmingham, believes that scientists and policy makers are far more aware today of the critical need for a diversity of clinical trial participants than they were when the NIH issued its mandate. But the challenge is figuring out how best to achieve a representative mix, and to keep the recruitment of minority volunteers from being an afterthought.

“There must be a shared power,” he says, “between science and laypeople.”

The almost four-year-old Mississippi State Department of Health’s Community Research Fellows Training Program is considered one leading model of change. It schools community members in how trials work and partners with grassroots organizations that directors of the fellows project view as deeply invested in public health and wellness. It’s creating a community-clinician conversation about trials in the hope, among others, of keeping doctors from mentioning clinical trial enrollment oppor-

helped ensure that patients stay on board until the trial ends. Yet navigators are not spread across the entire clinical trials system, and some health systems who do have them struggle with how to compensate them for their time and effort.

Meanwhile, experts say that private physicians, no matter the many demands on their time at work, must do more to change the racial makeup of trials. Referrals to trials may be more common at university-run medical centers, where staff members know about on-campus research and help funnel patients to those researchers. Unfortunately, not every doctor has this access or will make the effort.

Epilogue

In November 2016, Eli Lilly reported that solanezumab had no effect on people with mild Alzheimer's symptoms and began winding down the trial. Monica forwarded the e-mails from the NYU researchers to me. She and her mother were crushed by the drug's failings. Monica tried not to show her mother the fullness of her disappointment and anger, afraid it would rub off. They decided that Sandra's thirty-fourth appointment at Bellevue would be her last, though she had been given the option to make more visits to the clinic.

Monica requested all of her mother's

Experts say that private physicians, no matter the many demands on their time at work, must do more to change the racial makeup of trials.

clinical trial files, the stuff in the black vinyl binder that nurses annotated during Sandra's monthly visits. For being a trial volunteer, Sandra had gotten a \$40 monthly stipend and extra-vigilant checks of her weight loss, blood pressure, cholesterol level, and assorted physiological markers. Monica wanted those notations.

"I want a written report of their findings and her progress, if she made any," she tells me. "I just want more insight into my mom's health."

Today Sandra is no longer avidly reading the *New York Times*. She does head to a senior citizen center several afternoons a week, but only if Monica lists the landmarks along the way for her, a new kind of crutch.

For fourteen consecutive days this March, Sandra phoned the doorman of her high-rise co-op apartment building for instructions on using the elevator that had ferried her for four decades.

"She just stands in front of it at times, totally bewildered," Monica says.

Monica and the home health aide decided that Sandra should no longer light the stove to cook anything. She has grudgingly surrendered her driver's license and the keys to her Toyota. Except for sporadic engagement with a handful of friends, she is more isolated than ever.

Yet when I talk to her after the clinical trial ended, Sandra sounds pretty chipper, all things considered. She once told me that she veers toward joy, no matter what life throws at her.

"Thank you," she tells me, "for being my balm in Gilead."

An emotion I cannot name rears up in me. My eyes tear.

"You're my jewel and joy," I say. "Let's get our nails done and go to lunch soon."

"Absolutely," she says. "And you never know. The drug they were giving me might kick in."

Monica shares her mother's cautious optimism.

"We still hope, somehow, that all of this will lead to a cure," she says. "We can feel like my mom was a part of that." ■

Katti Gray (katti@kattigray.com) is a freelance writer, editor, and journalism lecturer who specializes in covering health, criminal justice, and education for a range of national publications. She splits her time between Monticello, New York, and Little Rock, Arkansas.