

RESEARCHERS HOPE TO MAKE DRUGS MORE EFFECTIVE BY TAILORING THEM TO PATIENTS' LIFESTYLES, GENETICS AND ENVIRONMENT

DRUG DESIGN

By Daniel Chang
Miami Herald

South Florida's ethnic diversity will play a key role in an ambitious, five-year medical research effort aimed at making treatments and drugs more effective by tailoring them to the lifestyles, genetics and environment of individual patients.

Led by the University of Miami's Miller School of Medicine and funded by a \$60 million grant from the National Institutes of Health, a group of academic institutions in Florida and Georgia — including the University of Florida, Emory University, and Morehouse School of Medicine — have begun to recruit 100,000 people from the Southeastern United States to participate in a nationwide research program called "All of Us."

The program's goal is to recruit one million or more U.S. residents over the next five years — including 40,000 from South Florida — to

"It's not enough to study just one kind of people."

— Dr. Stephan Zuchner

help create a rich pool of data that will account for individual differences in genetics, behavior and geography in biomedical research. That database will then be used for future studies into a wide variety of health conditions and to help scientists develop more precise medical interventions.

Until now, most biomedical research has been conducted primarily with non-Hispanic white subjects, mostly men, though the U.S. Census shows that minorities make up nearly 40 percent of the population.

"It's not enough to study just one kind of people," said Dr. Stephan Zuchner, principal investigator for the All of Us program's South East Enrollment Center and chair of UM's Department of Human Genetics. "It's very impor-

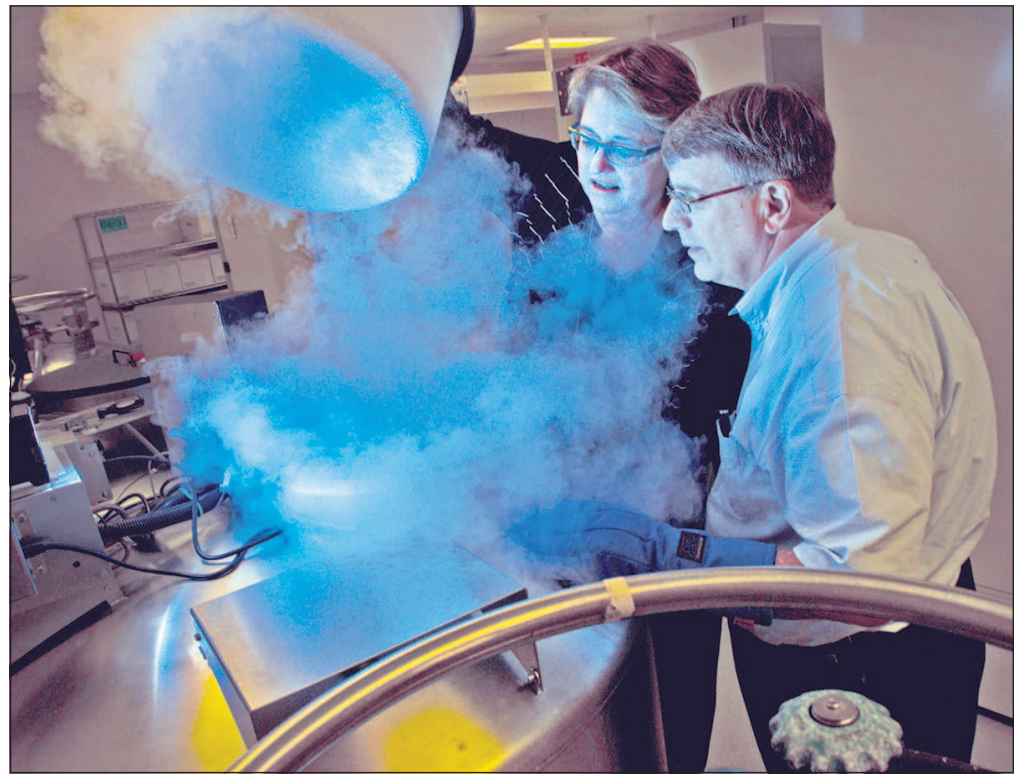
tant that we understand the genomes of all people on the planet."

For instance, he said, people from Southeast Asia tend to have fast metabolisms, which causes certain drugs to have little or no effect on them.

"In Mexico," he said, "there's a much higher risk to develop diabetes. We don't know why. But it might well have to do with genetics." Similarly, Zuchner added, "We cannot treat African Americans accordingly if we do not realize they have a higher risk for certain cardiovascular disorders."

The program is open to all adults, regardless of race or ethnicity, health status, education or income level. Anyone interested in participating can sign up through the All of Us online portal at www.joinallofus.org/en.

Those selected will receive genomic sequencing. But scientists want to understand more than genetics.



Patrick Farrell / Miami Herald-TNS

University of Miami medical researchers, from right, Dr. Jeffrey Vance and Dr. Margaret Pericak-Vance, peer into a tank of nitrogen where tissue used for DNA is stored at frigid temperatures.

They want to figure out how individual behaviors, such as exercising, smoking or overeating, and a person's environment, from the climate to the availability of fresh fruits and vegetables, affect the way genetics function, said Dr. Olveen Carrasquillo, a lead researcher for the program and an internal medicine physician with the UM Health System.

"Health is composed of many things," he said. "But we don't know the right balance of these things and how they contribute to health and health outcomes."

Carrasquillo said the All of Us program will follow participants for at least five years and collect a wide range of data from them, including any diagnosed

diseases, medications they're taking and diet, with the aim of helping researchers one day figure out what medicines work best for individual patients based on their unique traits.

"It's a much more nuanced approach to treatment that's really much more targeted for that individual person," Carrasquillo said.

The NIH and researchers will hold conferences over the coming years to decide next steps for studying participants. One idea that has gained traction is using technology, such as wearable activity trackers and electronic health records, to measure participants' behaviors and gather their information.

Zuchner said patient data collected as part of the All of

Us program will be safeguarded and used only by researchers. "This is as good as it gets when it comes to data protection," he said.

Studying a million people also may produce better research results than prior studies because of the unprecedented scale, Zuchner said. And though he expects it will take a decade or longer before biomedical researchers can make good use of the data — perhaps too long for participants to benefit personally — Zuchner believes the effort will be worth it in the long run.

"It's almost like you invest a little bit, you give a little bit of your personal data," he said, "so your children and your family will benefit from it."

Aspirin might not help avoid first heart attack

By Marilyn Marchione
Associated Press

If you've already had a stroke, taking a low-dose aspirin every day has long been known to cut the chances of another stroke. The same goes for a heart attack or similar heart problem. But if you haven't had any one of those, then taking that aspirin may be too risky, major new research finds.

Although it's been used for more than a century, aspirin's value in many situations is still unclear. The latest studies are some of the largest and longest to test this pennies-a-day blood thinner in people who don't yet have heart disease or a blood vessel-related problem.

One found that aspirin did not help prevent first strokes or heart attacks in people at moderate risk for one because they had several health threats such as smoking, high blood pressure or high cholesterol.

Another tested aspirin in people with diabetes, who are more likely to develop or die from heart problems, and found that the modest benefit it gave was offset by a greater risk of serious bleeding.

Aspirin did not help prevent cancer as had been hoped.

And fish oil supplements, also tested in the study of people with diabetes, failed to help.

"There's been a lot of uncertainty among doctors around the world about prescribing aspirin" beyond those for whom it's now recommended, said one study leader, Dr. Jane Armitage of the University of Oxford in England. "If you're healthy, it's probably not worth taking it."

The research was discussed Sunday at the European Society of Cardiology meeting in Munich. The aspirin studies used 100 milligrams a day, more than the 81-milligram pills commonly sold in the United States but still considered low dose. Adult strength is 325 milligrams.

Who's really at risk?

A Boston-led study gave aspirin or dummy pills to 12,546 people who were thought to have a moderate risk of suffering a heart attack or stroke within a decade because of other health issues.

After five years, 4 percent of each group had suffered a heart problem — far fewer than expected, suggesting these people were actually at low risk, not moderate. Other medicines they were taking to lower blood pressure and cholesterol may have cut their heart risk so much that aspirin had little chance of helping more, said the study leader, Dr. J. Michael Gaziano of

Brigham and Women's Hospital.

One percent of aspirin takers had stomach or intestinal bleeding, mostly mild — twice as many as those on dummy pills. Aspirin users also had more nosebleeds, indigestion, reflux or belly pain.

Bayer sponsored the study, and many researchers consult for the aspirin maker. Results were published by the journal *Lancet*.

Aspirin for people with diabetes?

People with diabetes have a higher risk of heart problems and strokes from a blood clot, but also a higher risk of bleeding. Guidelines vary on which of them should consider aspirin.

Oxford researchers randomly assigned 15,480 adults with Type 1 or 2 diabetes but otherwise in good health and with no history of heart problems to take either aspirin, 1 gram of fish oil, both substances, or dummy pills every day.

After seven and a half years, there were fewer heart problems among aspirin users but more cases of serious bleeding, so they largely traded one risk for another.

Fish oil results

The same study also tested omega-3 fatty acids, the good oils found in salmon, tuna and other fish. Supplement takers fared no better than those given dummy capsules — 9 percent of each group suffered a heart problem.

"We feel very confident that there doesn't seem to be a role for fish oil supplements for preventing heart disease," said study leader Dr. Louise Bowman of the University of Oxford.

The British Heart Foundation was the study's main sponsor. Bayer and Mylan provided aspirin and fish oil, respectively. Results were published by the *New England Journal of Medicine*.

Other studies are testing different amounts and prescription versions of fish oil, "but I can't tell people go spend your money on it; we think it's probably better to eat fish," said Dr. Holly Andersen, a heart disease prevention specialist at New York-Presbyterian/Weill Cornell who was not involved in the study.

The new research doesn't alter guidelines on aspirin or fish oil, said Dr. Nieca Goldberg, a cardiologist at NYU Langone Medical Center and an American Heart Association spokeswoman. They recommend fish oil only for certain heart failure patients and say it's reasonable to consider for people who have already suffered a heart attack.

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