

**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)**

6001 Executive Blvd.
Rockville, MD

February 5, 2019
8:00 a.m. – 2:00 p.m.

MEETING MINUTES

COUNCIL MEMBERS PRESENT

Eliseo J. Pérez-Stable, MD, Chairperson; Director, NIMHD
Maria R. Araneta, PhD, University of California San Diego
Marshall Chin, MD, MPH, FACP, University of Chicago
Giselle M. Corbie-Smith, MD, MS, University of North Carolina at Chapel Hill
Sandro Galea, MD, MPH, DrPH, Boston University
Linda S. Greene, BA, JD, University of Wisconsin
Joseph Keawe'aimoku Kaholokula, University of Hawai'i at Manoa
Spero Manson, PhD, University of Colorado
Fernando Sanchez Mendoza, MD, MPH, Stanford University
Brian Mustanski, PhD, Northwestern University
Amelie G. Ramirez, DrPH, MPH, BS, University of Texas Health Sciences Center
Brian Rivers, PhD, MPH, Morehouse School of Medicine
Gregory A. Talavera, MD, MPH, San Diego State University
Carmen Zorrilla, MD, University of Puerto Rico, Medical Sciences Campus

COUNCIL MEMBERS ABSENT

Ross Hammond, PhD, The Brookings Institute
Joan Y. Reede, MD, Harvard Medical School

EX OFFICIO MEMBERS PRESENT

Cara Krulewicz, CNM, PhD, FACNM, Office of the Assistant Secretary of Defense for Health Affairs
William Riley, PhD, Office of Behavioral and Social Sciences Research

EXECUTIVE SECRETARY

Joyce A. Hunter, PhD, NIMHD

PRESENTERS

Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases (NIAID)
Dr. Gregory Talavera, Professor, Division of Behavioral Science and Health Promotion, Graduate School of Public Health, San Diego State University, NACMHD Member
Dr. David Wilson, Director, Tribal Health Research Office, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH
Dr. Joyce Hunter, Senior Advisor to the Director, NIMHD

CALL TO ORDER AND INTRODUCTORY REMARKS

Eliseo J. Pérez-Stable, MD, Director of the National Institute on Minority Health and Health Disparities (NIMHD), called to order the Open Session of the 50th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) at 8:10 a.m.

INTRODUCTION OF MEMBERS

Council members and others present introduced themselves and their affiliations.

COUNCIL MINUTES REVIEW

Dr. Joyce Hunter brought the minutes before the Council and called for a motion to approve the minutes. The Council unanimously approved the minutes of the September 2018 Council meeting. Dr. Hunter informed the Council that its next meeting was scheduled for May 20-21, 2019, with the exact location to be determined.

NIMHD DIRECTOR'S REPORT AND DISCUSSION

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

HHS/NIH News

- Dr. Pérez-Stable commemorated Dr. Steven Katz, the long-time Director of the National Institute on Arthritis and Musculoskeletal and Skin Diseases (NIAMS), who passed away on December 20, 2018. Dr. Katz joined NIH in 1974 as an intramural investigator in the dermatology branch of the National Cancer Institute. Dr. Katz was a leader in investigative dermatology and trained a large number of outstanding immuno-dermatologist in the United States, Japan, Korea, and Europe. Dr. Pérez-Stable noted that he would miss Dr. Katz's advice and wisdom. Dr. Robert Carter will serve as acting Director of NIAMS while NIH searches for his replacement.
- Several other NIH Institutes are conducting searches for a new Directors, including the Center for Scientific Review (CSR), the National Institute on Deafness and Other Communication Disorders (NIDCD), and the National Institute of Nursing Research (NINR).
- On January 31th, Captain Felicia Collins was appointed Deputy Assistant Secretary for Minority Health and Director, Office of Minority Health, of the Department of Health and Human Services (HHS). Previously she was with the Health Resources and Services Administration (HRSA), where she was Senior Advisor in the Bureau of Primary Health Care (BPHC). Captain Collins received her undergraduate degree from Yale, a medical degree from Harvard, and completed residency training in primary care pediatrics at Children's Hospital in Boston. She replaces Dr. Matthew Lin and would work closely with NIMHD on many issues.
- NIH recently released an update to its Approaches to Prevent and Address Sexual Harassment. A climate survey, launched this month, was developed to take the pulse of the situation at NIH. It will give a sense of what the prevalence of the problem is, has been, in terms of historical and current situations. There has been a lot of effort on the part of NIH leadership to raise the consciousness about this. A significant portion of the October NIH Leadership Forum was devoted to this topic. At NIMHD, the NIH Civil Group presented at the Leadership Meeting. Dr. Pérez-Stable noted that while the primary aim of this effort was to eliminate sexual harassment, it would discourage harassment of any kind from inappropriate behaviors between people of any kind related to beliefs, appearance, disability, race, ethnicity, language ability, sexual identity or orientation or any other characteristic.
- The Next Generation Researchers Initiative (NGRI) has been a long discussion topic of the Advisory Committee of the NIH Director. A special task force generated a long list of recommendations including: lengthening the period of the Early Stage Investigators beyond the current ten years; at risk investigators, individuals with their first R01 at risk for not being refunded; promote sustainable training opportunities that incorporate diversity and inclusion; monitoring the workforce stability through metrics; and continuing transparency efforts and engagement with scientist across career stages to inform policy decisions. The recommendations are being processed by the NIH Leadership and will likely impact NIH's extramural policies. Dr. Pérez-Stable stated he would continue to update NACMHD as the project moved forward.

NIMHD News

- In December, Dr. Joan Wasserman, Director of the Office of Extramural Research Administration (OERA) since 2015, left NIMHD. She is the new Director of Research at the School of Nursing in the Uniformed Services University of Health Sciences (USUHS). She came to NIMHD as Program Officer 2014. She led the Health Disparities Research Institute. Dr. Thomas Vollberg will serve as Acting Director of OERA while a search is conducted.

- Dr. Mainés Larissa Avilés-Santa was appointed Director of NIMHD's Clinical Health Services Research Program. She comes from the National Heart, Lung, and Blood Institute (NHLBI), where she worked in the Epidemiology Branch, Prevention and Population Sciences Program, Division of Cardiovascular Sciences as the main Program Director for the HCHS/SOL. She received her MD from the University of Puerto Rico and completed an internal medicine residency at University Hospital in San Juan Puerto Rico, and an endocrine fellowship at the University of Texas, Southwestern. She is a Fellow in the American College of Physicians and the American College of Endocrinology. Dr. Avilés-Santa will start on March 4th. Dr. Pérez-Stable thanked Dr. Hunter for leading the Clinical Health Services Research program over the last year.
- In other staff news: Soon Moon was appointed NIMHD's Chief Administrative Officer in the Office of Administrative Management (OAM). This position is important to internal administrative functions. Dr. Xinzhi Zhang, Program Director, left NIMHD for a position with the National Center for Advancing Translational Sciences (NCATS). His departure means NIMHD needs to carefully consider how to address data science in the future. Starsky Cheng, Administrative Officer, OAM left NIMHD for a position with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). There are a number of new hires in the Intramural Program. Saida Coreas, Post Baccalaureate Fellow; Lucy Jin, Post-Baccalaureate Fellow; Kristyn Kame Postdoctoral Fellow; Tolu Omole, Post-Baccalaureate Fellow; Asmi Panigrahi, Post-Baccalaureate Fellow and part of the Medical Research Scholars Program for medical students; and Bonita Salmeron, Post-Baccalaureate Fellow.

Legislative Updates

- On January 9th Dr. Pérez-Stable met with Representative Terri Sewell, who represents the 7th District of Alabama. They spoke about health disparities and grants in her district.
- On October 24th Congress passed the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. Not a lot in the ACT is related to the NIH HEAL Program. Dr. Pérez-Stable said NIH's HEAL (Helping to End Addiction Long-term) which will also combat the opioid epidemic is continuing.

NIMHD Director Activities

- On September 12th Dr. Pérez-Stable met with the National Black Caucus of State Legislators in Washington, D.C., where he encouraged the saying to act locally and think globally. This has more potential for effective change in policy at the state level than there is at the federal level.
- On September 17th Dr. Pérez-Stable spoke at the 12th National Symposium on Prostate Cancer at Clark Atlanta University.
- On September 24th Dr. Pérez-Stable spoke at the Biennial Asian American, Native Hawaiian and Pacific Islander Conference at New York University (NYU). One of the Centers of Excellence grantees sponsored the conference.
- On October 3rd Dr. Pérez-Stable attended the Annual International Hispanic Sciences Network Conference in Rockville, Maryland. Several of the grantees from the Social Epigenomics Program me had a special session. The Network is in its fourth year and Council Member Sandro Galea was a recent president. Dr. Pérez-Stable stated that while the Network was developed to support Latino early-stage investigators interested in substance use, they have expanded their agenda to include other behavioral and clinical topics.
- On October 5th Dr. Pérez-Stable spoke on a panel at the Annual Meeting of the International Association for Population Health Sciences (IAPHS). The meeting was held at the National Academy of Medicine (NAM).
- On October 17th Dr. Pérez-Stable was a visiting professor at the Rutgers Cancer Institute of New Jersey. They proposed a panel
- On October 30th Dr. Pérez-Stable gave three talks at the Department of Psychiatry at the University of California, San Francisco (UCSF) as part of the Evelyn Lee Visiting Scholar Lecture series.
- On November 5th Dr. Pérez-Stable led a panel on "Research at NIMHD" at the Association of American Medical Colleges (AAMC) meeting in Austin, Texas and he invited two NIMHD-funded scientists to join him — Mona Fouad, MD and Esteban Gonzalez Burchard, MD.

- On December 4th Dr. Pérez-Stable visited the University of Southern California's (USC) Keck School of Medicine for the Dean's Distinguished Lecture Series.

NIMHD Activities

- Dr. Pérez-Stable's spoke about the NIMHD's supplement to the American Journal of Public Health (AJPH). The supplement was entitled "New Perspectives to Advance Minority Health and Health Disparities Research." It summarizes the hard work of the Science Visioning process that started before he came to NIMHD and culminated with three days of workshops. A lot work went into producing the supplement. Dr. Pérez-Stable commended Drs. Nancy Breen, Rina Das, Tilda Farhat, Nancy Jones, and Richard Palmer for their leadership through the process. Dr. Francis by providing the Editor's Choice brief introduction.
- NIMHD is continuing its Director's Seminar Series, which already included presentations from Drs. Giselle Corbie-Smith, Amelie Ramirez, and Sandro Galea. Dr. Monica Peek will present in March and Dr. Denise Dillard in November.
- NIMHD's Health Disparities Research Institute (HDRI) launched the opening for applications. This will be the fourth time for this version of the program. HDRI session is a week-long intensive training experience. The idea is to attract senior postdocs or assistant professors who are poised to write a grant within the next year. Roughly 50 applicants are selected. NIMHD averages about 200 applications each cycle. Staff will review the applications and make selections based on a variety of factors. Th week is not a comprehensive review of the field, but of selected topics. There is a mock review organized by Tom Vollberg and about two and half days spent with Program Staff from NIMHD and other ICs. Dr. Pérez-Stable stated that about 80% of the minority health and health disparities research at NIH is not funded by NIMHD. So, it is important to make sure that people are able to connect with other institutes. NIMHD collaborates with the AAMC on this project on career development and grant writing skills.

Budget

- Dr. Pérez-Stable displayed a chart showing NIH's budget from Fiscal Year (FY) 2016 to the present. NIMHD has received has received increases each year, which is reflective of the NIH overall budget increase. NIMHD's current budget is \$314 million. Dr. Pérez-Stable stated that the President's budget would likely be published within two weeks of the State of the Union. The Congressional Committees process the budget decisions. A breakdown of the NIMHD budget by proportions: Research Project Grants (RPG) made up 45% of NIMHD's budget, Research Centers in Minority Institutions (RCMI) 20%, Non-RCMI Centers 11%, Research Management and Support (RMS) 7%, Other Programs in training and contracts (includes programs like the Jackson Heart Study) 8%, Research and Development (R&D) 5%, Small Business Innovation Research/Small Business Technology Transfer Program (SBIR/STTR) 3%, and Intramural Research 1%.
- Dr. Pérez-Stable displayed information on the funding results of NIMHD grants. For FY18 the success rate of R01/R56 grants was 14.5%, which was higher than R21 awards (8.3%) and R03 awards (5.1%). R15 grants will be phased out and changed. NIMHD continues to provide funds for the Indian Health Service Tribal Epidemiology Centers (TEC), the NHLBI funded Jackson Heart Study, and the Loan Repayment Program. NIMHD has taken over the CFARS Adelante program support through Emory. NIMHD continues to support the different AIDS Research Centers. Since his arrival at the end of FY 2015, a transition period, there has been an increase in research grants. NIMHD was posed for an increase in research grants with the Centers of Excellence Program (a large portion of the budget, over 50 funded at one point) was coming to an end, although some were extended and recompeted. NIMHD will keep the level Centers where it is now as opposed to either re-expanding or shrinking at least for the foreseeable future.
- Dr. Pérez-Stable commented that NIMHD would have to look for more steady state sources of funding going forward, as they should not expect to receive a 2%-3% budget increase each year.
- Dr. Pérez-Stable displayed information on the number of applications NIMHD received each year. NIMHD received 219 applications in FY15, 290 in FY16, 432 in FY17, and 656 in FY18. Estimates for FY19 and FY20 indicated additional increases in applications. Some of the increase is due to putting out program announcements request ion applications. A consistent message that

potential applicants have heard. NIMHD did not sign up for the parent R01 until 2014, prior to that it was through RFAs for R01s. The institute functioned primarily by set asides at that time. The number of R01s has increased from 2015-2018.

NIMHD Activities

- Dr. Pérez-Stable displayed a photo from the Precision Medicine Centers Annual meeting in December meeting. Five Centers have been funded. They presented their work. He thanked Drs. Mike Sayre, Meryl Sufian, and Nishadi Rajapakse for their work on this effort.
- On October 16-17 NIMHD and NHLBI held a conference on Sleep Health and the Health of Women. This conference included a panel with the Hispanic Community Health Study/SOL investigator and Dr. Chandra Jackson, an NIH Intramural Investigator (supported by NIMHD).
- Many NIMHD staff attended the annual meeting of the American Public Health Association (APHA) on November 10th, which was held in San Diego, California. It focused on the Science Visioning Panel that led to the finalization of the Supplement that was distributed.
- Dr. Pérez-Stable noted that on January 24-25 the NIMHD, NIEHS, and the Environmental Protection Agency (EPA) Centers of Excellence held a conference on environmental health disparities in Baltimore. This is joint program that was funded in 2015. Unfortunately, the EPA was not able to attend due to the government shutdown. It was interesting science. There are five Centers: two in the southwest (focused on American Indians), one at USC (focused on Latinas), one at Hopkins (focused on chronic lung disease in rural settings), and one at Harvard (focused on poor urban communities).
- The Division of Intramural Research also had an active presence at the APHA conference. Drs. Choi, Williams, Napoles, and Postdoctoral Fellow Julia Chen presented on tobacco use, cancer incidents and health inequities. There was also an NCI symposium on cancer health disparities. Drs. Anna Nápoles and Jung Byun presented on a number of topics on cancer, healthy equity, and the intersection of pathology and genotyping of tissues in minority health and health disparities.

Scientific Advances

- A recent study in *Morbidity and Mortality Weekly Report (MMWR)* analyzed the prevalence of high impact chronic pain. The opioid use epidemic disproportionately affects rural communities and those of low socio-economic status (SES). If chronic pain is the principal pathway to opioid addiction, there is a social class gradient to the epidemic. If you have less than a high school education, you're much more likely to have high impact chronic pain than if you have a bachelor's degree. This is consistent with other data that says education is good for your health. It also reinforces the idea that the more formal education, the better off the population health will be. The slide showed that there was not a significant difference by race/ethnicity between Whites, Latinos, and Blacks. This does not explain the disproportionate effects of opioid use disorder by race/ethnicity.
- Dr. Meredith Shields and NCI colleagues examined national data linking death index with area variables. Appearing in this month's *Lancet Public Health*, the report looks at drug overdose deaths by county and characteristics in race/ethnicity, particularly the percent of unemployment, education, and income. The study only used data for Whites, Blacks, and Latinos. Much of the deaths of Latinos and Blacks in counties where there are very few was suppressed because of confidentiality. Drug poisoning and mortality rates increased in the lowest SES in rural counties, with a large SES gradient for Whites. There was not a robust SES gradient for Blacks and Latinos. The study also shows 76% of deaths occurred in metropolitan areas where most people live.
- One paper looked at quality of sleep during gestation and how it could increase the risk of gestational diabetes. Results showed higher incidence of poor sleep in pregnant vs. non-pregnant women and found poor sleep quality positively correlated with higher HbA1c in both groups. Conceptualizing sleep as a behavioral factor and there is little known about how it affects our overall health. Scientist and clinicians have worked on sleep disorders: insomnia, sleep apnea,

narcolepsy and other kinds of diseases for a long time. Sleep is an important time for our health but there were not good ways to measure it until recently. Does it lead to adverse consequences like chronic diseases? Does it regulate metabolic pathways? Does it cause problems with cellular control of mutations? Perhaps adequate quality helps prevent cognitive impairments. It is a critical factor that should be put up there with physical activity and nutrition as not only risk factors, but also protective factors for health on the long term.

- One study used census data to examine ways to develop the means to assess community needs assets in a Geographic Information System (GIS). Community stakeholders and academic experts created a novel spatial healthfulness index. Participants were recruited from the Flint Center for Health Equity (FCHES). The focus was to identify variables that may affect behavior changes, establish GIS-based metrics for variable, and to determine the weight of variables using an analytic hierarchy process. This would inform scientists and policy makers about where to go with interventions. With better tools linking people and communities, the results provide a better assessment of built environmental factors that influence the uptake of behavioral changes during public health interventions.
- In one study on chromosome 6 from *The Journal of the American Medical Association (JAMA)*, four alleles were linked to warfarin-related bleeding in African Americans. African Americans are at higher risk of major bleeding from warfarin compared to whites. Dr. Pérez-Stable said a similar study found that African Americans were less likely to receive direct-acting oral anticoagulants when they had atrial fibrillation than Whites.
- Another study from the group in Pittsburgh, looked at DNA methylation signatures of atopy and asthma in Puerto Rican children. Nasal epithelium DNA methylation profiles differed between children with and without atopy and could predict atopy versus asthma in a discovery cohort and two independent replicate cohorts. Dr. Pérez-Stable stated that Puerto Ricans have a high rate of asthma. Much recent research has been focused not only on clinical and environmental factors but also on biological factors and individual factors. With the biological focus on genetics and gene environment interactions. Given the high incidence and mortality rates over the last 20 years, it was becoming clear the cause for asthma was neither solely genetic nor environmental.
- One report from the *Annals of Internal Medicine* attempted to improve cardiovascular risk estimates. A high risk is 1 percent per year and will lead to the clinician recommendation of medication for the rest of your life. Many of the clinical trials that this draws upon did not include minority populations. They were robust and showed benefit in people with established disease (explains the 1 percent). The bar is higher for people without established disease. A cardiology n group has recommended that this be lowered to 7.5 percent. This recommendation has not been widely accepted by the primary care community. There is a debate between cardiologists and primary care physicians. In the study presented, there is an effort to recalculate risks based on factors not typically used in cohorts like Framingham. This may a show a much lower risk than the AMH risk calculator. The NHBLI cohorts HCHS/SOL is only Latino/Hispanic and MESA includes Mexican Americans, have their own calculator.
- One paper in the *Journal of Pain* examined the of associations between perceived injustice, in pain, disability, and depression in a racially diverse sample of individuals with chronic low back pain. Hispanics, Blacks, and Whites were in the sample. The study found that Blacks were more likely to report perceived injustice related to their chronic pain and have associated increased depression and disability with their back pain. While this may not translate to higher incidence of opioid use among Blacks, it may help to explain why they are prescribed opioids less often than Whites.
- One paper studied the availability of the National Diabetes Prevention Program (DPP) in U.S. counties. DPP has been shown to help prevent progression from pre-diabetes to diabetes. It is a structured program of diet and physical activity or changing the content if your nutrition. DPP is reimbursed by Medicare. It has been reproduced in a number of settings. The principle is the same, change lifestyle and prevent progression of glucose intolerance (impaired glucose tolerance) will in the long run will be beneficial to the individual for not developing diabetes, or stunt it. Metformin has been used as well as an intervention, particularly in younger adults.
- One study out of Kevin Choi's lab looks at the Health Information National Trends Survey (HINTS), funded by NCI, desegregates marital status into different group. The study found

cohabiting Blacks had the highest prevalence of smoking, followed by separated Whites. Dr. Pérez-Stable commented that marriage was good for some people's health. An implication from the study is that research on marital status and health should separate marital categories.

- Work from Dr. Anna Nápoles, completed before coming to NIMHD, looked at willingness to participate in research based on a sample of Whites, Latinos, and Blacks from Louisiana. In general, invasive studies are likely to engender less willingness to participate in research, though Dr. Pérez-Stable noted the differences between groups were not very stark. Much has been made about minorities lack of participation in research studies because of distrust related to the Tuskegee Study, the diabetes work with Pima Indians, and birth control studies in Puerto Rico, but it can be overcome with appropriate methods. The myth that the barriers to recruitment of minorities are insurmountable needs to be eliminated.
- Dr. Pérez-Stable mentioned one study that looked at breast cancer hot spots among Latinas in the U.S. Breast cancer is about 30 percent less common among Latinas compared to Whites. Some evidence exists of increased early breast cancer mortality triple negative in younger Latinas under 50. Though not at the level for African Americans. Many border areas are breast cancer hot spots. Lack of access to care and early detection could be the main drivers of this problem.

Director's Role

- Dr. Pérez-Stable said that after 3.5 years at NIH, he felt that NIMHD now has his mark on it. He has to look forward and build on the legacy of NIMHD. It has a remarkable and rich history. NIMHD has exerted influence throughout the Agency. There is a tremendous amount of collegiality and mutual support and opportunities to find overlap.
- While many ICs gain traction through influential industry groups—such as the Alzheimer's Association, AARP, the American Heart Association, and the Cancer Society—disparities do not get that traction, but NIMHD continues to do good work without those robust resources. Dr. Pérez-Stable said he has known that were constituents out there who would be supportive of NIMHD and was delighted to have the restart of the Friend Network. With a background as a General Internist, he said he was encouraged to see that the Society of General Internal Medicine had a strong minority health and health disparities focus that has grown over the years. Cultivating that support is critical for NIMHD.
- Dr. Pérez-Stable stated that NIMHD is absolutely committed to diversity of scientists. He takes every opportunity to remind everyone that we are facing a crisis. Dr. Pérez-Stable stated that 50% of U.S. children today are minorities. The future will look very different than what the professions look like now, with only 12% being from underrepresented racial/ethnic groups, and what the leadership looks like across society. So, we need to address this urgently.
- Dr. Pérez-Stable stated that advancing science is what NIH is about. The special supplement, the book that will be published this year, the research that is being funded is setting the standard for what empirical questions can lead to. He said, we are scientist and are driven by data, but there has to be certain goals about equity and decreasing disparities. It has to be done on the basis of evidence, in terms of addressing the disparities and understanding mechanism, so we know where to push in ultimately promoting health equities. He thanked the audience.

PRESENTATIONS

The First Decade of Findings: Results from the Hispanic Community Health Study/Study of Latinos (HCHS/SOL): Dr. Gregory Talavera, Professor, Division of Behavioral Science and Health Promotion, Graduate School of Public Health, San Diego State University, NACMHD Member.

Dr. Talavera said last year the SOL completed its second examination of the cohort. Funded primarily by NHLBI, SOL is made up of 16,000 individuals from four cities across age ranges, and has the primary goal of determining cardiovascular end points. Dr. Talavera is the PI at the San Diego SOL site and was on the Steering Committee for the project, which was relatively new compared to the Framingham and Jackson Heart studies. He has always been interested in Latino health, which was how he got involved with SOL. Unfortunately the era of the well-funded, massive NIH cohorts may be in their twilight years, and future cohort studies may need to find alternative methods to acquire data.

Dr. Talavera said the other senior members of the project included Drs. Martha Daviglius, Robert Kaplan, and Neil Schneiderman. Dr. Talavera said SOL has collected a diverse data set, and their main scientific interest groups include aging, genetics, anthropometry, oral health, physical health, respiratory information, and reproductive information. In addition, some children of SOL participants have been brought in to the study, which has led to a number of ancillary studies. Because they have little funds to keep the cohort intact, these ancillary studies were useful for attracting researchers. Dr. Talavera said current ancillary studies focused on genetics, echosonography, paxgene collection, environmental factors, early neurocognitive impairment, brain MRI, and hormones.

One the exciting aspects of SOL was that they had acquired genetic and psycho-social data. With this rich data set scientists can test a number of hypotheses that simpler studies could not achieve, as they can account for factors as diverse as mortgage foreclosure, employment, and allostatic load. There have been just over 800 approved manuscripts as a result of SOL, and 214 are in print. Nearly half of the studies have been published by early-career and/or diverse investigators.

Dr. Talavera displayed the distribution of race and ethnic groups in the survey, which included people of Mexican, Dominican, Cuban, and Puerto Rican heritage. He noted the group was not trying to label people by their race or ethnic group because approximately 20% of the sample was U.S. born, and were in many cases third generation Americans. Dr. Talavera noted that the genetic data shows that race is largely a social construct, as many people who strongly self-identified with their Latino ethnic group had strong genetic connections with Europe. European entities who want to use SOL's data may be disappointed to discover the amount of European genes in the cohort.

Using spirometry reference equations, SOL was able to contribute for more diverse groups. While there were already some reference equations for pulmonary functions in Mexican-heritage individuals, this research gives more comprehensive data on people with respiratory conditions. Much work has also been done on cardiometabolic assessments: one SOL-related paper in *JAMA* found that 71% of the women and 80% of the men in the study had one or more of the major cardiovascular risk factors.

Dr. Talavera shared one article on the prevalence of diabetes in the different heritage groups. These numbers indicated prevalence was higher than the American Diabetes Association's (ADA) data indicated. Dr. Talavera admitted SOL researchers could have gotten these figures because they used three measures of glycemic control: fasting blood sugar, A1c, and a two-hour postprandial glucose.

Another SOL study looked at the relationship between acculturation and diabetes by length of residence in the U.S. As Latinos live here longer, their prevalence of diabetes goes up. This study has several measures for acculturation, including language, length of residence, and the Short Acculturation Scale for Hispanics (SASH), which focuses on media use. Still, length of residence is the best input for cardiovascular health.

One study on the prevalence of smoking was also done with Dr. Pérez-Stable's input. Dr. Talavera said the study focused on nondaily and daily smokers. Dr. Talavera displayed the results of the study, which found that over half of the Mexican participants were nondaily current smokers. Future aspects of the study will look at the genetic and cultural aspects of smoking among Latinos.

Now that the cohort's second visit has been completed, SOL will likely shift from looking at prevalence to examining incidence and building predictive models. One study that is indicative of this transformation looked at the association of depressive symptoms with the incidence of diabetes. The findings suggest that the association between depression and diabetes varied by background.

SOL is also beginning to look at environmental and lifestyle behaviors, and the San Diego site is looking at micro-environmental data. One such study out of the San Diego site used Dr. Jim Sallis' Microscale Audit of Pedestrian Streetscapes (MAPS) to measure how the geographic routes patients take in their

day to day lives affect their health. In this study researchers go on Google maps and physically walk a subject's route.

SOL is facing issues of representation and lack of information on U.S. born Latinos. Currently they rely on comparison groups and consortiums for this information. Unfortunately some of their data is still identifiable, and they are very conscious about who they share findings with. In addition, the relatively small size of the cohort causes some difficulties. The lexicon of terms in this current sociopolitical environment is also of concern, and authors are looking at ways to present data in non-inflammatory ways (including using terms like Latinx). In an effort to give back to the community, Dr. Talavera said researchers gave participants a Data Book.

Ending the HIV/AIDS Pandemic: Follow the Science: Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID).

Dr. Fauci stated that although it sounded bold to speak of ending the HIV/AIDS pandemic, researchers were in fact closer to that reality than many realized. When looking at historical pandemics, HIV/AIDS is among the most lethal, with roughly 35 million deaths and another 80 million infected (and 36 million still living with HIV). In addition, there are 1.8 million new infections every year. In the U.S. 1.1 million people live with HIV, and 15% of them do not know they are infected. Roughly 700,000 people have died from HIV, 38,000 new infections occur each year, and there are significant disparities with regard to this disease.

Dr. Fauci shared his 2015 paper in the *The New England Journal of Medicine (NEJM)*, which argued that present day experts had the tools to end the epidemic. Since it began in 1981, significant knowledge had been gained about the disease. Treatment has changed dramatically; in 1981 the median age of survival was about one year, with almost 100% dying in 2-3 years. Over time scientists began to understand the cycle of the virus, which allowed them to develop targeted antiretroviral therapy. Dr. Fauci said that when they first developed azidothymidine (AZT) in 1987 they dropped the level of the virus modestly without any duration. In 1993 they were able to drop the virus lower, and durability was not strong. With the advent of the protease inhibitors in 1996, they were able to drop and maintain the virus. The import of that discovery would only become clear in time.

Today there are upwards of thirty drugs, and the lives of people with HIV/AIDS have improved. Dr. Fauci said that today a person can take one pill containing three antiretroviral drugs. With the President's Emergency Plan for AIDS Relief and the Global Fund, 21.7 million people around the world receive antiretroviral therapy, meaning approximately 11 million deaths have been averted from 2000 to 2017.

Improvements in prevention are equally striking. Dr. Fauci displayed information on the prevention modalities available today, of which treatment as prevention is an option. He said they did a study on people in discordant relationships (one infected, one not infected), in which infected persons started therapy immediately or waited until their CD4 count dropped to start therapy. People that were treated immediately saw a 96% reduction in the transmissibility to their uninfected sexual partner. Five years later this study did a follow up only measuring viral load, and found that when the viral load was undetectable individuals did not transmit to their sexual partner. In subsequent studies, they were able to prove that there were zero linked transmissions out of 35,000 condom-less acts of anal intercourse between gay men in committed relationships. In another study looking at 77,000 condom-less acts of anal intercourse, there were also zero linked transmissions. Taking this as an effective method of prevention, Dr. Fauci said he recently wrote an article saying that an undetectable viral load is un-transmittable.

Today programs like the Rapid ART Program Initiative for HIV Diagnoses (RAPID) in cities like San Francisco and New York are capitalizing on these findings, getting people into therapy and decreasing transmissibility. Theoretically if experts could get everyone with the disease into therapy the disease would be gone tomorrow. For individuals that are not infected but have high risk, taking a pre-exposure prophylaxis (PrEP) drug like Truvada—which contains emtricitabine and tenofovir—once a day reduces the likelihood of contraction by up to 95%. Because of this, the U.S. Preventive Services Task Force

(USPSTF) made pre-exposure prophylaxis for high-risk individuals a Grade A recommendation, meaning insurance companies would pay for it.

Dr. Fauci said that the problem they now had in addressing the pandemic was the implementation gap. 15.2 million people today are not receiving antiretroviral therapy. While the numbers for a good continuum of care in the United States should be between 95%-100%, they are currently at 51%, a figure that is even lower worldwide. In addition, while 1.1 million people could benefit from PrEP, only about 200,000 receive it. There are also great health disparities in the reception of PrEP, as African American and Hispanic individuals receive treatment less often than Whites. Without increases in implementation, the pandemic could progress for decades. HIV is not an equal opportunity disease, and there are geographic hot spots that need more attention. Areas such as the KwaZulu-Natal—which includes Durban, South Africa—have incredibly high incidence rates. Dr. Fauci displayed a heat map showing the geographic clustering of the disease. Of 3,007 U.S. counties, 50% of infections occur in 48 and 52% of all new infections occur in the rural South. Because of this, the Centers for AIDS Research (CFAR) are supplementing their facilities in the South, particularly in Alabama, Georgia, Washington, D.C., and Tennessee. There are also demographic hot spots. In South Africa, pregnant women between the ages of 25-29 that went to an antenatal clinic had a 57% prevalence rate of HIV infection. Although African Americans comprise only 12% of the U.S. population, they represent 44% of new HIV diagnoses.

While a vaccine to treat the disease would be revolutionary, a recent vaccine study in Thailand showed only 31% efficacy in treatment. Still, that study gave a signal of the correlative immunity of the disease. Dr. Fauci mentioned two trials that were taking place in Africa: one looking at men and women in Africa, and another looking at just women in Sub-Saharan Africa. By the end of 2020 results for the trials should be final. If experts assume that neutralizing antibodies are necessary to protect against HIV infection, the challenge is to take the neutralizing epitopes and develop them into immunogens and eventually vaccines. Dr. Fauci said there were a number of studies at NIH that were working on this. While an HIV vaccine may never be as effective as the measles vaccine—which is 97% effective—a 50%-60% effective vaccine could be possible if combined with other treatment. To conclude, Dr. Fauci said that they had the tools to end the epidemic globally, and added that given the resources in the U.S. they had a moral obligation to try to stop it.

Recognition of Retiring NACMHS Members

Dr. Pérez-Stable said he wanted to recognize retiring members: Drs. Araneta, Galea, Greene, Rivers. Dr. Pérez-Stable said that she had been instrumental in the work of the Council. She said it was an honor to serve with the NIMHD, particularly for the opportunities to learn and work with NACMHD.

Dr. Pérez-Stable thanked Dr. Galea for his broad view of public health throughout his years of service. Dr. Galea thanked everyone for the privilege to serve and noted how much progress had been made since Dr. Pérez-Stable took over NIMHD.

Dr. Pérez-Stable thanked Dr. Greene for her service to the Committee. He noted she kept the Committee connected outside the scientist world. She said it had been an honor to serve, and that her grandfather—who established the second hospital for Blacks in New Orleans in the 1940s and focused on disparities in care—would be extremely proud of her today.

Dr. Pérez-Stable thanked Dr. Brian Rivers for his service. Dr. Rivers said it was an honor and privilege to serve and noted he had been working with NIMHD since 2013, before Dr. John Ruffin retired. Dr. Rivers said he had followed the work of NIMHD since he was in graduate school, and he wished them well going forward. Dr. Pérez-Stable reminded retiring members that they would always be a welcome part of the NIMHD family.

Introduction and Update on the Tribal Health Research Office (THRO): Dr. David Wilson, Director, Tribal Health Research Office (THRO).

Dr. Wilson showed a map of the diminution of tribal lands over the course of American colonization. As the U.S. recognizes tribal nations as sovereign they operate in a government-government relationship,

and healthcare is outlined in many treaties. There are currently 573 recognized tribes in the U.S. The THRO collaborates with the different offices across the American healthcare system. The THRO was Created in 2015. Dr. Wilson has been working with THRO since 2017. Its mission is to help close the healthcare gap faced by tribal communities.

There are two main ways the THRO carries out its work, the first being the Trans-NIH Health Research Coordinating Committee (THRCC). Meeting once a month, the THRCC considers ways to contribute to the THRO. The THRO also works through the NIH Tribal Advisory Committee, which is made up of tribal leaders from around the country. Dr. Wilson showed a map from the Indian Health Service (IHS) that he said corresponded with the way tribal leaders saw themselves.

At their last meeting, the THRO worked with the American Indian Science and Engineering Society (AISES), which educates students so that they can better serve their tribal communities. There are two foundational documents that guide the THRO. The first is the American Indian/Alaska Native Portfolio Analysis, which provides a snapshot of the Agency's investment in tribal health research. Secondly, Dr. Wilson said they were very close to releasing the Trans-NIH Strategic Plan. Ultimately the goal of the THRO's current work is to improve how they use their research funds. Dr. Wilson noted that tribal communities valued these documents because they focused on things that are relevant to their lives.

There were four strategic goals the THRO would be focused on: 1) to enhance communication and coordination, 2) to build research capacity, to expand research and, 3) to enhance cultural competency and community engagement. Dr. Wilson said THRO recently held a tri-operating division consultation with tribal nations in Minnesota. Collaborating with NIH, IHS, and the Substance Abuse and Mental Health Services Administration (SAMHSA), THRO would be putting out a request for information (RFI) to get additional information on issues these communities are facing. Dr. Nora Volkow and Dr. Pérez-Stable attended the event, and Dr. Wilson said it was rare to have two IC Directors engaged in consultation. Tribal leaders also thought it was effective, and would serve as an operating model for other HHS engagements. Importantly, this event allowed THRO to clarify that it was a research organization and not a healthcare provider.

Another function of the THRO is community engagement, and Dr. Wilson said they recently spoke about a data sharing program with the Navajo Nation. Often skeptical of data projects, Navajo leaders wanted to know if they would be able to get information on the environmental influence on child health with regard to open uranium mine pits if they participated in the program. This conversation could lead to a roadmap for engaging with other tribes. Dr. Wilson said that THRO also visited a traditional healing camp in Alaska. Dr. Wilson said working with these communities locally builds trust between both parties and added that he was able to speak to a woman who had been involved in the controversial Havasupai study. Dr. Wilson said the woman was very happy to hear about THRO's current research, and added that it was up to NIH to be more open about their research. Within each of these meetings they had with tribal leaders, Dr. Wilson said they consistently identified 5-10 items that various ICs could address.

If THRO's first year was about advertising its presence and its second year was about unifying the relationship program, it was now working to disseminate information about its office. Therefore it is crucial to connect with both students and the scientific community on the need for addressing tribal health. Dr. Wilson said at a recent event Dr. Joe Gone hosted a talk in which he discussed the interface between traditional and Western medicine. In this talk Dr. Gone emphasized the ways traditional medicine is tailored to each specific patient.

Dr. Wilson said THRO is also trying to take advantage of NIH's rich data sets, creating an interactive map highlighting specific research projects in a particular geographic area. One such data set focused on the Yakama Nation, and students benefited from working on the project. In fall 2017 THRO held a genetics workshop with NHGRI at the University of New Mexico's Comprehensive Cancer Center, which was covered in *Nature*. THRO is also talking with communities about mistakes made in the Belmont report.

Dr. Wilson said he wanted to end by speaking about social value, as THRO always starts with community engagement when working with tribal nations. Dr. Wilson introduced members of the THRO team: Dr. Juliana Blome, Dr. Jay Revilla, and Ted Keane. He said this year THRO would be participating with the *All of Us* Research Program in holding formal consultations, and would also be holding a tribal consultation on intellectual property (IP).

Inclusion of Women and Minorities Triennial Report: Dr. Joyce A. Hunter, Senior Advisor to the Director, NIMHD

Dr. Hunter said she would speak briefly about the Triennial Report. NIH is required by law to include women and minorities in all clinical research studies. Further, Phase III clinical trials must provide valid analysis concerning sex/gender and/or race/ethnicity. Results must be posted on clinicaltrials.gov. Clinical research includes patient-oriented research, epidemiological and behavioral studies, outcomes research, and health services research. Clinical research does not include research done on existing data.

The Triennial Report was once the Biennial Report. This was changed with the 21st Century Cures Act, and must be presented with the NIH Director's Report. The 2019 report includes aggregate data from 2016-2018. Implementation of the policy involves an agreement between researchers, NIH staff, and study participants. NIH is responsible for training staff, researchers, and reviewers. Applicants are responsible for having an inclusion plan in their application, as well as providing enrollment tables and yearly updates.

Reviewers are responsible for evaluating the plan to ensure compliance and for rating the plan as acceptable or unacceptable. A rating of unacceptable is a bar to award. Program also review the plan for compliance with the Inclusion policy and must work with investigators to clear an unacceptable rating before an award can be made. Program staff also monitor the progress made in recruitment of participants to reach the planned enrollment goals established in the application. They must also ensure that inclusion information appears in all FOAs. Grants management staff must ensure the appropriate terms and conditions are included in the Notice of Award, and they must verify that the official files are documented.

Regarding records, Dr. Hunter stated that 364 records were pulled in 2016, compared to 370 in 2017 and 551 in 2018. From these records staff was able to identify studies that did not have any enrollment, which could mean that the study had not yet begun enrollment. Only one study over this triennial reporting period took place on a foreign site. Next, female-only studies and male-only studies are removed from the data set. Dr. Hunter noted this data was monitored by the Office of Extramural Research (OER) and the Office of the Director (OD). With these adjustments, Dr. Hunter said the final number of records for 2016, 2017, and 2018 were 234, 220, and 309, respectively.

Dr. Hunter turned to the NIMHD enrollment data based on sex/gender. NIMHD was roughly at the 50% level of inclusion of women in their research. What's more, NIMHD's minority enrollment from 2016-2018 was 64.7%, 67.1%, and 66.6%, respectively. NIMHD's numbers are good compared to the overall NIH data, whose 2016-2018 female representation in clinical studies was 36.4%, 28.3%, and 29.3%, respectively.

Dr. Hunter said race/ethnicity data collected information on Whites, Native Hawaiians, African Americans, Asians, American Indian/Alaska Natives, those of more than one race, and not reported. From 2016-2018, NIMHD's inclusion of African Americans from 2016-2018 was fairly steady at 40.8%, 47.3%, and 46.1% respectively. White participant inclusion went from 35.4% to 39.1% to 38.8%. Regarding Hispanic/Latino ethnicity, Dr. Hunter said that from 2016-2018 the recruitment of Hispanic/Latino participants went from 13.8% to 16.1% to 16.8%. Dr. Hunter summarized that NIMHD complied with the inclusion policy in enrolling women and minorities.

CONCEPT CLEARANCE

Measurements Research on Minority Health and Health Disparities Related Constructs: Dr. Jennifer Alvidrez, Program Director, NIMHD.

The concept's goal is to advance the measurement/assessment of complex constructs relevant to minority health and health disparities. Dr. Alvidrez displayed the NIMHD research framework. There are many components of measurement, and adequate measurement is needed to generate knowledge. Common topics of inquiry in health disparities measurement research include the best way to measure the presence and magnitude of health disparities, how to define disparities, and what indicators to use in studies. However, less attention is given to the interplay of social determinants of health in one's lived experience.

Dr. Alvidrez said a specific measurement initiative is needed, but noted that measurement-related applications are often considered vague and expensive. While there are some existing FOAs on measurement—including one by the Office of Behavioral and Social Sciences Research (OBSSR) and others that are carefully tailored to particular fields—the applications submitted to these FOAs are focused on technological aspects of measurements rather than capturing one's lived experience.

The objective is to produce knowledge to inform the field about what kinds of measurement approaches of complex constructs may be most suitable for different health disparities. Rather than finding the perfect measure, the study seeks to find what kinds of measures may be most appropriate for particular scopes of inquiry. While in data studies often people collect as much data as possible and figure out what to do with it later, this concept will look to more holistic aspects of a person, what kinds of information these approaches provide, the usability of the data, what it takes to analyze the data, and how relevant they are to respondents.

Because the initiative is focused on lived experience, the kinds of projects concept leaders would want to see are the multi-level data from a variety of sources, with an emphasis on self-reported measures. Complex constructs of specific interests include:

1. The lived experience of intersectionality and belonging to multiple marginalized groups. One such example is actor Jussie Smollett, a gay African American who was recently targeted in a hate crime, which could be measured more fully with a new understanding of lived experience.
2. Composite and cumulative exposure to adversity. Many existing measures account for the ways a person experiences discrimination, but not for the way that discrimination can affect people over the course of their life. While comprehensive approaches to this exposure may do justice to a person's experience, that assessment could be time-consuming or even traumatizing.
3. Social support and social networks. There is a growing expectation that researchers must collect enough data to fully account for each person in a support network, whereas it might be more relevant to understand a person's overall satisfaction with the social support they receive.
4. The relationship between individual experiences and community-level factors. As researchers examine more geospatial features, experts are seeing more neighborhood-level factors affecting individual health. However, little is understood of their interrelation. In addition, there is a need to know whether there is differential information from objective measures of structural variables.

Dr. Alvidrez said helpful studies could look at: how different measures operate and the findings they produce, b) how existing measures of the same construct work together in the same project, c) mixed method approaches, d) measurement equivalence across health disparity populations, and e) examination of ethical issues related to different measurement strategies.

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.

Family Level Research: Family Health, Well-Being, and Resilience: Dr. Derrick Tabor, Program Director, NIMHD.

Dr. Tabor said the objective of the concept is to advance the science of minority health and health disparities by supporting research on family health, well-being, and resilience. He defined a family as any two or more individuals of any gender who share enduring, intimate social relationships, residence, economic cooperation, sense of responsibilities and/or collective obligations. Family members could be connected legally or by less formal means. Family resilience is defined as the ways families deal with adversity and life challenges, as well as the processes that foster positive foundations for those groups. Family adversity and stressors come in many forms, including poverty, early death, discrimination, acculturation, and immigration.

Dr. Tabor said that much of NIMHD's research focuses on individuals, and the purpose of this initiative is to support more family-level research. In many cultures, entire families are involved in one's personal professional medical care. Traditionally family health research focuses on the individual rather than the well-being of the family. Few research studies target the entire family. Dr. Tabor said only 18% of the 90 funded R01s focused on interpersonal or family-level outcomes. Visual inspection of the data shows that only 2% of total R01 grants include family-level outcomes. These figures demonstrate the need for this concept, as economic and social adversity drastically affects families exposed to minority health disparities.

Dr. Tabor said when his team did a review of NIH research using the terms "family functioning" and "family resilience," they identified gaps in understanding the impacts of stressors on the family unit, as well as the comprehension of adversity faced by many families. Although there is ample research on the mother-child and parent-child dyads, little attention is given to other family members. If advanced, this initiative would support multidisciplinary family-level research to examine how racial/ethnic minority families that encounter health disparities promote, sustain, and enhance health. The initiative will measure people's lived experience within the context of the collective familial response. In addition, this research seeks to clarify the dynamic mechanisms and process that operate at the family level.

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 COMMENTS

Dr. Pérez-Stable opened the floor for public comment.

CLOSING REMARKS AND ADJOURNMENT

With no further business to attend to, Dr. Pérez-Stable adjourned the meeting at 2:15 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 1:30 pm on February 4, 2019. Dr. Hunter led the second level review of grant applications submitted to NIMHD programs. The Council considered 361 applications requesting an estimated \$86,286,785 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.