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On Site: Recent Errors Highlight Need for Increased Minority Recruitment in Clinical Trials

Researchers' inability to recruit minorities into clinical trials may have warped heart disease prevention guidelines, a new study is claiming — highlighting an ongoing problem for the industry.

In 2013, researchers published a 10-year risk forecast for heart disease. Curious about whether it was accurate, a team led by Stanford University research scientist Steve Yadlowsky reviewed contemporary records of nearly 27,000 adults and found that guidelines overstate risk by an average of 20 percent across all groups — especially among African Americans, whose risks were over-estimated by 33%, Yadlowsky wrote in the Annals of Internal Medicine journal.

The error seems to stem from the fact that not enough African Americans were included in the initial trials that led to the guidelines, Yadlowsky and his fellow researchers found. Minority recruitment is a perennial problem in the industry. As medicine evolves into increasingly tailored approaches to health, many are worried that the data will be less trustworthy.

Part of the problem may be that sites and sponsors haven't been thinking very scientifically about minority recruitment, said Jonathan Jackson, director of research at Massachusetts General Hospital's Community Access, Recruitment and Engagement Center.

Jackson and his colleagues launched their center a few years ago with the hope of improving overall enrollment. Since the center opened its doors, overall recruitment has grown by nearly a third and minority enrollment has more than doubled. The key strategic decision was to hire patient navigators — people from the area who could help explain the glossaries and the vagaries of insurance, clinical research, and hospital policies, Jackson said.

It might help if navigators are of the same racial or ethnic group of the target population, but it's even more important that they're familiar with the neighborhoods that the targeted populations are coming from, Jackson said.

"What is more likely to be effective is to hire someone local. If you are trying to recruit from Boston, hire somebody who has lived here for a while," he said.

Spanish language skills can be enormously helpful in recruiting Latinos, for instance, Jackson said. But if you're recruiting in Miami, someone from San Antonio might not understand all the subtleties of the local population.

"You never want to say, 'I've hired somebody of color or somebody who can speak Lakota and therefore I've covered minority enrollment.' That's usually only the first step, not the last," Jackson said.

One of the things local navigators have helped Mass General researchers unpack is the psychology behind patient worries over "travel," Jackson said. Patients often cite travel difficulties as a barrier to trial enrollment. Yet some sites in Wisconsin, for instance, have no trouble recruiting patients to drive hundreds of miles while Boston sites have trouble getting some patients to take a bus a few blocks away.

"It turns out that when we talk about transportation, there's a societal component, there's a psychological barrier, as well," Jackson said. "The real, the underlying concerns, are much more related to the perception of being welcomed."

In cities with a history of racial or ethnic tensions, then, "travel" can become a stand-in for "wrong neighborhood," Jackson said. "I would encourage people to unpack what those words mean," he said.

Travel isn't always a barrier. A recent study by researchers at the University of Miami found that having sponsors subsidize Next-Generation Sequencing — a precursor to molecular-driven oncology trials — increased the number of women and minorities who enrolled in a trial.

"Financial aid should help," said study author Jared Cotta, project coordinator for the Precision Medicine Initiative at Miami's Sylvester Comprehensive Cancer Center. "Who's to say that $100 isn't a lot to pay? A lot of patients already have a lot of financial burdens based on their illness."

Another barrier might be sponsors' insistence that patients show up as "triathletes," said Louis Weiner, director of the Lombardi Comprehensive Cancer Center at Georgetown University. A great many patients in poor, minority communities have comorbidities that exclude them from trials, Weiner said.

"If the only problem you have is cancer and you don't have heart disease or kidney disease or HIV and you're in great shape and you're working out still, yeah, you're going to be eligible for clinical trials," Weiner said. "Frequently, we don't know if they're safe to use for people with hepatitis or COPD or any of the other things that we see in people who live in poverty."

Regulators and sponsors could help themselves by setting up rules whereby people with comorbidities are allowed into trials and their outcomes do not necessarily slow down or stop a trial, Weiner said. "There needs to be some kind of strategy for this."

— Suz Redfearn

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