

**U.S. Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
National Institute on Minority Health and Health Disparities (NIMHD)
National Advisory Council on Minority Health and Health Disparities (NACMHD)**

9000 Rockville Pike, Bethesda, MD
Building 31, 6th Floor Conference Room
September 7, 2017 (Closed Session) 1:00pm-5:00 pm
September 8, 2017 (Open Session) 8:00 am -2:00 pm

Meeting Minutes

Council Members Present

Eliseo J. Pérez-Stable, MD, Chairperson; Director, NIMHD
Margarita Alegría, PhD
Maria R. Araneta, PhD, University of California San Diego
Linda Burhansstipanov, MSPH, DrPH, Native American Cancer Initiatives
Sandro Galea, MD, MPH, DrPH, Boston University
Linda S. Greene, JD, University of Wisconsin
Ross Hammond, PhD, The Brookings Institute
Fernando Sanchez Mendoza, MD, MPH, Stanford University
Brian Rivers, PhD, MPH, Morehouse School of Medicine
Gregory A. Talavera, MD, MPH, San Diego State University

Council Members Absent

Hilton Hudson, II MD, FACS, FCCP, University of Chicago

Ex Officio Members Present

William Riley, PhD, Office of Behavioral and Social Sciences Research, NIH

Ex Officio Members Absent

Said A. Ibrahim, MD, MPH, University of Medicine
Cara Krulewicz, CNM, PhD, FACNM, Department of Defense

Adhoc Members Present

Giselle M. Corbie-Smith, MD, MS, University of North Carolina at Chapel Hill
Amelie G. Ramirez, DrPH, MPH, BS, University of Texas Health Sciences Center

Executive Secretary

Joyce A. Hunter, Ph.D.

Presenters

Eric Dishman, All of Us Research Program, Precision Medicine Initiative, NIH
Maria R. Araneta, PhD, University of California San Diego
David M. Murray, PhD, Associate Director for Prevention and Director, Office of Disease Prevention

CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Eliseo Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD), called to order the Open Session of the 46th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) at 8:15 a.m.

INTRODUCTION OF MEMBERS & AD HOC MEMBERS

Council members and others present introduced themselves and their affiliations. Dr. Pérez-Stable introduced Margo Edmunds, Abdul Sahikh, and Sinsi Hernandez-Cancio from Friends of NIMHD.

COUNCIL MINUTES APPROVAL – June 2017

Dr. Hunter call for a motion to approve the minutes from the June 2017 meeting. The Council unanimously approved the minutes of the June 2017 Council meeting. Dr. Hunter informed the Council that the 2018 Council meetings will take place in February, May, and September, as noted in the Agenda. The present meeting was the last time the Council would convene in Building 31. The subsequent meeting will take place in the Natcher Building.

2018 Council Dates

February 26-27, 2018

May 10-11, 2018

September 10-11, 2018

NIMHD DIRECTOR'S REPORT AND DISCUSSION

Dr. Pérez-Stable provided the report on activities relevant to NIMHD since the June meeting.

NIH News

- Dr. Francis Collins was reappointed NIH Director by President Trump. Larry Tabak will remain the Principal Deputy Director. Carrie Wolinetz has been named Acting Chief of Staff, and Alfred Johnson has been named Deputy Director for Administration.
- Dr. Josie Briggs will be retiring next month from her position as Director of the National Center for Complementary and Integrative Health (NCCIH). A nephrologist and former leader of the Precision Medicine Initiative (now called the All of Us Research Program), Dr. Briggs will become Editor in Chief of the *Journal of the American Society of Nephrology*.
- Dr. Norman “Ned” Sharpless was appointed Director of the National Cancer Institute (NCI), the only political appointment at NIH other than the Director. Dr. Sharpless, a medical oncologist and basic science researcher, was a member of the NIA Advisory Council and Director of the Cancer Center at the University of North Carolina at the time of his appointment.
- Dr. Jerome Adams succeeded Dr. Vivek Murthy as the U.S. Surgeon General. He is an anesthesiologist, pain specialist and formerly of the Indiana State Department of Health. Dr. Adams once held the position of Chair of the Pharmacy and Therapeutics Committee in Indiana.
- Dr. Matthew Lin was appointed Deputy Assistant Secretary for the Office of Minority Health (OMH) in the U.S. Department of Health and Human Services (HHS). Dr. Lin is a hand surgeon. He has worked extensively with racial/ethnic populations. Dr. Lin previously received the leadership award for public service from the California Hospital Association, it's Leadership in Governance Award, and once served as Mayor of San Marino, California. This appointment is important for NIMHD since the Directors of the Federal Offices of Minority Health meet on and monthly schedule to exchange information and plan strategies on minority health issues.
- Drs. Douglas Lowy and John Schiller received the Lasker-Debakey Clinical Medical Research Award for their work on the human papillomavirus (HPV) vaccine. This is a highly prestigious award that has been called the “American Nobel Prize”. An awards luncheon will be held in New York in late September.
- The Next Generation Researchers Initiative will be going forward to emphasize increased funding for early stage investigators. This plan extends the pay line further for early stage investigators. (within ten years of one's last training). This initiative is also intended to support mid-career investigators coming in for their R01 renewal or a 2nd R01. Though this policy will not affect NIMHD as much as other ICs, the Institute will implement a limit on the number of grants awarded to individual established PIs. Dr. Pérez-Stable noted one of the beneficial outcomes of this initiative will be the monitoring of gender and race/ethnic diversities of PIs.
- The All of Us Research Program—which has been launched in a beta testing format—awarded community grants to FiftyForward (Nashville), the National Alliance for Hispanic Health (aka

COSMD), Delta Research and Educational Foundation, and the San Francisco General Hospital Foundation. Eric Dishman will provide more information on this program during his presentation.

- In August, The Discovery Channel aired three documentaries featuring footage of the NIH Clinical Center. This was an important outreach activity to let the public know what NIH does.
- Dr. Pérez-Stable attended the NIH Advisory Committee to the Director meeting in June. Dr. Larry Tabak gave a presentation on the grant support index report, Dr. Hannah Valentine gave a presentation on diversity in the workforce, and Dr. Nora Volkow gave a presentation on the opioid epidemic.
- NIH is reforming its clinical trials, due to the fact that many funded trials do not always reach their recruit goals or publish findings. To do this, NIH is creating a system that better determines what trials are being conducted. Instituting the Single Institutional Review Board (sIRB) was a preliminary step. The next step will be defining the characteristics of a clinical trial, and then providing a single clinical trial FOA for those trials. According to the guidelines, a clinical trial should: 1) involve humans; 2) employ one or more intervention; 3) prospectively assigned participants; 4) have a health related biomedical or behavioral outcome; and 5) must be registered in clinicaltrials.gov. Dr. Pérez-Stable expects that NIMHD will sign on for a clinical trial-specific FOA, which Dr. Lauer will discuss in more detail at the February 2018 meeting.
- The Council reviewed Dr. Meredith Temple-O'Connor's presentation on Inclusions in Clinical Research at NIH from the February 28, 2017 meeting. Data presented indicated a steady state for minority inclusion, in the 25-30 percent range. The goal now should be to set the bar for inclusion higher. The data did not address that about 60 percent of participants in clinical studies are women and that men are actually underrepresented, nor the issue of inclusion of certain diseases. This is an area that NIMHD would be interested.
- Drs. Collins, Fauci, Gibbons, Gordon, Hodes, Lowy, and Volkow testified before the Senate Appropriations Subcommittee in June. Congressional support for NIH remains robust across the aisle, especially from Representative Tom Cole and Senator Roy Blount. There is a lot of interest in Alzheimer's disease, continuing support for the All of Us Program, and the BRAIN Initiative.

NIMHD Activities

- In late September Dr. Pérez-Stable will serve on a panel called "African American Participation in Clinical Trials: Challenging the Gold Standard" at the Annual Legislative Conference of the Congressional Black Caucus Foundation. David Satcher will deliver the keynote address.
- Earlier in the summer Dr. Wasserman met with staff from the offices of Representatives Henry Cuellar and Filemon Vela to discuss STEM and health programs. Dr. Pat Grady, Director of the National Institute of Nursing Research (NINR), also participated in the meeting.
- On June 14, Dr. Pérez-Stable and Dr. Lowy spoke on cancer health disparities at Thomas Jefferson University's Sidney Kimmel Cancer Center. Congressmen Donald Payne and Charlie Dent were also in attendance.
- Dr. Pérez-Stable said the final budget for FY17 would be presented at the Council's February 2018 meeting. The Research Centers in Minority Institutions Program (RCMI) accounts for approximately 20% of the budget. The RPG budget category has increased and is expected to grow further. The Research, Management, and Support (RMS) the operational budget, is comparable to what other ICs have. The Intramural research program accounts for only 2% of the budget and should increase in 2018. The training budget—which includes the loan repayment program, the MHIRT program, fellowship awards (F31 and F32), and the K program—accounts for 5% of the budget. The Endowment program accounts for 4% of the budget. Dr. Pérez-Stable plans to give a detailed budget report at the February meeting. The report will include how many R01 and R21 applications have been received since signing onto the parent announcements and will give a trajectory for the last three or four years.
- Dr. Pérez-Stable and Carl Hill from the National Institute on Aging (NIA) attended a reception for the National Medical Fellowships (NMF). This is a foundation which works with underrepresented medical students who have financial needs. Many minority leaders have been beneficiaries of the program.

- NIMHD continues to have a strong relationship with the Association of American Medical Colleges (AAMC). Dr. Pérez-Stable presented at the Minority Faculty Leadership seminar, during their meeting in June.
- Dr. Pérez-Stable attended a dinner for advocates of Henrietta Lacks hosted by the Susan G. Komen Foundation.
- In late August Dr. Pérez-Stable attended two NHLBI workshops, one on illumination of disparities through community-engaged research and another on training the next generation of implementation scientists. The latter workshop was a webinar developed by the Urban Universities for HEALTH. They have developed a number of programs to enhance diversity in the workforce.
- Dr. Pérez-Stable spoke to NIMHD's summer trainees, and then individually met with a small group. Based on their interest, he tried to connect them with colleagues in South America and West Africa.
- NIMHD representatives attended a meeting with officials from the Robert Wood Johnson Foundation. Bob Croyle from NCI, Cara James from the Centers for Medicare and Medicaid Services (CMS), and a Centers for Disease Control and Prevention (CDC) representative also attended.
- Dr. Pérez-Stable spoke at an event for the National Medical Association (NMA) in Philadelphia at the invitation of Edith Mitchell. Elena Rios spoke on the same panel, and Dr. Satcher was in attendance.
- In August, Dr. Pérez-Stable attended a health summit at a Seventh-day Adventist Church in Hyattsville, Maryland. The participants, who were predominantly African American, wanted to hear perspectives on minority health.
- Dr. Griff Rogers from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) does a radio broadcast of public service announcements on health. Dr. Pérez-Stable read one of the announcements in Spanish. A first time for the program.
- NIMHD was involved in a number of scientific workshops, including, The Science of Caregiving and Bringing Voices Together (Drs. Rosario and Jones participated), The Human Microbiome (Dr. Michael Sayre participated), and an Implementation Science workshop (Dr. Xinhi Zhang).
- NIMHD's scientific staff coordinates a monthly scientific seminar called Inspired Science Lecture Series: Incorporating Science in Programming to Reduce Disparities. Dr. Ngo-Metzger—the scientific director for the U.S. Preventive Services Task Force (USPSTF)—presented at the seminar. In August, Dr. Volkow gave a compelling talk on the opioid epidemic. She had Fellow present data on D2, D3 receptor availability that was differentiated by race. Then Dr. Weatherspoon—the Program Director of Health Disparity Research at the National Institute of Dental and Craniofacial Research (NIDCR)—also presented.
- The intramural division hosts monthly seminars. Examples of these seminars and their presenters include: Dr. Jung Byun (Staff Scientist working with Dr. Gardner) on genomic profiling among diverse cohorts, Dr. Erik Rodriguez (a Staff Scientist that works with Dr. Pérez-Stable) on minority health, health disparities, and unhealthy behaviors, and Dr. Sherine El-Toukhy (who previously worked as a Fellow with Kelvin Choi) on patient-clinician communication analyzing the HINTS survey. In thinking about the next generation, the summer students presented at the NIH Poster Day. A photo showed Kaylyn Williams, Abel Amare, Michael Ramsey, Catherine Trad, and Myriam Alcantar Rama. They made presentations at the Intramural Seminar Series.
- The Health Disparities Research Institute (HDRI) is in year two of its new format. A diverse set of 52 scholars participated in August 2017. They were either postdocs or junior faculty, 41 PhD scientists and about 11 physicians. Many seemed interested in continuing to work with NIMHD in health disparities research. In small group discussions, the participants noted that the program was valuable in that they felt safe sharing their ideas. Dr. Pérez-Stable shared demographic data on the scholars. Visiting scientists did talks on selected topics. The scholars also spent time with the NIMHD program staff and with program staff from other ICs and Agencies. HDRI received support from the Office of Sexual and Gender Minority Research, and we hope to engage the Office of Tribal Health Research in the future.

- Another program that NIMHD supports, is the NIH Medical Research Scholars Program (MRSP). Dr. Maddox started the NIMHD support of the program, For the first time, NIMHD engaged a couple of scholars. Jennifer Bayly (Dr. Choi) and Sophie Claudel (Wiley-Powell) will be continuing to work with NIH this year. Nathan Stinson and Regina James have also been mentoring students in this program.
- Dr. Jean Kabakambira, an internist, is a new Rwandan Fellow. Dr. Anne Sumner from NIDDK who is also a NIMHD Adjunct Faculty—studies the metabolic health of African immigrants—started this program. NIMHD provides salary support for five years and NIDDK/Anne Sumner provides the infrastructure support for the research.
- Rada Dahger, a new American Association for the Advancement of Science (AAAS) Fellow with NIMHD came in late August and works with Dr. Regina James.
- Dr. Pérez-Stable shared a photo of Dr. DeLoris Hunter and Dr. Collins with members of the National Native American Youth Initiative (NNAYI) who visited NIH this summer. This program is a great way to introduce young people of Native backgrounds to biomedical research careers.
- The new RCMI funding opportunity announcement (FOA) was published with the modified guidelines discussed earlier.
- NIMHD is moving forward with the American Journal of Public Health Supplement on Science Visioning, which should be published by May 2018. This is a product of our workshops. The numerous visioning recommendations were trimmed down to 30 to get at the critical crosscutting areas. These will give a sense of where the field needs to go and will allow the Council to provide input on where the fields need to go in the next five years.
- NIMHD is editing a book, a project spearheaded by Xinzhi Zhang and Adi Rosario.
- NIMHD will be more engaged with the BUILD and NRMN diversity programs. Originally developed at NIMHD, the program migrated to the National Institute of General Medical Sciences (NIGMS). The program is modelled to support the pipeline and is linked to ten BUILD sites that exist around the country. The National Research Mentoring Network (NRMN) is a virtual mentoring network with various foci coordinated out of Boston College. The grantees will be up for competitive renewal in about a year. Two NIMHD program scientist will be more engaged with the program.
- Dr. Pérez-Stable provided updates on NIH Health Disparities Strategic Plan, which has been principally developed by Deborah Duran and a trans-NIH committee. The Science Visioning process really contributed to this, and the portfolio analysis. This ought to reveal what has been done over the last twenty years, as well as what they could do better to ameliorate health disparities. Research sustaining activities are another important aspect of this plan. Workforce diversity and capacity building to conduct research are also important areas of focus. The Council received the outline which is divided into the goals, research sustaining goals, and outreach collaborations goals. Dr. Pérez-Stable concluded that the shared strategic plan provided a good framework for understanding how NIMHD's efforts are being utilized.

NIMHD Staff Updates

- On September 1, Dr. Collins held the Awards Ceremony for NIH. Courtney Aklin, Joyce Hunter, Priscilla Grant, Jennifer Alvidrez, Derrick Tabor, Rina Das, Mike Sayre, and Phoung-Te Le were among the recognized NIMHD staff.
- Recently, Ranae Harris (Administrative Officer), Bambi Jewett (a clinical nurse), and Shelly Pollard (public affairs specialist) joined NIMHD staff.
- There has been a number of transitions. Chris Spates retired and Jessica Escobedo moved to the private sector as Director of Science Policy at a consulting firm. Sherine El-Toukhy transferred to Dr. Pérez-Stable's lab in NHLBI. She is recipient of a K99 award. Melanie Sabado accepted a faculty position at California State University, Los Angeles.

Scientific Advancements

- Back to back articles in the *Annals of Internal Medicine* showed that drinking coffee could prolong life. Without regard to the caffeine content of the coffee, the study showed two-three cups of coffee could prolong life by one-two years and could be considered healthy eating. One article

analyzed Northern Europeans while the other study looked at a Multiethnic Cohort Study (which included Native Hawaiians, Latinos, African Americans, and Japanese Americans). The Multiethnic Cohort Study was out of NCI Intramural Research Program.

- Andrea Garcia published a study that analyzed AAMC graduate data over three years and the outcome of intent to work in underserved communities. She adjusted for demographics, specialty plans, and debt burden, and found that women are more likely to work in underserved communities. Also, primary care doctors are more likely to work in underserved communities
- One paper published in the *JAMA Internal Medicine* analyzed membership in Alpha Omega Alpha, the medical honors society. The data suggests an unconscious racial bias in the selection of members. This is an important observation for diversity in the pipeline.
- Dr. Pérez-Stable was a funded PI in the NIA Resource Centers for Minority Aging Research (RCMAR) program. Results from the RCMAR study were published in the *Journal of Clinical Translational Sciences* in early 2017. Overall about 266 scholars, from 12 different RCMAR Centers were awarded R01s or equivalents over the course of 18 years. They have remained in research. Dr. Pérez-Stable said this program would be developed further as a model for RCMI and Centers nationwide.
- Kelvin Choi published a study on tobacco use and tobacco direct mail marketing, which found that those with lower income and less education were more susceptible to those marketing strategies. Direct mail denotes junk mail as well as online marketing and marketing in public settings. This strategy was associated with a progression of smoking among non-smokers and more difficulty in smoking cessation among smokers.
- In early September, the *Morbidity and Mortality Weekly Report* (MMWR) published a study showing that stroke mortality decreased roughly 40% from 2000-2015. There was no significant variation among race/ethnic diversities. Treatment in hypertension, not smoking, and management of vascular disease with secondary prevention contributed to this decline.
- One analysis from the National Survey of Drug Use and Health (NSDUH) examined perceived needs across all levels of mental illness and showed that minority groups (which included Asians, Latinos, and African American) all had lower levels of perceived needs. This reinforces the idea of the stigma about mental illness that is in minority communities.
- One study published by NIMHD R01 grantee Jennifer Lorvick (also a Presidential award recipient) examined the role of substance abuse treatment, facilitating HIV and Hepatitis C testing in this setting, and HIV care if one was already HIV affected. Dr. Pérez-Stable indicated the study highlights a point of intervention for future research.
- A RCMI-related project from the Morehouse School of Medicine looked at gene expression for sleep regulation. This study was performed on mice and could lead to a targeted study on restoring the gene in skeletal muscle. The RCMI program is one in which NIMHD will continue to fund basic research.
- A study in *Health Affairs* by Dr. Patzer, a R01 recipient, focused on kidney allocation and found that white individuals with end stage renal disease were more likely to get transplants than African Americans and Latinos. This has been well documented. In 2014 a new allocation system narrowed the gap in transplantation rates by 29% in the case of African Americans and 24% for Latinos.

Funding Opportunities

- RCMI FOA mentioned earlier, has been published.
- A new NIMHD FOA, will support the conduct research in the Caribbean, which has an expiration date of November 2019. The study would be based in the U.S. and would have Caribbean-based partners to study individuals in the Caribbean. A couple ICs co-signed onto this FOA.
- Dr. Pérez-Stable shared that there are ongoing health-services research, social epigenomic, and surgical disparity funding opportunities still available. The first wave of applications have been funded.
- In November 2016 a FOA that focuses on etiology and interventions in immigrant health outcomes was published.

- Another FOA on mechanisms of disparities in chronic liver disease and liver cancer came out in April 2017. Applications for this study have been received but not reviewed.
- The sleep disparities FOA came out in July.
- NIMHD signed onto the Trans-NIH Research Group FOA. Some of the initiatives include electronic nicotine delivery systems (NCI), the Ethical, Legal, and Social Implications (ELSI) in genome (NHGRI), and the multidisciplinary studies in HIV/AIDS in aging (NIA).
- Several NIMHD FOAs are still in development, namely youth violence prevention interventions that incorporate racism and discrimination, the simulation and modelling in systems science to address health disparities, and the limited application of the Tribal Epidemiology Centers. These projects are in their final stages and NIMHD is presently looking to collaborate with other ICs.
- NIMHD will also be working on future activities in HIV/AIDS research, specifically Pre-Exposure Prophylaxis to prevent HIV in women of color.

Statement of Understanding (SOU)

Priscilla Grant, NIMHD's Chief Grants Management Officer, presented the Statement of Understanding. NACMHD is charged with helping NIMHD achieve its goals by providing advice and recommendations to the Director on matters related to research activities and functions of the Institute. Working groups can occasionally be formed to address scientific or policy issues that have been deemed critical by NIMHD. The Institute will inform the Council of any scientific, legislative, budgetary, or other issues that will affect the mission of NIMHD and its constituencies. Two of the Council's most important functions are clearance of new initiatives (in open session) and secondary review of grant applications (in closed session). Individually considered actions include funding plans under RFAs, applications of high or low program priority, fundable applications from foreign institutions, summary statements requiring special discussions, co-funding of applications for which other ICs have responsibility, and some investigator-initiated applications.

NIH-published requests for applications (RFAs) do not allow appeals of initial peer review. Administrative actions related to change of PI, change of domestic institution, or administrative supplements for increased cost within the previously peer-reviewed and approved scope of a funded grant do not need to be brought before NACMHD. The Council cannot alter scores given by the Scientific Review Groups (SRGs) in closed session. Rather, they can only concur with the SRGs, not concur with the SRGs, recommend high or low program priority, or defer to obtain additional information at a later time. Ms. Grant also reviewed the Institute's processes for *en bloc* summary statements during the Close session as well as the options available to the Council when reviewing Concepts for Clearance in the open session. Although the SOU is comprehensive, not all actions will apply at every Council.

Dr. Nathaniel Stinson proposed two changes to the Statement of Understanding's section that discusses special actions brought to the Council. The first proposal stipulates only co-funds of applications that NIMHD did not have a primary or secondary assignment on the competing application be brought to Council. For example, in the proposal with the CDC, the administrative supplement applications would be brought before the Council, but co-funds with a NIMHD primary or secondary assignment that come in automatically, would not. The second proposal would eliminate the need for phase-three clinical trial application to be separate council actions. Dr. Hunter opened the floor for questions and discussion of the proposed changes and accepted recommendations. The Council passed the recommendation to accept those changes.

Accelerating Precision Health for All of Us

Mr. Eric Dishman, Director of the Precision Medicine Initiative (PMI), gave a presentation on the All of Us Research Program and its efforts to accelerate precision health. Mr. Dishman began his presentation with a story about how his own cancer treatments paved the way for his career as a patient advocate. He is a social scientist whose expertise is in independent living technologies for seniors (particularly those eligible for both Medicare and Medicaid). To treat patients effectively, Mr. Dishman explained, caregivers have to understand the whole person's health, which is the primary goal of the Precision Medicine Initiative and the All of Us Research Program.

The All of Us Research Program evolved out of the Precision Medicine Initiative announced by President Obama in his 2015 State of the Union Address. A Precision Initiative Working Group was established, which Mr. Dishman was asked to join due to his unique background as well as his personal experience with precision medicine. On July 6, 2016 the organization kicked off its implementation and development phase, in which it took the months of research it had been doing and started building the national team. Currently in the closed beta phase, the webpage joinallofus.org has informational resources but is not currently available for registration. A national launch will take place in the Spring of 2018.

With the goal of accelerating health breakthroughs that will enable individualized prevention, treatment, and care, the All of Us Research Program has three fundamental strategic objectives. First, the organization has to nurture relationships with one million or more people from different backgrounds. This relationship will be reciprocal, with both researchers and participants giving and receiving information. If this objective is accomplished, the second strategic goal will be to build one of the most comprehensive biomedical data sets ever created, which would be safe and allow for easy user access. While elite research institutions and Tier I universities will use this data set, the program aims to introduce community colleges, high school students, and citizen scientists to the data as well. The third primary strategic objective is to build the data infrastructure so that researchers and funders contribute their research to the project. The All of Us organization will be meeting with other NIH ICs, advocacy groups, scientists, and outside funders at a workshop in March 2018 to accomplish this goal for the first ten years.

In essence, the program emphasizes that people will have to be involved with the project for the duration of their life, and the gathered data will be used to address a multitude of factors that affect health (behavioral, social, community, biology, and genetics). Mr. Dishman called the project a quadruple-diversity program: diversity of people, diversity of places, diversity of data types, and a diversity of researchers. Handling data for a project of this size is a critical endeavor, and awards for that work have been made to Vanderbilt University, Verily Life Sciences, and The Broad Institute. The Mayo Clinic will be storing the blood and urine samples (35 million vials in the first protocol alone), and over time this could become the largest biobank in history. The participant center will be responsible for building the direct volunteer mechanism, which will build apps designed to recruit people into the study. More than thirty regional medical centers are presently signed on to the project, including six Federally Qualified Health Centers (FQHCs) and the Veterans Administration. Walgreens and Quest have signed on to do collect bio samples around the country. Community partners are crucial to the development of the program, and they range in size from small NGOs and churches to nationwide organizations. These community partners serve as the face of the program in a given place, and then Walgreens or Quest can collect the sample. The Southern All of Us Network, South East Enrollment Center, and All of Us Wisconsin are three of the newest member organizations.

The project's protocol contains a number of surveys developed by the National Health and Nutrition Examination Survey (NHANES) to gather basic information about participants. These surveys calculate a variety of basic physical measurements (blood pressure, BMI, heart rate, height, and hip circumference), as well as bio samples (blood and urine). Currently there are 137 locations enrolling 10,000-15,000 people in the program.

One of the core values of this project is its foundational commitment to diversity. As such, the program has to build relationships with diverse communities to be successful, which necessitates that groups like NACMHD remain involved with the study to provide input on health disparities. There are two design principles that drive this "diversity engine." One is building the health research capacity at the local level to reach the edges of communities previously excluded from research. The second principle is accommodating people physically, culturally, and socially.

The 'skinny' on health disparities in diabetes, regional fat, and preterm birth in Asian Americans and Pacific Islanders

Council member Maria Araneta, PhD gave a presentation on the elevated risk of Type II diabetes among Asian populations. In 2013 the International Diabetes Federation shared an atlas showing that China and India are the diabetes capitals of the world, due to their population size and the high prevalence of the disease there. This is important for the American context because The Pew Research Center estimates that by 2065 Asians will comprise 14% of America's population and will be the nation's largest immigrant group. In California, about 60% of the population is from a race/ethnic minority group and 15% of residents are Asian or Pacific Islander. Diabetes in that population is 21-22%, and Asians account for 51% of those with undiagnosed diabetes.

The earliest medical literature on diabetes in Asians was published almost sixty years ago and was based on almost 38,000 residents of Oahu. In 1896, when Queen Liliuokalani was placed on house arrest and Sanford Dole became the President of the Republic of Hawai'i, many Asians (especially Filipinos) were recruited to work in pineapple fields. In this study, Chinese participants had twice the prevalence of diabetes than Whites, and Filipinos, Japanese, and Koreans had roughly three times the diabetes prevalence as Whites. Ten years ago, Kaiser in northern California published data showing that Pacific Islanders, Filipinos, South Asians, and those from Pakistan, India, and Nepal have the highest diabetes prevalence in the state. In disaggregating that data, every Asian subpopulation showed higher diabetes prevalence than Whites, and exhibited a roughly 50% higher prevalence than Latino, African American, and American Indian populations.

When those in the Asian subpopulation were found to have high diabetes prevalence despite being below the clinical definition of obesity of BMI ≥ 30 , the American Diabetes Association (ADA) contacted the investigators with Asian clinical cohorts to evaluate BMI cut-points for diabetes screening. The data was gathered through the oral glucose tolerance test and included the MASALA study (run by Alka Kanya), the North Kohala study (run by Healani Chang), the Seattle Japanese Diabetes Community Study (run by Will Fujimoto), and Dr. Araneta's cohort in San Diego. Participants had to be over the age of forty-five and had to have no non-Asian admixture in their ethnicity. Screening merely by BMI was found to miss 36% of Asians with newly diagnosed diabetes. Since there were no cohorts for Chinese Americans, Korean Americans, or Vietnamese Americans, Dr. Araneta and her colleagues could not determine if their findings applied to those populations. As a result of this study, in January 2015 the ADA revised their guidelines to make a BMI of 23 the cut-point for diabetes screening in Asian Americans. The "Screen at 23" campaign is supported by NIDDK.

Sometimes called metabolically abnormal but normal weight, Dr. Araneta explained this characteristic affects nearly one-third of normal weight adults in the U.S., including 21% of Whites, 40% of Latinos, 32% of Chinese, 31% African Americans, and 40% of South Asians. While the study found that any of the three diabetes diagnostic criteria revealed 18% of people with the disease, screening only utilizing the more convenient A1c test found 9% of cases and including a fasting glucose measure identified only 5% of diabetes cases. Because many of the Asians surveyed had isolated post-challenge hyperglycemia, they would appear to have normal A1c and fasting glucose levels; only a two-hour glucose test revealed they have diabetes.

Thus, A1c is not sufficient to measure diabetes prevalence in Asian populations, especially among the Japanese. Dr. Araneta suggested cultural or religious factors could influence metabolic markers, which could be promising because of The Diabetes Prevention Program's (DPP) contention that lifestyle changes and Metformin could decrease diabetes risk by 58% and 31%, respectively. While Metformin is effective in the obese, it only reduces diabetes in Asians with a low BMI by 3%.

Dr. Araneta's Filipino cohort was started in 1995 with Dr. Elizabeth Barrett-Connor's Rancho Bernardo Study. In 1995 Dr. Barrett-Connor noticed most of the dialysis patients at the local VA Medical Center were thin Filipino men, whose diabetes was only found after they began to lose kidney function. From 1995-1999 the study focused predominantly on women with a follow-up visit after five years in 2002 and

ten years in 2007. About 453 women and 109 men were enrolled, of which 99% were immigrants. A study question was why do Filipinos have excess diabetes despite the absence of general obesity?

The cohort's interest in coronary artery calcium allowed an opportunity to study visceral adipose tissue (an active endocrine organ which produces inflammatory markers). Dr. Araneta showed a slide with samples from between the L4 and L5 vertebrae of an African American woman with a BMI of 25, and a Filipina woman with a BMI of 20. With the red areas denoting visceral fat, the Filipina woman had three times the amount of visceral adipose tissue as the overweight subject. Several other studies over the years have shown that other Asian subgroups also have excess adipose tissue. Thus, even with the ADA's new screening guidelines, diabetes in Filipinas could go undiagnosed. This information has been reproduced in the MESA (Multi-Ethnic Study of Atherosclerosis) report and the MASALA study, which showed African Americans had the most visible fat and Asians had the most visceral fat.

Dr. Araneta explained that Filipinas also have more pericardial fat as well as more fat in the rectus abdominis, which the MESA study reproduced in Chinese Americans in the Los Angeles area. In looking to eliminate visceral fat, it was important to note that the majority of the participants in the cohort were born in the 1940's and 1950's. Dr. Araneta then cited a relevant study from Dr. Richard Armenta which showed that regardless of race a woman who breastfed for four months in her 20's and 30's had less visceral fat in her 50's and 60's. Because of this study, Dr. Araneta's organization has partnered with a group to make an app that promotes the health benefits of breastfeeding.

Because adiponectin is reduced in the presence of visceral fat, it plays an important role in glucose homeostasis. Dr. Araneta's study found that Filipinas and African Americans exhibited 40%-50% of the adiponectin levels of Caucasians, and another study in the Philippines found a polymorphism in the adiponectin gene. Dr. Araneta suggested that analyzing adiponectin levels could be a useful screening tool in measuring diabetes in Asian populations, because those with the least adiponectin levels had the highest risk of diabetes, and some Filipinas with low adiponectin levels were as high risk for diabetes as Pima Indians.

Regarding sociocultural risk factors, the study found that education, low English proficiency, low adult interaction with mainstream society, being Catholic, having six or more live births, sustained social disadvantage, and insufficient sleep were all independently associated with diabetes. There is a misperception that Asians have high educational attainment and thus access to care; although 15% of Dr. Araneta's cohort had college education, 30% had only a high school education or less. One of three participants in study had three or more children, and while BMI does not increase with having children, visceral fat does. Therefore, social factors in highly religious Asian countries could contribute to high diabetes prevalence. Filipinas and African Americans also sleep 40-50%, less than the recommended seven hours, which may be due to shift work and cultural notions of sleep. The shorter sleep duration in Filipinos and African Americans increases the risk of diabetes.

Dr. Araneta speculated one of the reasons the risk of diabetes was so high among Asians was because the risk for diabetes occurs at infancy. In one study of 230,000 births in San Diego, gestational diabetes was highest among foreign-born Filipinas, Pacific Islanders, and Asians, and lowest among U.S.-born whites, African Americans, Latinas. Another study showed that several foreign-born groups—including Asians, Mexicans, Whites, and Somalis—had a much lower risk of spontaneous preterm diabetes prevalence than U.S.-born Whites, which demonstrated a health advantage that could benefit all Americans.

Dr. Araneta briefly discussed some of the interventions being undertaken. A CDC study is focused on working with restaurants and grocery stores to provide healthy food options. This study has enrolled 15 restaurants, two grocery stores, and 11 farmer's markets. The "Halt the Soy Sauce Campaign" has showed a reduction in condiments use in restaurants and there is an increase in vegetable consumptions in Korean and Vietnamese groceries.

Developing a Strategic Plan for the NIH Office of Disease Prevention

Dr. David Murray, Associate Director for Prevention and Director of the Office of Disease Prevention (ODP), gave a presentation on ODP's ongoing work to develop a strategic plan to work with NIMHD to enhance prevention research across NIH. ODP is a part of the Division of Program Coordination Planning and Strategic Initiatives (DPCPSI) and has a mission to improve public health by increasing the scope, quality, dissemination, and impact of prevention research supported by NIH. ODP defines prevention research in primary terms (promoting health and preventing the onset of diseases, disorders, and injuries) and secondary terms (detecting and preventing asymptomatic diseases).

ODP's current activities include: managing the Tobacco Regulatory Science Program (TRSP), acting as a liaison between NIH and the U.S. Preventative Services Task Force (USPSTF) and Community Services Task Force (CPSTF), spearheading the Healthy People Initiative, offering evidence-based assessment through the Pathways to Prevention workshop, providing training through the Mind the Gap Series and the Gordon Lecture, as well as co-funding research projects.

ODP has five strategic priorities. The first strategic objective of ODP is to monitor NIH's Prevention investments, which Dr. David Murray likened to portfolio analysis. When Dr. Murray first arrived at NIH in 2012, portfolio analysis needed improvement. To rectify this, they developed a taxonomy of prevention research with eight categories and 135 topics, subsequently using that taxonomy to create a coding system for grant awards. That coding method was then used to create automated tools to code awards. ODP intends to continue developing computer systems to further refine their work in coding classifications.

ODP's second strategic objective is to identify gaps in prevention research, especially by improving interaction with stakeholders like USPSTF and CPSTF. Coordination between NIH and USPSTF has indeed improved, especially with the latter's Insufficient Evidence Statement Survey that allows ICs to hone their recommendations. In this second strategic objective, ODP has also developed a Pathways to Prevention workshop series, which has already hosted events on opioids, myalgic encephalomyelitis, chronic fatigue syndrome, total worker health, and prevention of youth suicide. Three additional workshops through 2019 include methods to evaluate natural experiments in obesity prevention and control, medications in fracture prevention, and achieving health equity in preventive services.

The third strategic objective is to support projects and applications that use the best methods. To do this, ODP has posted prevention methods training opportunities and methods-related FOAs on their website. To improve the quality of incoming applications, ODP developed an online course on pragmatic and group randomized trials as well as a research methods guidance application guide for incoming NIH researchers with clinical trials applications. ODP also administered a Prevention Research Expertise Survey with more than 3,000 respondents. In the future, ODP will support their online catalogs, provide resources to review staff, recruit experts to their respective panels, and provide training to staff. Establishing ODP as a resource for ICs that are developing prevention initiatives and methods review, Dr. Murray expects to work closely with the Office of Extramural Research (OER) and the Center for Scientific Review (CSR). Finally, ODP will be to continue performing methods review, particularly in methods for prevention research.

ODP's fourth strategic priority of is to promote collaborative prevention research projects. Because NIH has so many sectors, it is critical for ODP to coordinate collaboration efforts among ICs. Since his arrival, Dr. Murray has involved ODP in a number of trans-government initiatives, including the National Nutrition Research Roadmap, which works with various government agencies on nutrition research. ODP also works with HHS on matters related to physical activity, as well as Scientific Interest Groups to develop funding opportunities for prevention research. ODP has posted hundreds of FOAs related to prevention research on their website and are listed as a coordinating office of the 2018 Physical Activity Guidelines for Americans. Going forward ODP will continue supporting infrastructures that facilitate collaboration across ICs and will host a State of Prevention conference every three years.

ODP's fifth strategic objective is to increase the visibility of prevention research. Given that NIH focuses mostly on basic research and treatment, ODP highlights prevention methods in the Agency and nationwide. ODP's website was updated to give a more robust online presence, and the communications team has been strengthened to disseminate their message. Dr. Murray added that this was especially helpful to junior investigators looking for career opportunities.

Regarding the timeline of implementing these strategic objectives, Dr. Murray said there was a plan to post a Request for Information (RFI) later in the fall of 2017, prepare milestones in early 2018, submit the package for approval by summer 2018, and release the final plan before FY19. Dr. Murray asked the Council for input on the strategic objectives with a focus on enhancing prevention research across NIH.

CONCEPT CLEARANCES

Title: Addressing the Challenges Posed by the Opioid Epidemic in Health Disparities Populations- Dr. Andrew Loudon This initiative will support multidisciplinary research projects that examine the following: sociodemographic, cultural, economic, and biological factors in opioid care specific to rural and urban populations that increase risk of OUD; the consequences of OUD; ways to improve resource availability in rural settings to reduce opioid treatment gap (MAT access); and underlying mechanisms for the variation in the prevalence of Opioid Use Disorder (OUD) in minority health and health disparities populations. Areas of research interest include but are not limited to the following: 1) identifying factors Socioeconomic, and cultural factors specific to rural and urban populations that increase risk of POM, 2) addressing disparity in access to treatment (MAT), 3) supporting community strategies to address the opioid epidemic and encouraging community collaborations and partnerships that address the root causes of the opioid epidemic, and 4) assessing the long-term outcomes of opioid-dependent newborns.

Council engaged in detailed discussions. While generally supportive, members had several questions and recommendations for consideration. Program staff made note of the suggestions for incorporation into the future funding opportunity announcement. Dr. Hunter requested a motion to approve the concept, which was seconded, and passed unanimously.

Public Comment

Dr. Hunter opened the floor for public comments and questions. There were none.

Closing Remarks and Adjournment

Chair Pérez-Stable adjourned the meeting at 1:51 p.m.

CLOSED SESSION

A portion of the meeting was closed to the public in accordance with provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended, U.S.C. Appendix 2.

REVIEW OF GRANT APPLICATIONS

Dr. Pérez-Stable called the Closed Session to order at 3:00 pm. Dr. Hunter led the second level review of grant applications submitted to NIMHD programs. The Council considered 279 applications requesting an estimated \$152,506,991 in total costs. Funding recommendations for all applications submitted in response to program announcements and special program review announcements were made by the Council through *en bloc* voting.

Eliseo J. Pérez Stable, M.D.
Director, NIMHD, NIH

Date

Joyce A. Hunter, Ph.D.
Executive Secretary, NACMHD

Date