All of Us Research Program

The Power of Precision Medicine for Alaskan Native and American Indian People

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Program Lead: Special Populations Engagement

All of Us Research Program at UA-Banner
Objectives

- Understand the Medical Model of Precision Medicine
- Understand the impact that the All of Us Program can have on improving health outcomes
- Understand the role of genetic research in improving population health
- Understand the importance of Alaskan Native and American Indian tribal consultation
“Personalized medicine” is an older term with a meaning similar to "precision medicine."

- Diagnostic testing employed for selecting appropriate and optimal therapies based on the context of a patient’s genetic content or other molecular or cellular analysis

“Precision Medicine” focuses on identifying which approaches will be effective for which patients based on genetic, environmental, and lifestyle factors.

The National Research Council prefers the term "precision medicine" to "personalized medicine." The two terms may be used interchangeably.

Pharmacogenomics is a part of precision medicine. Pharmacogenomics is the study of how genes affect a person’s response to particular drugs.

- Attempts to develop effective, safe medications and doses tailored to a person’s genes

The Precision Medicine Initiative

All of Us
THE FUTURE OF HEALTH BEGINS WITH YOU

The Precision Medicine Initiative®
Support from the 21st Century Cures Act

Signed into law on December 13, 2016, this act authorizes an additional $1.5 billion of funding over 10 years for NIH’s Precision Medicine Initiative activities, including All of Us.

From the White House Statement:

“The bipartisan passage of the 21st Century Cures Act is an example of the progress we can make when people from both parties work together to improve the health of our families, friends, and neighbors.”
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A Transformational Approach to Diversity

Reflecting the country’s rich diversity to produce meaningful health outcomes for communities historically underrepresented in biomedical research.
The *All of Us* Research Program

- One million or more volunteers, reflecting the broad diversity of the U.S, providing data on an ongoing basis.
- Lifestyle, Genes, Environment.
- Not a study on any one disease, but a huge data resource to inform many research studies on a wide variety of health conditions.
- Opportunities for researchers from citizen scientists to university researchers to access one of the world’s largest biomedical databases to accelerate breakthroughs.
A Transformational Approach to Participation

Participants in the *All of Us* Research Program will be true partners—not patients, not subjects—in the research process.

Involved in every step of program development:

- ✓ What data we collect
- ✓ What lab analyses we do
- ✓ What research is conducted
- ✓ How data gets returned
Scientific Opportunities

- Develop ways to measure risk for a range of diseases based on environmental exposure, genetic factors and interactions between the two
- Identify sex-based differences in disease development
- Identify the causes of individual difference in response to commonly used drugs
- Discover new biological markers
- Use mobile health (mHealth) technologies
- Development of new disease classification and relationships
- Empower participants
Two Methods of Engagement

DIRECT VOLUNTEERS

HEALTH CARE PROVIDER ORGANIZATIONS
Value of Genomics in Medical Care

- Medical genomics attempts to identify susceptible positions of a particular gene on a human chromosome responsible for many complex and common diseases.
- Systematic approaches in medical genomics are starting to provide deeper insights into the mechanisms of human diseases.
- Facilitates the development of better diagnostic and biomarkers that may predict the outcome for cancers and many other diseases.

- Native Americans have begun to believe their own metaphors: “in our blood” is giving way to “in our DNA.”

https://genomemedicine.biomedcentral.com/articles/10.1186/gm2
Sources of Healthcare Data

Most Useful Sources of Health Care Data Today and in 5 Years

What do you consider the top three most useful sources of health care data today and in 5 years?

Clinical data: 95% today, 82% in 5 years
Cost data: 56% today, 58% in 5 years
Claims data: 45% today, 40% in 5 years
Patient-generated data: 30% today, 40% in 5 years
Pharmaceutical data: 25% today, 32% in 5 years
Patient preference data (e.g., HCAHPS): 21% today, 23% in 5 years
Genomic data: 17% today, 17% in 5 years

Base = 682 (Multiple responses)
NEJM Catalyst (catalyst.nejm.org) © Massachusetts Medical Society
Holistic Integrative Model

Circle of Life

Physical

Spiritual

Mental

Behavioral

By: Stephanie Big Crow (Oglala Lakota) M.Ed., DBA-HCAL©
Health Status of American Indian and Alaskan Natives (AI/ANs)

Death rates from preventable diseases among AI/ANs are significantly higher than non-Indians:

- Diabetes 420% greater
- Alcoholism 770% greater
- Accidents 280% greater
- Suicide 60% greater
- Tuberculosis 650%
- Influenza 52%

Social Determinates of Health (Lifestyle Factors)

- Disease patterns among American Indians and Alaska Natives are strongly associated with the adverse consequences of Social Determinates of Health:
  - Poverty
  - Limited access to health services
  - Cultural dislocation
  - Inadequate education
  - High rates of unemployment
  - Discrimination based on cultural differences
- All contribute to unhealthy lifestyles and disparities in access to health care

Concerns about Precision Medicine

- Lack of evidence in using genetic biomarkers to effectively identify diagnosis and prognosis to disease
- Risk of diverting attention and money from much more potent public health interventions.
- Ethical, social, and legal issues
- Protecting the participants’ privacy and confidentiality of their health information
- Benefits to communities
- Understanding the risks and benefits of participating in research
- Ownership and control of research data

http://journals.lww.com/academicmedicine/Fulltext/2009/05000/More_About_Prospective_Health_Care.3.aspx
Collaborations with Genetic Researchers

- “I tell my non-Native colleagues at Harvard and beyond that we’re not anti-science. We [Native Americans] merely want research conducted on our terms” - Dr. Lee Bitsóí

- The Salt River Pima-Maricopa Indian Community (SRPMIC) partnered with the Translational Genomics Research Institute (TGen) to conduct genetics research on diabetes and other diseases.

- In Mexico, the National Institute for Genomic Medicine (INMEGEN) is conducting disease-related genomic studies to address their health problems and to study their genomic diversity.

- The Walking Forward cancer screening program in South Dakota incorporates a genetic research study on a gene thought to be associated with response to radiation therapy.

- Key to success: Community involvement and partnership with researchers.

The University of Arizona and Banner Health (UA-Banner) jointly received one of the 8 regional medical center awards (grants) across the country.

The grant focuses on enrolling a diverse cohort of participants into this program, which includes our American Indians and Alaskan Natives (AI/AN) relatives.

Most of the enrollment of AI/ANs will be done at Banner Health facilities and other private health facilities located across Arizona.
American Indian/Alaska Native Engagement

- Working with University of Arizona (UA) Tribal Relations office
- Hosted an open dialogue conference with Tribal leaders and community members
- Co-Chairs:
  - Karen Francis-Begay, Assistant Vice President, Tribal Relations (Dine; Navajo Nation)
  - John Molina, M.D. J.D., Corporate Compliance Officer, Native Health (Pascua Yaqui/San Carlos Apache)
AI/AN Engagement Conference Details

**Planning Committee**

- Michael Allison, Native American Liaison, Division of Policy and Intergovernmental Affairs ADHS, (Dine)
- Dedra Buchwald, PhD, Professor of Medicine, Epidemiology, WSU; Director IREACH
- Linda Burhansstipanov, DrPH, Founder, Native American Cancer Research Corporation; President, Native American Cancer Initiatives, Incorporated (Cherokee Nation of Oklahoma)
- Francine Gachupin, PhD, Assistant Professor, Family and Community Medicine, American Indian Studies (Jemez Pueblo)
- Jeff Henderson, M.D., M.P.H., President & CEO, Black Hills Center for American Indian Health (Lakota, Cheyenne River Sioux Tribe)
- Claudia Nelson, Director, Native Peoples Technical Assistance Office at UA
AI/AN Engagement Conference Details

- Conference Goals
  - Open dialogue
  - Raise awareness and answer questions
  - Attend to tribal concerns regarding research studies in AI/AN communities
  - Plan with the community for strategic directions going forward
AI/AN Engagement Conference Details

- Discussion of All of Us program components
  - Consent
  - Data Repository
  - Biobank
  - Data sovereignty
- Traditional Medicine
- Clinical studies in Precision Medicine
- Event attended by 98 individuals representing 18 different Tribes/Nations

- The conference was evaluated very positively. (3.8 out of 4.0)
- The main concern was how we provide our AI/AN people with meaningful and relevant information so that they can make a well-informed decision to voluntarily enroll in this program.
The mission of this Strategic Plan is to engage the AI/AN community members, leaders, and healthcare providers with the *All of Us* Research Program through multiple outreach activities, meaningful dialogue and consultation, education, and partnership development.
Summary: Objectives of the All of Us Program

- To implement the Arizona Board of Regents’ Tribal Consultation Policy
- To increase awareness and knowledge of the All of Us Research Program among AI/AN community members and community leaders
- To consensually develop partnerships with AI/AN community members, community leaders, and healthcare providers for our Native people
- To increase Precision Medicine literacy among health care practitioners and their staff
- To engage AI/AN health care practitioners as advocates/champions of the All of Us Program
- To ‘give back’ to the AI/AN community, the value and benefits of the All of Us Research Program, to improve the health status of AI/ANs
- To remain sensitive to the culture and bio-ethical issues related to research among the AI/AN population
“[Her doctor] did not know how to heal an illness, only how to cut it out... more to herself... she added, He [doctor] did not know my clan, my family, my history. How could [the doctor] know how to heal me?”

- Cherokee Chief Wilma Mankiller
Our Future

- “In our every deliberation, we must consider the impact of our decisions on the next seven generations.” - Iroquois Confederacy Maxim

- “Let us put our minds together and see what life we can make for our children.” – Sitting Bull, Hunkpapa Lakota Holy Man
Ah’he’he – Wopila tanka ni’ci’ci

The *All of Us Research Program* is grateful to the exceptional care you provide to our people.

Our team is deeply committed to the respectful engagement of the AI/AN community

For more information:

https://allofus.nih.gov

https://www.joinallofus.org

We appreciate your feedback – email, text, or call:

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