THE HASTINGS CENTER

ISSUE BRIEF

Strategies to Support Equitable Access to Precision Medicine for *All of Us* Participants from Federally Qualified Health Centers

The problem

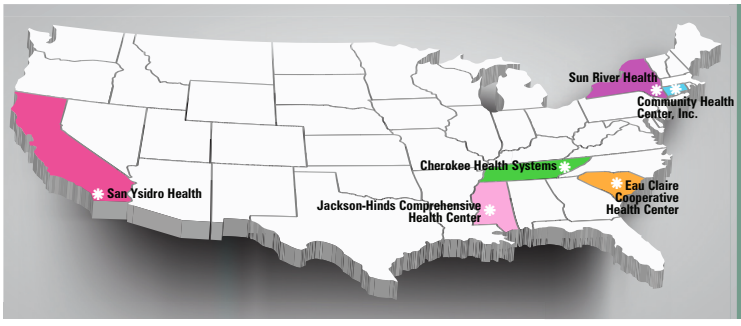
The United States is investing heavily in genetic-based precision medicine research, but many participants in the federally funded *All of Us* Research Program face barriers to follow-up services after they receive medically actionable genetic research results. Led by the National Institutes of Health (NIH), *All of Us* collects participants' medical history, demographic information, and genetic and other medical test results with the expectation that this information will lead to the development and prescription of effective preventive and treatment interventions based on a patient's genes and other medical information (precision medicine).

All of Us is unprecedented in the United States in its commitment to recruit 75% of research participants from groups historically underrepresented in research, including medically underserved communities. Underrepresentation in research can result in information deficits about populations. By creating a library of biological samples (a biobank) that is representative of the entire U.S. population, *All of Us* aims to support precision medicine for all.

All of Us will return medically actionable genetic research results to participants who opt to receive that information starting in spring 2022, via its online participant dashboard. Examples of medically actionable results include testing positive for the BRCA mutation associated with breast and ovarian cancers or having a genetic variation that can affect how certain medications will work (pharmacogenetics).

To achieve its ambitious enrollment target for underrepresented populations, *All of Us* partnered with six Federally Qualified Health Centers (FQHCs) to serve as recruitment and engagement sites. These non-profit community health centers meet stringent requirements to qualify for operating funds from the Health Resources & Services Administration (HRSA). HRSA funds enable FQHCs to deliver high-quality primary care to medically underserved communities. FQHC providers refer patients to diagnostic and specialty services when their needs cannot be met within primary care.

Some FQHC patients are motivated to enroll in *All of Us* to obtain genetic results that are actionable through prevention, treatment, or risk reduction. Individual results are also relevant to biological family members if findings reveal heritable genetic conditions.



All of Us Federally Qualified Health Center Sites

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Barriers to Medical Services

All of Us will make available genetic counseling services (via telehealth) and educational materials for participants who receive medically actionable genetic research results. Nonetheless, the presence of the following barriers may make it difficult for *All of Us* participants from FQHCs to obtain necessary or recommended follow-up diagnostic or medical services for themselves or family members when they receive medically actionable genetic research results:

Service Barriers

- Lack of access to or means to pay for necessary confirmatory clinical genetic testing following an actionable finding revealed by research genetic testing.
- Lack of readiness among FQHCs to incorporate genetic findings into primary care, due to lack of practitioner familiarity with genetic and pharmacogenetic findings, barriers to integrating genetic findings into electronic health records, or lack of patient education on genetic findings.

Insurance Barriers

- Lack of health insurance.
- Barriers to obtaining insurance, such as immigration status.
- "Underinsurance" due to inadequate coverage or high costs to policyholder.
- Reluctance among some providers or medical centers to accept non-emergency referrals of uninsured patients or patients insured by Medicaid.

Other Barriers

- Lack of access to genetic research results or to follow-up services via telemedicine due to "digital divide."
- Lack of familiarity or comfort with specialty medical providers and institutions beyond FQHCs or local hospitals.
- Lack of time and resources for travel to follow-up medical appointments.

Toward sustainable solutions via federal funding strategies

All of Us invited FQHCs to be recruitment and engagement sites to support the program's goal of enrolling underrepresented populations. There is a moral imperative to reduce barriers to obtaining medical follow-up services that FQHC participants foreseeably face after they receive medically actionable genetic research results. Because the federal government funds *All of Us* and FQHCs, it has an obligation to respond to this moral imperative. To fail to do so values the biological materials of these participants over their health and wellbeing.

Currently it falls on research participants and their primary care providers to navigate insurance, service, and other barriers. This ad hoc approach is inequitable and unsustainable in the context of precision medicine, which usually requires access to an academic medical center or other health system with relevant diagnostics and specialties.

Examples of federal funding strategies to create equitable and sustainable pathways to medical follow-up for *All of Us* participants (and their families) who enrolled via FQHCs are described on the next page.

Strategies to build genetic medicine and counseling capacity at FQHCs

- **Fund FQHC capacity** to hire or contract with genetic medicine specialists or genetic counselors to help patients and their families understand genetic diagnoses and navigate medical follow-up. FQHCs should be involved in identifying the specialists they need.
- **Provide genetic educational and training programs** or consultancy services to enhance the capacity of FQHC primary care providers to incorporate genetics into primary care.
- **Develop workflows t**o integrate genetic and pharmacogenetic results into FQHC operations, e.g., electronic health record integration and standard operating procedures.
- **Fund FQHC capacity** to hire an additional patient navigator to coordinate recommended follow-up diagnostic and specialty services.

Strategies to improve patient access to diagnostic and specialty services beyond FQHCs

- **Improve access** to existing telemedicine services provided by genetic and other specialists. Facilitate telemedicine services through secure internet access and user-friendly interfaces for video or phone visits. Provide equal reimbursement to providers regardless of visit modality.
- **Develop, pilot, and evaluate equitable payment models** to cover in-person diagnostic or specialty services for un/underinsured research participants and their family members, through mechanisms such as universal health insurance, expansion of existing benefits, or health care provided in fulfillment of nonprofit hospitals' community benefit requirements.

Conclusion

Advocates for precision medicine, genetic research, community health, and health equity should determine how to incorporate these strategies into their advocacy efforts, with attention to how federal agencies such as NIH, HRSA, and the Centers for Medicare and Medicaid Services can support these strategies. Individuals and institutions committed to advancing precision medicine research with "all of us" should enact a dual commitment to creating equitable and sustainable access to precision medicine for "all of us." ■

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