

Kidney News

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All of Us Research Program Aims to Catapult Personalized Medicine Forward

May Help Define Both Good Kidney Health and Disease Contributors

By Bridget M. Kuehn



In late May, the more than \$200 million project began enrolling the first of what will eventually be 1 million study participants, making it one of the largest research programs ever attempted. Participants will represent a broad range of health statuses, ages, and walks of life. Investigators plan to follow participants for decades and collect reams of biological, lifestyle, and healthcare data. This trove of data will provide a rich resource for researchers trying to better understand risk factors for disease, find ways to more precisely target treatments, reduce health disparities, and advance personalized care.

“The more we understand about individual differences, the better able we will be to effectively prevent and treat illness,” said NIH Director Francis S. Collins, MD, PhD, in a statement about the program.

Fully engaged and empowered patients will be essential to the massive program’s success.

“We still have to teach people to put the patient’s voice first,” Dishman told attendees at the May 2017 Kidney Health Initiative (KHI) meeting in Silver Spring, MD. KHI is a public-private partnership between the American Society of Nephrology, US Food and Drug Administration, and over 75 companies and organizations focused on enhancing patient safety and fostering innovation in kidney disease.

Dishman said his kidney transplant care was the first time he received truly comprehensive care. But if *All of Us* is successful in its goals, it may help accelerate the shift toward personalized medicine.

Beta testing

Already more than 300 participants age 18 and older have enrolled in the *All of Us* Research Program, according to Akinlolu Ojo, MD, MPH, PhD, MBA, a nephrologist at the University of Arizona and one of the project’s principle investigators.

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As a cancer patient for 23 years—who was eventually cured with the help of precision medicine—Eric Dishman brings a very patient-centric view to his work leading the National Institutes of Health’s (NIH) ambitious *All of Us* Research Program.

Catheters Continue to Be Linked to Most Bloodstream Infections in Dialysis Patients

By Tracy Hampton

Newly reported data representing nearly all US outpatient dialysis facilities reveal that most bloodstream infections in dialysis patients continue to occur in those with central venous catheters used for vascular access. The findings, which are published in a recent

Clinical Journal of the American Society of Nephrology study, come from the first year of data used by the Centers for Medicare & Medicaid Services to assess facility performance based on bloodstream infections.

Increasing attention is being paid to reducing vascular access-related infections in

dialysis patients. “Hemodialysis patients are at high risk for infections, which increase mortality, hospitalization, and healthcare costs. Therefore, surveillance of infectious adverse events among hemodialysis patients is very important,” said the Centers for Disease Control and Prevention’s (CDC’s) Duc Bui Nguyen, MD, lead author of the study. “Tracking infections helps guide intervention and prevention efforts to reduce severe events.”

In the late 1990s, the CDC initiated a system to help facilities track in-

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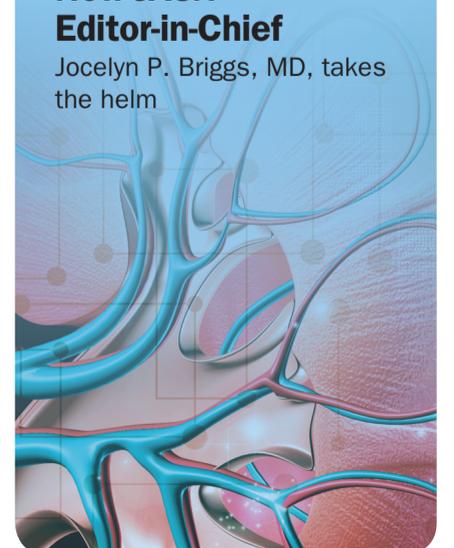
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All of Us Research Program

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tors. Eventually, the program will also enroll children.

“People are excited about the opportunity to understand more about themselves,” Ojo said. He noted they were also interested in learning more about disease processes that might affect them and their families.

Participants may enroll through dozens of organizations that provide health care, including regional medical centers, community health centers, and US Department of Veterans Affairs Medical Centers (<https://al-lobalofus.nih.gov/about/program-components/health-care-provider-organizations>). Or they can volunteer directly online at joinal-lobalofus.org or by calling the program. Those direct volunteers who are asked to provide biological samples and physical measurements may be directed to a local health clinic at a Walgreens or Quest Diagnostic.

Participants will fill out surveys about their medical history and lifestyle; may have measurements like height, weight, and blood pressure taken at their enrollment site; and may also submit blood or urine samples. Eventually, participants may be asked to have their whole genome sequenced.

The program has established very rigorous systems to protect patient privacy and data security, something deemed essential by focus groups of potential participants convened to help plan the study. Patient samples will be stored and managed by a state-of-the-art biobank at the Mayo Clinic in Rochester, MN. The program has also created online systems to manage and secure the project’s “big data.”

The study aims to enroll a racially, ethnically, and geographically diverse cohort. This may make the program a particularly rich source of data for those researching kidney disease because racial and ethnic mi-

norities in the US have a 3- to 4-fold risk of developing kidney disease, Ojo noted.

“It is important to have a diverse population to understand the complex processes and the pathways that lead to disease,” Ojo said.

The first data from the project should be available within a year. At that time, researchers from many different backgrounds—from traditional federally funded academic investigators to biotech company researchers and even citizen scientists—may be able to use data from the study, Ojo noted. A national institutional review board will review study proposals as needed.

“It’s going to occur very rapidly,” Ojo said.

The project is starting with a so-called beta testing phase in which the initial 10,000 participants will help to test and provide feedback on how the program and its systems are working. Such beta testing is a common practice for technology companies as they begin to roll out new products. It also reflects Dishman’s background in information technology. He previously served as vice president of the Health and Life Sciences Group at Intel Corporation.

“Our beta testers will help us find problems with our systems and processes, so we can fix them and improve the experience for everyone going forward,” Dishman explained in a statement. “And most importantly, they will help us evaluate and improve our messaging, our engagement approaches, and our relationship building with diverse communities across the country.”

Kidney health clues

Ojo said he expects the *All of Us* cohort may include about 50,000 people with kidney diseases, based on the incidence of kidney diseases in the US. The program may help speed the development of kidney disease treatments targeted to specific populations, Ojo said.

“The *All of Us* program will help us to

quickly find the causes of kidney disease in different populations and help us develop new treatments for it and other common diseases,” Ojo said.

Precision medicine initiatives, which target specific subgroups of patients to come up with personalized treatments, are particularly critical for kidney disease patients who may have very different genetic backgrounds and disease presentations, according to Dave White, a self-described kidney warrior and health care consultant who participated in the KHI meeting. White, who is African American, recently celebrated the 2nd anniversary of his kidney transplant. He is currently stable but carefully monitors his cholesterol and takes medication to manage high blood pressure. By way of example, he explained that another patient undergoing dialysis might have Asian or Hispanic ancestry and have diabetes but no high blood pressure.

“One size does not fit all,” White said. “Precision medicine tailors the right treatment to the right person at the right time.”

The data collected by the program, which aims to follow participants through their lifespan, might also help scientists better understand what causes kidney diseases and how to prevent them. Some patients will likely develop kidney diseases over the course of the study, which will provide genetic and physiological data that may help scientists “understand the background in which kidney disease develops,” Ojo said.

Engaged and informed

Significant challenges lie ahead for such a large, long-term, and ambitious project, Ojo acknowledged. Another large NIH-funded project, the National Children’s Study, which planned to follow 100,000 children from gestation to age 21, was cancelled in 2014. But he and his colleagues have studied what went wrong with the project to try to avoid replicating its difficulties.

“We have learned important lessons from the National Children’s Study,” he said.

A strong emphasis on community, participant, and investigator engagement across the country is one strategy the program hopes to use to promote its long-term success. Focus groups of potential participants and other stakeholders began before enrollment. Participant representatives have been invited to serve on the program’s Steering Committee, and several of the local sites have established participant advisory boards to help advise and guide the program.

“One of the core values [of the *All of Us* Research Program] is that participants and their representatives will have a prominent role not just as advisors to the research team, but they will also play a role in governance, determining which research will be done, monitoring studies, and disseminating research results,” Ojo said.

White agreed that patient engagement is critical to the success of any research project.

“Research is kind of pointless unless it results in outcomes important to the patient, and the only way to make sure that happens is to make sure that the patient voice is heard,” White said. “One of the most important considerations for patients is not letting kidney disease affect what you want to do with your life.”

The NIH is partnering with manufacturers of electronic medical records systems on a pilot program to allow individuals to access their electronic health records and share the information with researchers through mobile apps and websites.

“We plan to use information technology to the utmost, while making sure those without access can still participate,” Ojo said.

White encouraged patients who want to see advances in personalized medicine to get involved in research, like *All of Us*, or participate in advocacy programs.

“We all have a part to play in this,” White said. “Those of us who can kind of have a duty to get the best care possible and the best way to do that is to participate in advocacy and research.” ●

All of Us Research Program Announces National Tour to Engage Communities

By Ryan Murray

The *All of Us* Research Program, an element of the National Institutes of Health’s (NIH) Precision Medicine Initiative (PMI), will allow researchers, health care providers, and patients to work together and develop individualized care. In a truly historic effort, the *All of Us* Research Program aims to collect data from more than 1 million people to accelerate health research and medical innovation through precision medicine. This project is a network of US industry and universities that seeks to generate new knowledge on the biological, environmental, and behavioral influences on diseases with the goal of developing more effective therapies to treat them by leveraging the statistical power of a cohort of this significant size.

Currently in beta testing, the *All of Us* Research Program will look to identify and enroll a diverse group of interested and eligible participants later this year. Interested individuals over the age of 18 and living in the US are

encouraged to apply when enrollment opens by visiting www.joinalofus.org.

In order to spread awareness of the program, NIH has announced a 37-week national tour called the *All of Us* Journey. This traveling exhibit officially kicked off in July 2017 with dates through 2018. Recognizing the value of engaging with trusted health care partners in local communities, the *All of Us* Journey is looking to coordinate with local community members to participate in events. These events will educate the community on the *All of Us* Research Program and provide individuals the opportunity to have their questions answered and enroll on-site.

In response to the announcement, the Chair of the ASN Policy and Advocacy Committee, Crystal Gadegbeku, MD, stated: “ASN appreciates that the National Institutes of Health has recognized the value of individualized care and the benefits it could provide to patients.

I am truly excited about the promise that the *All of Us* Research Program offers for both the broader medical community and minority patients. By placing an emphasis on both a diversity of disease modalities and patient demographics, the cohort will serve as an invaluable tool for medical researchers and increase the likelihood of developing new therapies.”

While the *All of Us* Research Program will collect information from individuals with a variety of diseases, the American Society of Nephrology recognizes the value of the opportunity for patients with kidney diseases to participate in this program and encourages health care providers to collaborate with the *All of Us* Journey.

More information, including how to apply to host the *All of Us* Journey and where and when the tour will be traveling, can be found by visiting https://www.asn-online.org/policy/webdocs/All_of_Us_Journey.pdf. ●