The Precision Medicine Initiative® -- A Potential Resource for Research in Minority Health

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Outline

• An Overview of the Health of Minority Populations in the US
• Persistent Gaps in Knowledge and Challenges in Minority Health and Health Disparities Research
• The Need for a Paradigm Shift
• What is Precision Medicine?
• The Precision Medicine Initiative and the All of Us Research Program
• Opportunities, Promises and Challenges for Minority Health Research
• Despite improvements in the overall health of the US population, some racial/ethnic minority groups experience disproportionately higher burden of disease, adverse outcomes and premature death, and are referred to as health disparity populations.

• P.L. 106-525 defines a population as a health disparity population if “...there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates in the population as compared to the health status of the general population.”

• Racial/ethnic minorities (African Americans, American Indians and Alaska Natives, Asians, Hispanics, and Native Hawaiians and Other Pacific Islanders), persons with low socioeconomic status, and rural persons are currently designated as health disparity populations.
Phases of Research on Minority Health and Health Disparities

Detecting
- Define health disparities
- Define vulnerable populations
- Measure disparities in vulnerable populations
- Consider selection effects and confounding factors

Understanding
- Identifying determinants of health disparities at the following levels:
  - Patient/individual Provider
  - Clinical encounter
  - Health care system

Reducing
- Intervene
- Evaluate
- Translate and disseminate
- Change policy

The 3 phases of the disparities research agenda.

Efforts to Increase Minority Representation in Health Research

• Importance of racial/ethnic minority participation in health research has been well established, and includes:
  • Generalizability of research findings
  • Equity in provision of health care
  • Accurate information for specific race/ethnic group

• National Institutes of Health (NIH) Revitalization Act passed by United States Congress and signed into law by President Clinton in 1993.
  • The Act called for the NIH to require that all federally funded clinical research prioritize the inclusion of women and minorities.
<table>
<thead>
<tr>
<th>Year of First Examination</th>
<th>Name of Study</th>
<th>Race, Ethnicity</th>
<th>N</th>
<th>Age at Entry, Yrs</th>
<th>Website Address</th>
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<tr>
<td>1948</td>
<td>Framingham Heart Study</td>
<td>White</td>
<td>5,209</td>
<td>28-62</td>
<td><a href="http://www.framinghamheartstudy.org">www.framinghamheartstudy.org</a></td>
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<td>1971</td>
<td>Framingham Heart Study Offspring</td>
<td>White</td>
<td>5,124</td>
<td>5-70</td>
<td><a href="http://www.framinghamheartstudy.org">www.framinghamheartstudy.org</a></td>
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<td>1985</td>
<td>Coronary Artery Risk Development in Young Adults</td>
<td>White/black</td>
<td>5,115</td>
<td>18-30</td>
<td><a href="http://www.cscia.dopm.uab.edu">www.cscia.dopm.uab.edu</a></td>
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<td>1987</td>
<td>Atherosclerosis Risk in Communities</td>
<td>White/black</td>
<td>15,792</td>
<td>45-64</td>
<td><a href="http://www.cscia.unc.edu/aric">www.cscia.unc.edu/aric</a></td>
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<td>1989</td>
<td>Cardiovascular Health Study</td>
<td>White/black</td>
<td>5,888</td>
<td>65+</td>
<td><a href="http://www.chs-nihli.org">www.chs-nihli.org</a></td>
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<tr>
<td>1989</td>
<td>Strong Heart Study</td>
<td>American Indian</td>
<td>4,549</td>
<td>45-74</td>
<td><a href="http://www.strongheart.ouhsc.edu">www.strongheart.ouhsc.edu</a></td>
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<tr>
<td>1991</td>
<td>Women’s Health Initiative*</td>
<td>White (82%)/black/Asian</td>
<td>161,808</td>
<td>50-79</td>
<td><a href="http://www.nhlbi.nih.gov/whi/">www.nhlbi.nih.gov/whi/</a></td>
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<tr>
<td>2000</td>
<td>Jackson Heart Study</td>
<td>Black</td>
<td>5,301</td>
<td>21+</td>
<td><a href="http://www.jhs.jsums.edu/jhsinfo">www.jhs.jsums.edu/jhsinfo</a></td>
</tr>
<tr>
<td>2000</td>
<td>Multi-Ethnic Study of Atherosclerosis†</td>
<td>White/black/Hispanic/Chinese</td>
<td>6,814</td>
<td>45-84</td>
<td><a href="http://www.mesa-nihli.org">www.mesa-nihli.org</a></td>
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<td>2001</td>
<td>Strong Heart Study Family Study</td>
<td>American Indian</td>
<td>3,776</td>
<td>15+</td>
<td><a href="http://www.strongheart.ouhsc.edu">www.strongheart.ouhsc.edu</a></td>
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<td>2001</td>
<td>Genetics of Coronary Artery Disease in Alaska Natives</td>
<td>Alaska natives</td>
<td>1,214</td>
<td>18+</td>
<td><a href="http://www.gccan.sfbrgenetics.org">www.gccan.sfbrgenetics.org</a></td>
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<td>2002</td>
<td>Framingham Heart Study Generation 3</td>
<td>White</td>
<td>4,095</td>
<td>19-70</td>
<td><a href="http://www.framinghamheartstudy.org">www.framinghamheartstudy.org</a></td>
</tr>
<tr>
<td>2008</td>
<td>Hispanic Community Health Study/Study of Latinos</td>
<td>Mexican/Puerto Rican/Cuban/Central and South America/Dominican</td>
<td>16,000</td>
<td>18-74</td>
<td><a href="http://www.cscia.unc.edu/hchs">www.cscia.unc.edu/hchs</a></td>
</tr>
</tbody>
</table>

*The Women’s Health Initiative initially had both an observational and a clinical trial component; the clinical trial was later converted to a follow-up observational study after trial termination; limited to female participants (all other studies on this list recruited both male and female subjects). †The Multi-Ethnic Study of Atherosclerosis is the only study on the list that excluded at recruitment subjects with known clinical cardiovascular disease.

Sorlie and Wei. JACC Vol. 58, No. 19, 2011
Efforts to Detect, Understand, and Address Health Disparities
How Far Have We Come?
Life expectancy at birth

NOTE: Life expectancy data by Hispanic origin were available starting in 2006 and were corrected to address racial and ethnic misclassification.

SOURCE: CDC/NCHS, Health, United States, 2015, Figure 18. Data from the National Vital Statistics System (NVSS).
Cardiovascular Disease and Other Major Causes of Death by Sex and Race/Ethnicity (United States: 2013)
US Age-Standardized Death Rates Attributable to Cardiovascular Disease (CVD) by Race/ Ethnicity, 2000 to 2013.

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360

Copyright © American Heart Association, Inc. All rights reserved.
US Age-Standardized Death Rates Attributable to Stroke by Race/Ethnicity, 2000 to 2013

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360

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NOTE: Estimates are age-adjusted. Hypertension is having measured high blood pressure (systolic pressure of at least 140 mm Hg or diastolic pressure of at least 90 mm Hg) and/or respondent report of taking antihypertensive medication.

SOURCE: CDC/NCHS, Health, United States, 2015, Figure 23. Data from the National Health and Nutrition Examination Survey (NHANES).
Age-Adjusted Trends in Prevalence of High Blood Pressure in Adults Ages ≥20 Years by Race/Ethnicity and Sex

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360
Extent of Awareness, Treatment, and Control of High Blood Pressure by Race/Ethnicity (NHANES: 2007–2012)

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360
Current Cigarette Smoking: Adults Aged 18+

NOTES: Estimates are age-adjusted. Smoked 100 cigarettes in their lifetime and smokes now every day or some days.
SOURCE: CDC/NCHS, Health, United States, 2015, Figure 24. Data from the National Health Interview Survey (NHIS).

1Significantly different from non-Hispanic Asian persons.
2Significantly different from non-Hispanic white persons.
3Significantly different from Hispanic persons.
4Significantly different from women of the same race and Hispanic origin.

NOTE: All estimates are age-adjusted by the direct method to the 2000 U.S. census population using the age groups 20–39, 40–59, and 60 and over.


CVD risk factors were defined as follows: **Hypercholesterolemia**: total cholesterol >240 mg/dL, LDL cholesterol >160 mg/dL, HDL cholesterol <40 mg/dL, or on cholesterol-lowering medication; **Obesity**: body mass index >30.0 kg/m²; **Hypertension**: systolic blood pressure >140 mm Hg, diastolic blood pressure >90 mm Hg, or on antihypertensive medication; **Diabetes mellitus**: fasting plasma glucose >126 mg/dL, 2-hour-postload plasma glucose >200 mg/dL, an HbA₁c >6.5%, or on anti-hyperglycemic medications; **Smoking**: currently smoking cigarettes.

Daviglus et al., Progress in Cardiovascular Diseases. 2014. [http://dx.doi.org/10.1016/j.pcad.2014.07.006](http://dx.doi.org/10.1016/j.pcad.2014.07.006)

Daviglus et al., JAMA 2012;308(17):1775-1784
Prevalence of CVD Risk Profiles by Hispanic/Latino Group

Values weighted for survey design and non-response and adjusted for age. Prevalence with 95% CI are reported.

Risk factors: **Hypertension** SBP/DBP >140/>90 or on treatment. **Hypercholesterolemia**, total cholesterol >240 mg/dL HDL-C <40 mg/dL LDL-C >160 mg/dL or on treatment. **Obesity**, BMI >30kg/m2; **Diabetes**, fasting glucose >126 mg/dL 2h-post-load plasma glucose >200 mg/dL A1c >6.5%, or use of diabetes medications. **Smoking**, currently smoking cigarettes.

Daviglus et al. JAMA 2012;308(17):1775-84
The Need for a Paradigm Shift

- Over the past 5 decades, medical research has generated extensive knowledge on classification of chronic diseases and identification of risk factors.
- Rigorous investigation and evaluation of the safety and efficacy of preventive and therapeutic measures has led to reduced morbidity and mortality.
- This evidence has generated treatments that are expected to benefit the population as a whole.
- Individual patients can have markedly variable responses to therapy, i.e., the same treatment may be highly effective, have no effect, or have deleterious effects.
- To date, progress in identifying optimal individualized treatments has been modest, because of gaps in knowledge about disease causation in individuals and factors underlying variable responses to therapy.
What Is Precision Medicine?

• To date, most medical treatments have been designed for the “average patient.” However, with this “one-size-fits-all” approach, treatment can be very successful for some patients but not for others.

• **Precision medicine** is an emerging approach for disease treatment and prevention that takes into account individual variability in lifestyle, environment, and genes, with the goal of providing the best care possible based on each individual’s unique makeup.

• Precision medicine aims to give clinicians tools to better understand the complex mechanisms underlying a patient’s health, disease, or condition, and to better predict which treatments will be most effective.
The Precision Medicine Initiative® (PMI)

• Announced by President Barack Obama in his 2015 State of the Union address
• Bold new research effort to revolutionize how we improve health and treat disease.
• Aims to leverage advances in genomics and emerging methods for managing and analyzing large data sets through collaborative public and private efforts, while protecting privacy, and health information technology to accelerate biomedical discoveries.
• MISSION: To enable a new era of medicine through research, technology, and policies that empower patients, researchers, and providers to work together toward development of individualized care.

“My hope is that this becomes the foundation, the architecture, whereby in 10 years from now we can look back and say that we have revolutionized medicine.”

—President Barack Obama
The Promise of Precision Medicine

• Precision medicine is not a new concept (e.g., blood transfusions, etc.)

• Early successes of precision medicine approaches:
  • Targeted treatments for some types of cancer and for cystic fibrosis that are effective in patients who share an underlying causal genotype.
  • Progress in understanding how to optimize therapies based on how different polymorphisms predict therapeutic response.
  • Patients with previously undiagnosed genetic diseases been successfully diagnosed with individual genome sequencing.
  • New disease subtypes increasingly being defined through molecular profiling of affected tissues.

• Recent advances in basic research, technology development, genomics, proteomics, metabolomics, EMRs, Big Data, mHealth, etc. have expanded the prospects for broader application of precision medicine approaches.
The Promise of Precision Medicine

In the words of Eric Dishman, Director of the Precision Medicine Initiative® Program...
The All of Us℠ Research Program

- The cornerstone of the larger PMI -- led by the NIH
- Previously called the Precision Medicine Initiative® Cohort Program
- Landmark longitudinal research effort to improve disease prevention and treatment measures based on individual differences in lifestyle, environment and genetic factors
- Will provide the platform for expanding knowledge of precision medicine approaches that will benefit the nation for many years to come
- Data to be shared freely and rapidly to inform a variety of research studies.
The development and implementation of this program is being guided by a set of **core values**:

- Participation is open to all.
- Participants reflect the rich diversity of the U.S.
- Participants are partners.
- Participants have access to their information.
- Data will be accessed broadly for research purposes.
- Security and privacy will be of highest importance.
- The program will be a catalyst for positive change in research.
The *All of Us*℠ Research Program

- One million or more volunteers
  - To reflect the broad diversity of the U.S., not statistically representative
  - Children and adults ages 1 year and older
  - Men and women from diverse race/ethnic groups and geographic locations, and with differing health status
  - Longitudinal cohort, with continuing interactions
The All of Us℠ Research Program

• Two methods of recruitment
  • Direct volunteers (anyone can sign up directly)
  • Healthcare provider organizations (HPO)
Key Established Components of the *All of Us*<sup>SM</sup> Research Program

**DATA AND RESEARCH SUPPORT CENTER (DRC)**
Vanderbilt University Medical Center
with the Broad Institute and Verily

**BIOBANK**
Mayo Clinic

**PARTICIPANT TECHNOLOGIES CENTER (PTC)**
Scripps Research Institute
with Vibrent Health

**HEALTH CARE PROVIDER ORGANIZATIONS (HPOs)**
Regional Medical Centers, Health Centers
(including Federally Qualified Health Center pilots)
VA Medical Centers
Participant Recruitment Sites

HPO Regional Medical Centers
• Located in Illinois, New York, Pennsylvania (2), Arizona, California, Boston, and Michigan

HPOs: Federally Qualified Health Centers (FQHCs) – Pilot Sites
• Collaboration with Health Resources and Services Administration (HRSA)

HPOs: VA Medical Centers
• Collaboration with Department of Veterans Affairs to enroll veterans
• 20 participating sites anticipated
A Transformational Approach to Diversity

Reflecting the country’s rich diversity to produce meaningful health outcomes for historically underrepresented communities

People

Health Status

Geography

Data Types
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
The Program will start by collecting a limited set of standardized data from sources that will include:

- Participant questionnaires
- Electronic health records
- A baseline physical evaluation
- Biospecimens (blood and urine samples)
- Mobile/wearable technologies
- Geospatial/environmental data

Data types will grow and evolve with science, technology, and trust.
The *All of Us*℠ Research Program aims to generate:

- **A new model of research** based on collaboration among researchers, providers, and participants
- **A rich resource of data**, including biospecimens, to help accelerate research advances
- **Increased knowledge** leading to individualized care and improved health for future generations
Scientific Opportunities

- Develop quantitative estimates of risk for a range of diseases by integrating environmental exposures and genetic factors.

- Identify the causes of individual variation in response to commonly used therapeutics = pharmacogenomics.

- Discover biological markers that signal increased or decreased risk of developing common diseases.

- Develop targeted solutions to health disparities.

- Use mobile health technologies to correlate activity, physiological measures, and environmental exposures with health outcomes.

- Create a platform to enable trials of targeted therapies.

- Empower study participants with data and information.
Promises and Challenges

- Disease patterns, presentation, and response to treatment can vary markedly by race/ethnic background.
- However, many current medical treatments are informed by research findings from a largely homogeneous white, male, urban populations.
  - Unclear whether current knowledge on the biology of complex traits and the response to therapy is directly applicable to others. This has the potential to maintain or aggravate health disparities.
- By leveraging the rich diversity of the US population, the All of Us℠ Research Program will provide the ability to account for individual variation while providing opportunities to advance research that may reduce disparities and move towards health equity.
- Of note, concerns have been raised by some researchers that access to new genomic medicine technologies may be limited to wealthy individuals or those with high quality health insurance.
  - Concerns that such a technology divide may worsen health disparities for minorities with regards to access to genomic medicine.
“This range of information at the scale of 1 million people from all walks of life will be an unprecedented resource for researchers working to understand all of the factors that influence health and disease.”

“Over time, data provided by participants will help us answer important health questions, such as why some people with elevated genetic and environmental risk factors for disease still manage to maintain good health, and how people suffering from a chronic illness can maintain the highest possible quality of life. The more we understand about individual differences, the better able we will be to effectively prevent and treat illness.”

-- Dr. Francis S. Collins, NIH Director
The core values of the President’s PMI challenge the scientific community to advance population health in ways that create true benefits to all populations...

There are many benefits to recruiting diverse populations to participate in the Precision Medicine Initiative. This rich research resource provides a unique opportunity to understand the health issues impacting all population groups. The benefits extend far beyond the availability of genomics and other biomarkers for diverse populations. It will also include the systematic collection of social information, demographics and clinical data that will help us understand those mechanisms that lead to health disparities.”

NIMHD Director Dr. Eliseo J. Pérez-Stable.
More information on the Precision Medicine Initiative® is available at:
www.nih.gov/precisionmedicine

Thank you!
Advances in precision medicine have already led to some new treatments tailored to specific characteristics of individuals, such as a person’s genetic makeup, or the genetic profile of an individual’s tumor, transforming the treatment of diseases such as cancer.

The potential for precision medicine to improve care and speed the development of new treatments has only just begun to be tapped.

“...the prospect of applying this concept broadly has been dramatically improved by the recent development of large-scale biologic databases (such as the human genome sequence), powerful methods for characterizing patients (such as proteomics, metabolomics, genomics, diverse cellular assays, and even mobile health technology), and computational tools for analyzing large sets of data.” -- Francis S. Collins and Harold Varmus. A New Initiative on Precision Medicine. *N Engl J Med.* 2015;372(9): 793-795.

Coordinated and sustained national effort was needed to translate these early successes to large scale efforts.

“What is needed now is a broad research program to encourage creative approaches to precision medicine, test them rigorously, and ultimately use them to build the evidence base needed to guide clinical practice.” -- Francis S. Collins and Harold Varmus. A New Initiative on Precision Medicine. *N Engl J Med.* 2015;372(9): 793-795.
Objectives of All of Us<sup>SM</sup> Research Program HPO Enrollment Centers

- The objectives of the HPO Enrollment Centers are to:
  - Recruit and enroll participants
  - Promote study participation
  - Collect data and biospecimens
  - Foster participant engagement
  - Facilitate involvement of researchers in utilization of research resources developed by the program

- Participants enrolled through HPOs will be invited to participate regardless of disease status, and will be representative of all life stages as well as reflect the broad diversity of the U.S. population.
A Transformational Approach to Data Access

- Data sharing will be swift to both researchers and participants
- Participants will have access to study information and data about themselves
- Data collection will start small and will grow over time
- Privacy and security will adhere to the highest standards
- Will invest to level the playing field so diverse researchers can play
“The cancer-focused component of this initiative will be designed to address some of the obstacles that have already been encountered in ‘precision oncology.’”

(e.g., unexplained drug resistance and genomic heterogeneity of tumors)

“The initiative's second component entails pursuing research advances that will enable better assessment of disease risk, understanding of disease mechanisms, and prediction of optimal therapy for many more diseases, with the goal of expanding the benefits of precision medicine into myriad aspects of health and health care.”

“Although the precision medicine initiative will probably yield its greatest benefits years down the road, there should be some notable near-term successes.”

(e.g., cancer studies, early insights into pharmacogenomics, observations of benefits use of mobile health technologies leading to strategies for chronic disease prevention)

The Illinois Precision Medicine Initiative Consortium

- One of the regional health care provider organizations.
- Collaboration between Northwestern Memorial Hospital/Northwestern Medicine, University of Chicago Medical Center, and University of Illinois Hospital & Health Sciences System, and their partner institutions: Ann and Robert H. Lurie Children's Hospital, Rush University Medical Center, NorthShore University Health System, Cook County Health & Hospitals System, Mount Sinai Hospital, OSF HealthCare, Southern Illinois University HealthCare, Memorial Health System, Sarah Bush Lincoln Health System, Blessing Health System) and federally qualified health centers (Mile Square Health Center, Alliance of Chicago Community Health Services
IPMC Recruitment Goals

Target Population
• Patients from medical centers at the partner institutions and collaborating hospitals

Year 1 Enrollment
• At least 10,000 individuals ages 1 and older (≥3,334 per academic institution)
• Approximately 40% non-Hispanic white, 30% non-Hispanic black, 20% Hispanic/Latino, 5% Asian, and 5% other race participants; women to comprise about 50% of each group
• 10% will be children (ages <18 years)

Years 2-5 Enrollment
• At least 35,000 participants per year, yielding a total participant sample of at least 150,000 participants from the IPMC
• Additional HPOs that could participate as partner sites if needed

Participant enrollment activities will adhere to the PMI® Core Values:
• Participation is open to all
• Participants reflect America’s rich diversity
• Participants are partners
• Participants have full access to their information
• Data is broadly accessible for research purposes
• The program will be private and secure
• The program is a catalyst for positive change
Factors of Risk in the Development of Coronary Heart Disease—
Six-Year Follow-up Experience

The Framingham Study

WILLIAM B. KANNEL, m.d., THOMAS R. DAWBER, m.d., f.a.c.p.,
ABRAHAM KAGAN, m.d., f.a.c.p., NICHOLAS REVOTSKIE, m.d.,
AND JOSEPH STOKES, III, m.d.
Framingham, Massachusetts

Increasingly reliable estimates of the prevalence and incidence of coronary atherosclerosis is present for many

Age-Adjusted Trends in Mean Serum Total Cholesterol among Adults Ages ≥20 by Race/Ethnicity and NHANES Survey Year

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360

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Awareness, Treatment, and Control of High Blood Pressure by Hispanic/Latino Background (HCHS/SOL)

Source: HCHS/SOL Data Book
Age-Adjusted Prevalence of Physician-Diagnosed Diabetes Mellitus in Adults Ages ≥20 Years by Race/Ethnicity and Sex (NHANES: 2009–2012)

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360

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Age-Adjusted Prevalence of Low Risk Profile by Hispanic/Latino Background in Men (A) and Women (B) -- Findings from HCHS/SOL

Low Risk (LR) status was defined as having all of the following: total cholesterol <200 mg/dL and not taking cholesterol-lowering medication; systolic BP <120 mm Hg, diastolic BP <80 mm Hg, and not taking BP medication; BMI <25; not currently smoking; and fasting glucose <100 mg/dL, HbA1c <5.7%, not taking medication for DM, and no history of DM.

Participants not at LR were classified as having no adverse but ≥1 unfavorable or borderline risk factor, any single adverse risk factor, or ≥2 adverse risk factors.

All values were weighted for survey design and nonresponse.

Daviglus ML et al. J Am Heart Assoc 2016;5:e003929
Age-Standardized Prevalence of Number of Ideal Cardiovascular Health Criteria, US Adults Ages ≥20 Years -- Overall and by Race/Ethnicity (NHANES: 2011 to 2012)

Dariush Mozaffarian et al. Circulation. 2016;133:e38-e360

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NOTE: Preliminary estimates for the first 6 months of 2015 are shown with a dashed line.
SOURCE: CDC/NCHS, Health, United States, 2015, Figure 26. Data from the National Health Interview Survey (NHIS).
“... We need to learn much more about what causes disparities — including the role of society, the environment, genes and socioeconomics — and to find effective ways of overcoming or changing them. Our discoveries should translate into health benefits for everyone.”

-- Francis S. Collins, MD, PhD, NIH Director (Current)
[commenting on the transition of the National Center on Minority Health and Health Disparities (NCMHD) to the National Institute on Minority Health and Health Disparities (NIMHD)]