

**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)**

Building 45, Natcher Conference Room E1 and E2
45 Center Drive
Bethesda, MD

February 26, 2018 (Close Session) 3:00 pm - 5:00 pm
February 27, 2018 (Open Session) 8:00 am - 3:15 pm

Meeting Minutes

Council Members Present

Eliseo J. Pérez-Stable, MD, Director, NIMHD
Margarita Alegria, PhD, Massachusetts General Hospital
Maria R. Araneta, PhD, University of California San Diego
Linda Burhansstipanov, MSPH, DrPH, Native American Cancer Initiatives
Marshall Chin, MD, MPH, University of Chicago*
Sandro Galea, MD, MPH, DrPH, Boston University
Linda S. Greene, JD, University of Wisconsin
Ross Hammond, PhD, The Brookings Institute
Spero M. Manson, PhD, University of Colorado Denver
Fernando Mendoza, MD, MPH, Stanford University*
Brian Rivers, PhD, MPH, Morehouse School of Medicine
Amelie G. Ramirez, DrPH, MPH, University of Texas Health Science Center
Gregory A. Talavera, MD, MPH, San Diego State University

Council Members Absent

Giselle Corbie-Smith, MD, MS, University of North Carolina Chapel Hill
Hilton M. Hudson II, MD, University of Chicago; Franciscan Physicians Hospital

Ex Officio Members Present

Said A. Ibrahim, MD, MPH, University of Pennsylvania; Philadelphia VA Medical Center Annex
Cara Krulewicz, PhD, Office of the Assistant Secretary of Defense for Health Affairs
William Riley, PhD, Office of Behavioral and Social Sciences Research, NIH

Adhoc Members Present

James S. Jackson, PhD, University of Michigan

Executive Secretary

Joyce A. Hunter, Ph.D.

Presenters

Margarita Alegria, PhD, Massachusetts General Hospital
Neil S. Calman, MD, The Institute for Family Health; Icahn School of Medicine at Mount Sinai
Michael Lauer, MD, Deputy Director for Extramural Research, NIH
Nora Volkow, MD, Director, National Institute on Drug Abuse (NIDA)

* present via telephone

CALL TO ORDER

Dr. Eliseo Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD), called to order the Open Session of the 47th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) at 8:00 a.m.

INTRODUCTION OF MEMBERS & AD HOC MEMBERS

Council members and others present introduced themselves and their affiliations.

COUNCIL MINUTES REVIEW – September 2017

Dr. Joyce Hunter brought the minutes before the Council for approval. Dr. Margarita Alegria requested one correction to the minutes. She clarified that she attended the September meeting via telephone, which Dr. Hunter said she would correct. Dr. Hunter called for a motion to approve the minutes. The Council approved the minutes of the September 2017 Council meeting.

Dr. Hunter informed the Council that the May and September 2018 meetings were listed on the Agenda. The May meeting is set to take place in the NIH Neuroscience building, located at 6001 Executive Boulevard. Dr. Hunter reminded the Council that members are only allowed to miss one meeting per calendar year.

NIMHD DIRECTOR'S REPORT AND DISCUSSION

Dr. Pérez-Stable gave a brief overview of the meeting agenda and provided the report on activities relevant to NIMHD since the September meeting.

HHS/NIH News

- Alex Azar—a veteran of the George W. Bush administration—was named the new Secretary of the Department of Health and Human Services (HHS) and has been active with NIH Leadership since his appointment. Acting Secretary Eric Hargan returned to his role as Deputy Secretary of HHS.
- Dr. Roderic Pettigrew left the National Institute of Biomedical Imaging and Bioengineering (NIBIB) in November to become the CEO of Texas A&M's Engineering Health (EnHealth) department. This is a new enterprise that will combine medical education, engineering, and bioengineering. The goal is to train medical students to invent solutions to challenging medical problems. Dr. Jill Heemskerk is serving as Acting Director of NIBIB. Dr. Pettigrew was the founding Director of NIBIB.

NIMHD Staff Updates

- Dr. Pérez-Stable welcomed Dr. Anna Nápoles as the new Scientific Director at NIMHD. He has worked with her since first hiring her at the University of California San Francisco (UCSF) some 30 years ago. As the scientific director of the Division of Intramural Research (DIR), Dr. Nápoles is charged with building the intramural program, with a focus on intervention and translating research in minorities and other health disparities communities that have been tested outside of these communities with consideration of the complex role of social determinants.
- Other new staff: Dr. Jung Byun has joined NIMHD as a staff scientist. She worked with Dr. Kevin Gardner, who left NIH for a position at Columbia University Medical School's pathology department. Starsky Cheng took a position at the Office of Administrative Management (OAM). Dr. Juliet Chen will be working with Dr. Kelvin Choi as a post-doctoral fellow. Ms. Jeanne Jones also joined OAM. Thomas Moehlman took a position with the Office of Science Policy's Strategic Planning, Analysis, Reporting, and Data (OSPARD) team. Michael Ramsey is a new doctoral trainee in DIR. Ms. Malaika Staff has been hired in the Office of Extramural Research Administration. Matthew Wise has taken a position in OAM.

- Kenneth Sonnenberg is serving as NIMHD's Acting Budget Officer. The previous Budget Officer, Bryan Maynard, took a position at the Department of Housing and Urban Development (HUD). He made a huge difference in managing important budget issues.

NIMHD Director Activities

- In September 2017, Dr. Pérez-Stable served on a panel called "African American Participation in Clinical Trials: Challenging the Gold Standard" at the Annual Legislative Conference of the Congressional Black Caucus. Dr. David Satcher delivered the conference's keynote address. One patient participant on the panel gave a particularly moving testimony at the meeting.
- NIH also hosted members of the Congressional Black Caucus for presentations and a tour in late September. Dr. Pérez-Stable attended along with Dr. Gary Gibbons, Dr. Diana Bianchi, Dr. Hannah Valentine, Dr. Griffin Rogers, Dr. Francis Collins, and Dr. Larry Tabak. The Caucus heard presentations from the Directors, saw displays on prostate cancer diagnosis and sickle cell, met with trainees, and toured the Clinical Center (CC).
- On October 12th, NIH and NIMHD celebrated the legacy of Congressman Louis Stokes. Dr. Pérez-Stable was MC. The celebration was attended by several Institute and Center (IC) Directors, including Dr. Gibbons, Dr. Jon Lorsch, Dr. Richard Hodes, Dr. Martha Somerman, and Dr. Pettigrew. Dr. Collins hosted the conversation with the Stokes' three adult children. Representative Stokes was the first African American Congressman from Ohio when he was elected in 1968. There was book signing following the celebration.
- Dr. Pérez-Stable attended an event for the American Association for Cancer Research (AACR) in Atlanta. It was a very positive meeting. The majority of the meeting's 400 attendants were minority scientists.
- In October Dr. Pérez-Stable spoke at Jackson State University in Jackson, Mississippi, home to the Jackson Heart Study.
- In late October Dr. Pérez-Stable gave a presentation at Harvard Medical School hosted by Dr. Joan Reede in the OB/GYN department. He also met with Leaders and students.
- On October 30th, the NIMHD Research Center for Minority Institutions (RCMI) held a conference in Bethesda. While many NIMHD staff attended, several IC directors also presented at the meeting.
- Also in late October, Dr. Pérez-Stable presented at State University of New York (SUNY) Upstate Medical University in Syracuse, New York. Dr. Pérez-Stable noted Syracuse is looking to become a hub for the healthcare industry, and the public medical school strives to work with Latino, African American, and American Indian patients.
- Dr. Pérez-Stable served on a panel for the AcademyHealth Concordium meeting in November.
- For Dr. Martin Luther King week Dr. Pérez-Stable was at the University of Virginia, where he spent time with researchers, gave grand rounds, and did a community event.
- Dr. Pérez-Stable travelled to Austin and San Antonio, Texas in mid-February to speak on Advancing the Science of Cancer in Latinos with Dr. Amelie Ramirez.
- On February 23rd, Dr. Pérez-Stable went to a meeting in honor of Black History Month at the HHS Humphrey Building. The HHS Director of the Office of Minority Health, Dr. Matthew Lin invited him and Dr. Gibbons to speak. U.S. Surgeon General Jerome Adams, Secretary Azar and Assistant Secretary for Health (ASH) Dr. Brett Giroir were also present.

NIMHD Budget

- Dr. Pérez-Stable said NIMHD's 2017 funding was \$287.7 million. He broke down the budget by category, explaining that Operations entailed costs to run the IC. He added that Small Business has a mandated fixed percentage of the budget, as does RCMI which has a fixed dollar amount.
- The Center of Excellence portion of the budget is comprised of the recently-funded U54 Centers of Excellence as well as Transdisciplinary Centers (TCC), the latter of which includes the Precision Medicine and Chronic Disease programs.
- Research grants—R01, R21, and R03—comprise approximately 17% of the budget, whereas in some ICs it makes up almost 80% of the budget. NIMHD has a steady distribution for now. The Endowment Program was already discussed.

- Training consists of F and K awards (only K99 and K22 at the time), as well as the Loan Repayment Program and the Minority Health and Health Disparities Research Training program (MHRT).
- Other Research captures various contracts and support programs, such as the Adolescent Brain Cognitive Development Program (ABCD) and the Jackson Heart Study.
- NIMHD's intramural program makes up roughly 2% of the budget which is unchanged. DIR is expected to grow.
- Dr. Pérez-Stable presented the Operational Spending Levels for FY14-17. Notably, the Centers and Endowments have gone down, while the Loan Repayment has been steady at \$6 million during this time frame. Research grants and RCMI have increased.

NIMHD News

- Dr. Pérez-Stable stated that since early 2017 there has been an increased emphasis on efforts to fund early-stage investigators (ESI). He noted it is difficult to know the balance of how much funding ESIs should receive as opposed to established researchers, adding that it was important to invest in young scientists.
- Dr. Pérez-Stable displayed the R01 applicant award rates, which shows an increase in funding for ESIs from FY16-17. He noted that one of the goals is to have ESIs and new investigators funded at similar rates as established investigators. A new investigator is one that has not previously received NIH funding. Some new investigators may not be ESIs. There is also concern about ESI and new investigators successfully getting their second R01.
- Dr. Pérez-Stable also shared the racial and ethnic distribution of NIMHD funding for principal investigators (PI) for FY17. Notably, NIMHD funds proportionally more African American (15%), Latino (13%), American Indian, and Pacific Islander PIs than any other IC. NIMHD funds proportionally fewer Asian and White PIs than the rest of NIH.
- NIMHD recently launched its K program (which will award K01, K08, and K23s), and is still deciding how to best structure the program. They will continue to provide K99/R00 awards, as well as K18s for mid-career professionals looking to enhance their career.
- NIMHD has also been promoting the Diversity Supplements program, which Dr. Pérez-Stable commented is meant to emphasize opportunities for post-graduate scholars and junior faculty rather than for undergraduates or graduate students. NIMHD funded 89% of these applications in FY16 and 78% in FY17.
- NIMHD is hopefully in the final phases of the NIH-Wide Minority Health and Health Disparities Strategic Plan. The project's framework and content have been developed, and Dr. Pérez-Stable described the three main categories in which this project could advance knowledge:
 - 1) Science or Research: Analyze where NIH is committing research funding for minority health and health disparities, which includes socio-economic status (SES), rural populations, and sexual/gender minorities.
 - 2) Research Sustaining: Support workforce diversity and scientific expertise to build capacity, particularly at low-resource institutions.
 - 3) Inclusion: Include minorities in clinical studies, which has made substantial progress in recent years.

Within each of these categories, NIMHD will develop substantive areas along with other ICs. As the Strategic Plan will eventually be reported to Congress, it is extremely important to NIH. To measure the initiative's progress in developing responses to minority health, the ICs are using three measurement goals: what are we doing now to address health disparities, what are the next steps for the next five years, and what visionary reach goals could propel the project forward.

- From March to May 2018 NIMHD will hold listening sessions for the Strategic Plan across the country. The sessions will take place in six physical locations and two virtual sessions. Dr. Pérez-Stable noted that there has been no new NIH-Wide Strategic Plan on Minority Health and Health Disparities for the last five years.
- Dr. Pérez-Stable introduced the NIMHD Scientific Advancement Plan, which was packaged by the Communications team to promote the IC's mission. The first pillar in the Plan is the strength of the science, which Dr. Pérez-Stable believes they have achieved through their staff and

programs. The second pillar is increasing investigator research, which is intended to attract talented researchers to come to NIMHD. Dr. Pérez-Stable noted that with this plan NIMHD intends to stay ahead of the curve so they can invest their research funds efficiently. Reporting and Evaluation are also integral components to NIMHD's mission.

- NIMHD is highlighting several opportunities for early-stage investigators, with a particular focus on leveraging the Health Disparities Research Institute (HDRI) and building on the legacy programs (COEs, RCMI, and the Endowment). The HDRI will be a format to cultivate the next generation of researchers.

Scientific Advancements

- A recent *Morbidity and Mortality Weekly Report (MMWR)* examined the prevalence of youth (ages 2-19) with obesity. The study broke down the rates of obesity based on the educational status of the head of household. Dr. Pérez-Stable shared the findings and remarked that whether it was causal or associated the research shows an educated population seeks better health.
- A recent study in *Social Science & Medicine*—co-authored by David Williams—analyzed non-poor African Americans and Latinos and the role of discrimination when they seek care. This paper is notable because it studied middle-class minorities, and it suggested that discrimination can be worse than poverty when one is seeking care. The study examined the National Longitudinal Survey of Youth (NLSY79) and argued that while Whites experience less discrimination as they move up in SES, minority groups experience more discrimination.
- A grant supported by NIMHD conducted a study targeting weight loss interventions to reduce cardiovascular complications of Type II diabetes. The study found that intensive weight loss did not on average reduce cardiovascular events, although Dr. Pérez-Stable noted one could get a sub-group with well-controlled diabetes and poor self-rated health whose negative effects negated the overall affects. Thus, Dr. Pérez-Stable recommended caution when doing sub-group analysis.
- NIMHD supported grant studied the perspective older breast cancer survivors have towards physical activity. The study concluded that physical activity should focus on cancer treatment related concerns, particularly strength training. Dr. Pérez-Stable added this was important because aside from lung cancer the main cause of cancer morbidity and mortality is chronic disease.
- The Hispanic Community Health Study/Study on Latinos, in which Dr. Talavera (Council member) is a PI, did a study genome-wide association study on heavy smokers with funding from the National Heart, Lung, and Blood Institute (NHLBI). The study had two major findings:
 - 1) It confirmed that the CHRNA5 (which codes for alpha cholinergic nicotine receptor subunit) is often found in Caucasians and African Americans heavy smokers
 - 2) Identified two novel loci on chromosomes 2 and 4 that are associated with non-daily smoking. This was the first time anyone has found anything related to non-daily smoking. The study could not be replicated because there was no data.

Funding Opportunities

- Dr. Pérez-Stable said last fall NIMHD announced 10 R01 grants awarded under the social epigenomics FOA. Nine of the applications were recently funded to NIMHD and one by the National Cancer Institute (NCI). The grants included research on violence exposure, prenatal changes, epigenetic changes in asthma, social stress in prostate cancer, DNA methylation disparities in cardiovascular mortality, epigenomic predictors of post-traumatic stress disorder (PTSD), and traumatic stress.
- An NIMHD-funded grant on healthy lifestyle interventions for high-risk minority pregnant women. Dr. Pérez-Stable noted this was especially important because African American pregnant women and babies have disproportionately high mortality rates regardless of SES strata.
- A survivorship study on symptom experience after breast cancer chemotherapy was funded, as was a study on digital health for African American post-partum women.
- Dr. Pérez-Stable said Dr. Nora Volkow would be attending the meeting later in the day to present on NIH's response to the opioid epidemic. He noted the Funding Opportunity Announcement

(FOA) related to opioids that was approved in September was set to come out shortly. The opioid crisis is a critical topic in public health, as more people have died from opioids overdose or fentanyl overdoses recently than in either the Vietnam War or from HIV during the peak of the AIDS epidemic. Physicians have received scrutiny for overprescribing opioids and have scaled back their actions in the last several years. Notably, American Indians face a disproportionately high burden of opioid addiction, which has been largely overlooked in national media. Dr. Pérez-Stable contended the opioid crisis was a social class issue but noted that African Americans and Latinos exhibit lower proportional rates of opioid addiction than others. The assumption is that doctors wouldn't prescribe to patients because of bias. Data on this is scarce. In response to the crisis, NIMHD has developed a FOA that will focus on etiologic factors of addiction as well as healthcare quality. It is limited in that only 10 grants can be supported. The NIH effort is much greater.

- NIMHD continues to hold outreach activities, and Dr. Pérez-Stable will attend a Tribal Health Board consultation in May in Minnesota.

PRESENTATIONS

Scientific Solutions for the Opioid Crisis

Dr. Nora Volkow, Director of the National Institute on Drug Abuse (NIDA), gave a presentation on the opioid use crisis, beginning by explaining that substance abuse is highly stigmatized and criminalized, especially for minority communities. She added that one of the main goals of her entire career has been to understand how the brain contributes to addiction and how scientists can best characterize those abnormalities. Understanding the brain is crucial for comprehending the opioid crisis, and it is important to remember that people do not become addicted simply due to behavioral choices.

The opioid crisis is the most severe addiction crisis ever faced in the U.S. Fatalities associated with opioid overdoses have grown exponentially in recent years: from 25 per 100,000 people in 1999 to 53 per 100,000 in 2016 in some areas. The Appalachian region and New Mexico have a long history of opioid abuse, but over the last decade overdose fatalities have increased in the Northeast. The crisis was created by a well-intentioned healthcare system, particularly the over prescription of opioids in response to patient pain.

Dr. Volkow explained that opioids act on the mu-opioid receptors of the brain, entering the thalamus after passing through the periaqueductal gray matter and situating in the cortical areas, particularly the anterior cingulate cortex (ACC). The regions of the brain have numerous mu-opioid receptors, which is why opioid medications are so effective in decreasing pain. The need to provide care for patients experiencing pain led to wishful thinking and misinformation on the part of physicians, and they did not think individuals could get addicted to pain medications like oxycodone and hydrocodone. Furthermore, physicians failed to understand how patients could develop a tolerance to opioids, as well as the fact that the higher dosage a patient receives increases their risk for respiratory depression, the main cause of overdose fatalities. In 2011, there were 219 million prescriptions for oxycodone and hydrocodone in the U.S. alone, which accounts for 90% of the world's consumption for that year.

Over-prescription of opioids also led to drug diversion and abuse, and the healthcare system has subsequently reduced the number of opioid prescriptions by 15-17% since 2011. As prescriptions decreased, experts thought overdose fatalities would follow suit. However, there were 64,000 overdose fatalities in 2016, which was 22% higher than in 2015 and more prevalent than deaths related to shootings, car crashes, and HIV. Dr. Volkow stated that prescription opioid addiction has translated to heroin addiction, which along with the importation of high purity, low cost synthetic opioids like fentanyl has resulted in increased cases of overdose fatalities. Fentanyl fatalities alone accounted for 20,000 people in 2016; evidence suggests it is 50x more potent than heroin. The prevalence of synthetic opioids like fentanyl and carfentanil (which is 5000x more potent than heroin) and the fact that they are being laced with heroin has contributed to the growing amounts of overdose fatalities.

Regarding minority groups, cocaine and methamphetamine overdose fatalities have seen a marked increase in African Americans since 2013-2014. Dr. Volkow hypothesized these upsurges in non-opioid drug deaths signify increases in drug importation and that drugs are being laced with synthetic opioids. While many minorities were underrepresented in prescription opioid overdose fatalities, there have been increases in heroin-based deaths. One particular group that is overrepresented in opioid overdose fatalities is American Indians, especially as the epidemic spreads from affecting predominantly rural America and Whites to every race/ethnic group across the country.

NIDA has always placed the origin of the opioid epidemic on mismanagement of patient pain, especially given the fact that 23 million Americans suffer from chronic pain. Thus, there must be drugs apart from opioids that can serve as viable alternatives to treating pain. Achieving this goal has been and will continue to be extremely difficult, particularly because the pharmaceutical industry has not been compliant in researching and marketing drugs to treat addiction. Pharmaceutical companies have struggled to make a safe, non-addictive drug to treat pain, and they have not been able to develop an alternative to opioids. To facilitate a solution, NIDA has funded research on non-addictive opioid type drugs with minimal side effects, drugs that affect the endogenous cannabinoid system, and alternative methods of managing pain. NIDA has also been researching opioid analgesics that cannot be extracted for injection, as snorting or injecting opioids makes them dangerously potent.

There are drugs that treat opioid addiction; namely, methadone (a full agonist), buprenorphine (a partial agonist), and naltrexone (an antagonist that blocks receptors). Although these treatments do work, they are not being fully utilized due to social stigma, and they are not solely sufficient for treatment (approximate 50% of former addicts relapse within six months). Dr. Volkow explained the cascade of care for opioid abuse is extremely bad: of 2.5 million people addicted to opioids, only 300,000 receive treatment, and less than 100,000 sustain treatment for six months.

Many problems of the opioid crisis persist: 50% of addicts relapse in the first six months, the systems for managing addiction are sub-optimal, and the criminal justice system is underprepared to administer health services. Therefore, NIH has been developing extended release formulation, as a modified offering of drugs could increase effectiveness in combating addiction. Two such formulations have been developed through NIDA in partnership with the pharmaceutical industry. The first formulation is a buprenorphine implant that is effective for six months and the second is an extended release naltrexone. This crisis affords no luxury of time, which is causing the NIH to develop drugs and basic science that can be used to combat the epidemic. There are three main aims to contesting the opioid crisis:

- 1) Data sharing among various pharmaceutical companies
- 2) Develop an objective measure of pain
- 3) Solidify a clinical trial network that could route pain medications through clinical trials quickly

Dr. Volkow concluded by expressing that the NIH is in full support of stopping the opioid crisis.

Updates from Building 1: Next Generation Researchers Initiatives and Clinical Trial Reforms

Dr. Michael Lauer, Deputy Director for Extramural Research at NIH, spoke on the NIH's Next Generation Researchers Initiative, which was established to aid young investigators feeling career pressure. Dr. Lauer shared articles from *Nature* and *The New York Times* that discussed young researchers claiming they have an enormous burden to publish and few opportunities to secure funding. Dr. Lauer said he examined the data to see if it supported the contention that it is more difficult for ESIs to get funding and presented R01 success rates from 1995 forward. The grants were broken up into *de novo* grants (Type 1) and renewal grants (Type II). During the NIH doubling, the success rate for Type 2 grants was over 50%, whereas after the doubling in 2003 the success rate decreased for both types. Despite this decrease, today Type II grants retain a higher success rate than Type 1 grants (roughly 37% and 17%, respectively).

While the application-based analysis seemed to confirm media reports, the data told a different story if it was broken down by investigators in the early, middle, and late stages of their careers. In 1990, roughly 50% of grantees were early career (aged 45 or less). Those numbers dropped until 2007, when NIH

policies made it easier for ESIs to receive funding. Late career investigators (aged >60) represented 5% of NIH research funding in 1990, which has steadily increased to 20% today. Middle career investigators (aged 45-60) have received less funding since the NIH doubling.

Dr. Lauer shared a paper by Dr. Michael Levitt, which argued that older grantees are getting money at the expense of younger grantees due to age-based bias. Another paper—written by Dr. Judith Kimble following a series of workshops at the University of Wisconsin—identified two core funding problems: 1) Too many scientists are vying for too few dollars. 2) Too many post-docs are competing for too few faculty positions. To the first argument, Dr. Lauer's data shows that while the number of applicants has increased roughly 50% since 2003 (from 60,000 to 90,000), the number of awardees has increased only about 12% in the same time frame (from 25,000 to 28,000). Interestingly, since 2015 the number of applicants and applications declined.

The people most affected by this hyper competition are ESIs, as they must spend more time seeking funding opportunities. To ameliorate this, Congress passed the 21st Century Cures Act in December 2016, which invests in the next generation of researchers. In November 2017, Dr. Lauer, Francis Collins, and Larry Tabak posted an article in the *Proceedings of the National Academy of Sciences (PNAS)* explaining that several groups are working with NIH to discover and fund ESIs. Specifically, groups at the National Academy of Sciences (NAS), the Advisory Committee to the Director (ACD), and the Government Accountability Office (GAO) are working diligently on this topic. In contending with this problem, it is paramount NIH implements good programs for ESIs while enhancing the diversity of the workforce and maintaining the highest quality of science.

Switching topics, Dr. Lauer said that in 2012 investigators from Yale University published a study in the *British Medical Journal (BMJ)*, arguing that a large number of results from NIH clinical trials were not being published. The study analyzed 635 trials from the time the findings were discovered until the results were published and found that 30 months after discovery only 45% of trials were published. The 2012 report received ample negative press, which NIH sought to rebut by re-evaluating the data. To do this, Dr. Lauer studied 244 cardiovascular trials completed over ten years, tracking down results papers and/or contacting PIs to inquire about that research.

The results of this study were published in *The New England Journal of Medicine (NEJM)* in late 2013, and they found that trials focused on hard clinical end points were published about 66% of the time after one year and 100% after two years. While this was good news, hard clinical endpoint trials represented less than 20% of NIH's total portfolio. For other kinds of trials, only 10% were published after one year and 40% after two years. Thus, NIH replicated the Yale research study. Later, the group from Yale conducted another study examining 4,000 trials from 2007-2010 across different funding organizations. Published in *BMJ* in 2016, the study showed that the University of Minnesota was the most consistent organization at publishing trials within two years of research (55% compared to 30%-40% for most other institutions). The lead author of the paper, Dr. Harlan Krumholz, posted a column on National Public Radio (NPR) in conjunction with his academic research, in which he argued the bastions of medical research have a systems problem in underreporting results and wasting funding.

Another problem—identified by the GAO in 2016—is that as a federated, multi-disciplinary agency, there is no systematic way for NIH to identify which ICs are effective in publishing research and which are not. Many people at NIH have been working on this; notably, Dr. Sally Rockey, who posted a blog prompting HHS to consider a rule to develop better reporting systems. Additionally, Director Collins and Dr. Kathy Hudson posted an article in *The Journal of the American Medical Association (JAMA)*, airing their concerns and urging input on this issue. A subsequent proposed rule on this topic received 240 comments from the public. In September 2016 NIH leadership posted a final rule stating a fundamental principle of all Institute-funded research is to disseminate findings, particularly those that involve people. Since the rule was established, more writings on the topic have been released, including from Dr. Carrie Wolinetz and members of the communications staff. Dr. Lauer shared two news releases—one from 2014 and from 2017—both of which showed NIH has been working to correct this problem.

Structural Racism in the Healthcare System and its Impact on Health Disparities

Dr. Neil Calman, President and CEO of the Institute for Family Health, said he would start off by creating an environmental scan to examine the government, financing, and regulatory issues that lead to healthcare disparities. When the 2010 census came out, Dr. Calman said he plotted the ages against race, and his analysis found that Whites made up 67% of the population under five years old, 77% of those aged 37 (the average age of the U.S. population), and 83% of the population over 65 (when one is eligible for Medicare). This data demonstrates that Whites have significantly higher chance of survival than minorities, and suggests premature death rates for people of color in the U.S.

While overall health outcomes are improving across the U.S., health disparities remain. For example, from 1975 to 2006 all-cause cancer mortality survival rates after five years improved dramatically for both Whites (from 51% to 67%) and African Americans (43% to 60%). While both figures improved, the disparity between the two has endured at 7%. Dr. Calman asserted insurance rates contain a similar divide.

Dr. Calman defined structural racism as public policies, institutional practices, cultural representations, and other norms that work to reinforce and perpetuate racial group inequities and privilege for Whites. He added that structural racism emerges out of an environment that societies create, which manifest themselves in systems like Medicare trust fund payments, differential payments in Medicare and Medicaid, maldistribution of insurance, and physical institutions like hospitals.

Dr. Calman indicated that while everyone's taxes contribute to the Medicare trust fund, Whites will be able to benefit from it more fully than minorities due to their longer average life span. These policy decisions affect the environment of inequity, and Dr. Calman suggested one potential solution would be to modify the Medicare enrollment age depending on one's race/ethnicity, sex, or population characteristics. Further strengthening health disparities, Medicare is a federal program and Medicaid is a federally funded state-based program, which means the latter can be amended based on local politics. The Affordable Care Act (ACA) tried to improve this disparity by proposing a fee bump to fund Medicare and Medicaid services at the same rate for an initial period, bridging a gap that can be as high as 60% in some states. As a result, in many states the poor are covered at a much lower rate than the elderly.

Health insurance is also mal-distributed: Whites have a higher likelihood of obtaining employer-sponsored or private insurance (72%) while minority groups have a much lower chance (39% for Latinos). Thus, Dr. Calman argued, data that looks at the differentiation of care by type of insurance should always be examined under the guise of racial discrimination.

New York City has a particularly bizarre system of care. Only four private hospitals provide care to patients who are uninsured (15.7% of residents) or on Medicaid above the population rate of those phenomena. Hospitals that do not provide such care—which include Calvary, the Hospital for Joint Diseases, the Hospital for Special Surgery, Sloan Kettering, and NYU Rusk—are known as specialty institutions, effectively precluding low-income and uninsured individuals from receiving specialized care. Public and private hospitals are also geographically proximal in New York City, which enables healthcare institutions to discriminate based on source of payment. Dr. Calman urged this is important because the next generation of doctors is being trained in this environment.

Dr. Calman shared his recent research on the costs associated with care in New York-based hospitals, which showed that private institutions essentially recoup their operating losses while public hospitals lose an average of \$50 million/year. As a result, public institutions remain underfunded every year. Mayor Bill de Blasio has said public hospitals are now going to have to provide services even more cheaply, which is sure to exacerbate the problem. Dr. Calman proposed one public policy solution that would take the surplus of private hospitals and distribute it to the public hospitals.

Access to care is also differential based on race/ethnic diversity. Dr. Calman told an anecdote from his residency at Presbyterian-St. Luke's Medical Center in Chicago in 1974, in which a nursing shortage required inexperienced medical students to administer medications. When he tried to alert hospital management of this problem Dr. Calman was quickly rebuffed, an inequality by design he argued still occurs today. In another case during his residency—while observing mothers on general anesthesia during cesarean sections—Dr. Calman observed that private hospital births were done within three minutes while public births took as long as nine minutes, and mothers were subjected to tests for which they did not consent. Dr. Calman showed evidence of this to patients as well as *The Chicago Defender* and later *The Chicago Tribune*, which forced the medical center to fire certain doctors.

New York's academic medical center outpatient system also contains disparities in care. Dr. Calman noted that his care as a faculty member physician is significantly better than what is provided to those who go to the clinic. Furthermore, data shows it took twenty days to get a clinic appointment and three days to get a faculty practice appointment. Getting an appointment at the public orthopedic clinic took 70 days on average and three for those with faculty care. This is important because 80% of people given a specialty appointment in two days attend, while those who wait even 30 days show up 15% of the time.

Regarding discrimination in residency program acceptance rates, Dr. Calman said he knows of one program that was put on probation for failing to be above the 5th percentile in the percentage of graduates who pass their specialty boards the first time. Programs across the country primarily pick residents based on the U.S. State Medical Licensing Examination's (USMLE) Step 1 and Step 2 scores. The data indicates that African American students will be refused interviews for residency programs more often than Whites due to the bias in standardized scores.

When Dr. Calman started at Mt. Sinai hospital, he spent his time at grand rounds providing information on health disparities in surgical care. While social determinants are a major factor of these disparities, Dr. Calman stated the healthcare system should be a refuge from discrimination. Since 1999 his organization has been funded by the Center for Disease Control's (CDC) Racial and Ethnic Approaches to Community Health (REACH) to conduct research on diabetes in four zip codes in the Bronx. When trying to prove his organization was free of bias, the team analyzed average hemoglobin A1C levels in their study, finding that Caucasians had a level of 7.03 while African Americans had a level of 7.44. Thus, Dr. Calman's practice found they shared some of the same disparities as their peers.

Dr. Calman realized his organization was a microcosm of the larger community, wherein they are successful in providing treatment but not eliminating disparities. To correct this, Dr. Calman developed something he called Affirmative Healthcare Action, which implemented interventions targeted at specific populations. The study ran from January 2009 to November 2017 and provided extra services for those populations with historical disadvantages. With extra effort, Dr. Calman's clinic found they could do more good for targeted populations. While looking at what takes place across the country is important, healthcare disparities will not be solved unless physicians examine their own clinics. Although this study was published in medical literature, Dr. Calman noted he was more excited to print a monograph that could be easily distributed to the public. In addition, they filed a complaint with the New York Attorney General that systems of care needed to have more equity. This complaint was picked up by mainstream news sources like Sanjay Gupta's show on CNN. Additionally, one group travelled to New York's capital in Albany to show their support for ending healthcare disparities. Dr. Calman concluded by explaining four things that his organization will continue to do to mitigate healthcare disparities:

- 1) Study if Affirmative Healthcare Action can create healthcare equity
- 2) Develop methods to differentiate between bias and decision making
- 3) Examine the effect of documenting inequities to affect policy change
- 4) Understand the relationship between healthcare funding and quality of care.

Making the Connection: Our Best Strategy to Reduce Behavioral Health Disparities

Dr. Margarita Alegria, Chief of the Disparities Research Unit at Massachusetts General Hospital, gave the presentation. Dr. Alegria began by saying that one possibility for why researchers are gaining little traction

on mitigating healthcare disparities may be because they are asking the wrong questions. She commended her staff for their help on this research and explained her talk would consider three major themes: a) the role of social context in behavioral health, b) the clinical encounter and disparities, and c) co-creating solutions for addressing disparities with diverse stakeholders.

Dr. Alegria explicated that living in both Puerto Rico and Maine has shown her how incredibly different the social dynamics in those two places can be. One's location matters in regards to the quality of care, and Dr. Alegria displayed data indicating Massachusetts is in the fourth quartile of providing care, but also has among the highest levels of disparity. Comparatively, states like Alaska have poor care but low disparity.

In an effort to better understand social context's impact on health, Dr. Alegria examined the National Latino and Asian American Study (NLAAS), which found that Puerto Ricans had high rates of psychiatric illness. These findings ran counter to studies by Dr. Glorisa Canino, which showed people living in Puerto Rico had a low rate of psychiatric illness. Therefore, Dr. Alegria looked at whether being a minority put one at a higher risk for psychiatric disorders. Of course, minority status is a complex topic, and is comprised of language, culture, and affiliations with various groups and social power. Using a longitudinal study, Dr. Alegria's group collected data on 2,000 Puerto Rican children, half living in Puerto Rico and another half living in environments where they are minorities. The goal of the study was to see whether living as a minority caused individuals to develop major depressive disorder (MDD) and generalized anxiety disorder. The children and their parents were assessed from ages of five-thirteen.

Dr. Alegria displayed the results of her study, which showed children living as minorities had a higher risk for MDD. In addition, generalized anxiety disorder was 3x more prevalent in children living as a minority than those who live as a majority. A propensity score showed that the two scores were roughly equal, as well as that the rates change over time. The study had an 80% retention rate.

Overall, minority children faced higher likelihood of exposure to violence, acculturation, discrimination, as well as lower neighborhood monitoring and worse peer relationship than those that live as a majority. The study also uncovered two important mediators of these problems: peer relationships and social support for youth. Another interesting finding was that when minorities confront difficulties in their environment they do so through a friend-foe dichotomy. Therefore, people living in difficult surroundings are constantly performing social sorting, which is not a natural exercise for most. Another finding was that minority youth reported they have less social support, which could be due to the way they inhabit their community. One surprising finding was that greater acculturation was protective and higher in the minority environment, suggesting that station of life has to do with how that acculturation is perceived. In addition, while familism is seen as positive for young children the study found it could be detrimental for older youths.

Studying the role of the clinical encounter through an NIMHD EXPORT grant, Dr. Alegria explained one of her projects videotaped and analyzed provider relationships. Videotaped sessions showed examples of provider bias, wherein well-meaning physicians made assumptions about particular patients. For instance, for patients seeking help with substance abuse, some providers focused on depression when talking to women and substance abuse with men. Blind spots such as these are ego syntonic, Dr. Alegria explained, and oftentimes cause providers to make patient attributions. In addition to active or cognitive discrimination, statistical discrimination preserves healthcare disparities. Dr. Alegria's study found that clinicians have little time to reflect on the care they provide, which is needed to find out what really matters to patients.

Dr. Alegria spoke about a study she conducted with Patient-Centered Outcomes Research Institute (PCORI), in which interventions were developed for patients as well as providers to support the Agency for Healthcare Research and Quality's (AHRQ) efforts on shared decision-making. To do this, one study "activated" 312 patients, training them on how to ask pointed questions to 74 providers to become "co-producers" of their care across 13 clinics. The trial had four arms: trained patients with trained providers, untrained patients with trained providers, trained patients with untrained providers, and untrained patients with untrained providers. Four goals of the study were established:

- a) Work on attributional errors
- b) Improve communication between patients and providers
- c) Activate patients
- d) Ask providers to be more attuned to the preferences of their patients.

Blind coders listened to audio tapes of sessions and scored providers on their care. Providers were then given specific information on how they could improve over six sessions. This study showed that patients and providers can be taught shared decision-making, though neither group recognized a change. Further, findings showed that patient's interventions affected their perception of quality of care.

Moving to her final example, Dr. Alegria argued researchers needed to innovate to better translate their findings. To study this, Dr. Alegria developed a grant proposing to present research findings to stakeholder groups to determine how those groups would use that information to make change, which required examining the assumptions stakeholder groups employ to make decisions. Partnering with Goshen College, the National Academy of State Health Policy (NASHP), and the Transformation Center, Dr. Alegria studied the ways epidemiological findings could be translated into specific healthcare targets.

Using different methods—including focus groups and a simulation study—the team found that increasing employment was significantly correlated with improvements in mental health outcomes (more so than social determinants like education and income supplements). They presented this information to the stakeholders, which stimulated a discussion about using that information to drive change. The study also found that when translating findings it is most effective to cast the information in terms of how it will affect a particular individual.

As a result of these workshops, NASHP decided to host panels on supported employment, as well as a blog on using research to guide policy decisions. Members of the community are also writing a letter to Substance Abuse and Mental Health Services Administration (SAMHSA), and community groups are asking for tools to identify people in need. Dr. Alegria hypothesized the lack of connection in modern life will eventually be seen as a tragedy, as it erodes empathy and potentially deepens healthcare disparities. She ended by quoting *The New York Times*, which stated that the average attention span has fallen to eight seconds in 2016 (from 12 seconds in 2000).

Retiring Members Appreciation

Dr. Pérez-Stable took a few moments to acknowledge and recognize two retiring members and presented them with framed certificates. Dr. Linda Burhansstipanov, who has worked on American Indian public health issues since she began her career in 1971. She taught at Cal State Long Beach and UCLA. She also worked at NCI and the AMC Cancer Center before taking her current post at the Native American Cancer Initiatives. She serves on multiple boards, is the PI for several grants, and has published 125 peer-reviewed papers. Dr. Pérez-Stable thanked her for her presence and contribution to the Council. Dr. Pérez-Stable also recognized Dr. Margarita Alegria, who had just finished presenting, for her service. He also mentioned her leadership in research on behavioral health and Latino health. He said he greatly appreciated her contributions to the Council.

CONCEPTS CLEARANCE

Expedited Concept Review

Title of Initiative: Time-Sensitive Research on Health Risk and Resilience after Hurricanes Irma and Maria in Puerto Rico and the US Virgin Islands presented by Dr. Jennifer Alvidrez, Program Officer. Dr. Pérez-Stable said the Council conducted an expedited review of the concept in order to develop a funding opportunity announcement (FOA) on the time-sensitive health risks following hurricanes Irma and Maria. Objectives: The purpose of this initiative is to support time-sensitive research on risk and resilience factors related to chronic disease morbidity and mortality following Hurricanes Irma and Maria in Puerto Rico and the US Virgin Islands. The emphasis of this initiative is on understanding the short-term health impacts of the hurricanes. Projects supported under this initiative can be used as

the basis for future studies of longer-term health impacts. Projects are expected to examine interrelationships among psychosocial stressors; and current physical health or mental health status and risk factors for chronic disease. Projects including individuals with heightened vulnerability, including pregnant women, children, older adults, and individuals with pre-existing disabilities or chronic conditions, are encouraged. Projects may involve quantitative and/or qualitative methods, and the collection of information that can be used as baseline data for future longitudinal studies or follow-up studies is strongly encouraged. Applicant organizations must be US organizations physically located in PR or USVI, as these organizations are the best positioned to develop relevant research questions and appropriate data collection strategies. The FOA was developed and submitted to the NIH Guide for review and approval. Several ICs have signed on to support the initiative, including NIAID, NIDA and NCI.

Title of Initiative: NIMHD Minority Health and Health Disparities Research Training (MHRT; T37)

Presenter: Dr. Richard Berzon

Objectives: The Minority Health and Health Disparities Research Training (MHRT) Program (T37) supports research education and training opportunities in minority health and health disparities research for individuals from health disparity populations underrepresented in biomedical and behavioral research. The training program will provide research training at the undergraduate, post-baccalaureate, graduate, postdoctoral, resident or fellow level. The awards support programs at domestic institutions and specified foreign regions. The primary goals of the program are to: (1) support courses for skill development to in NIMHD research interest areas, including clinical and health services research; integrative and behavioral research; and community health and populations sciences; and (2) support research experiences to develop a group of clinical and behavioral researchers who have the necessary knowledge and skills to pursue minority health and health disparities research particularly addressing diseases and conditions that disproportionately impact those populations. The discussion of the Concept by Council was supportive overall. Dr. Hunter requested a motion to move the Concept forward to FOA development. Approval was moved and seconded. Members voted in favor of the motion.

Title of Initiative: Mechanisms of Lung Cancer Disparities in U.S.- Role of Risk & Protective Factors; Presenter: Dr. Rina Das

Objectives: This joint initiative with NCI and NIMHD will support research to understand the etiologic factors and the underlying mechanisms for lung cancer disparities among health disparity (HD) populations in the U.S. Areas of interest include two major areas-Etiology and Health services: 1) Influence of biological risk factors in African American population that may cause worse outcomes with lower smoking rates. Interactions of social factors with biological factors. Genetic and gene-environment interactions that contribute to lung cancer in AA or AI/AN, or rural SES, or Sexual Gender Minority populations. 2) Studies to understand lung tumor biology, identify biological subtypes that are more aggressive lung cancers among AAs, AI/ANs and other high-risk HD populations. 3) Associations between Genetic Ancestries and Nicotine Metabolism Biomarkers among HD populations. 4) Protective factors that prevent Latino/Asian sub-populations from poor health outcomes in lung cancer. 5) Causes and risk factors for lung cancer among never smokers in various racial/ethnic minority subgroups. 6) Interactions of contextual multiple factors (smoking, genes, built environment, social stressors such as discrimination) among various racial and ethnic groups that contributes to lung cancer disparities. 7) Risk/protective factors and health outcomes in various geographic regions of U.S. 8) Causes for screening and treatment disparities for lung cancer among low SES and other racial/ethnic populations.9) Role of healthcare access and quality in explaining disparities in lung cancer among HD populations. Council engaged in a detailed discussion of the concept. Members had several questions and recommendations including considerations of ways to innovate the diagnostic reimbursement system such that it is open to more than 30 pack-year smokers without diagnosing everyone. Program staff made note of the suggestions for incorporation into the future FOA. Dr. Hunter requested a motion to approve the concept for FOA development. The motion was seconded and passed unanimously.

Title of Initiative: Leveraging Health Information Technology (Health IT) to Address Minority Health Disparities; **Presenter:** Dr. Beda Jean-Francois

Objective(s): The proposed initiative will support research that examines the impact of health information technology (health IT) adoption on health disparity populations (e.g., racial/ethnic, low SES, rural, sexual/gender minority) in access to care, quality of care, patient engagement, and health outcomes. initiative will support the use of randomized and pragmatic clinical trials, comparative effectiveness research, observational studies, and implementation science to investigate how to leverage health information technology (health IT) to address health disparities by increasing access to care, delivery of higher quality care, and improving patient-clinician communication. Areas of research interest include but are not limited to the following: Best practices for the inclusion of social determinants of health (SDH) in EHRs and CDS to assist clinicians to deliver context informed care and evaluation of when in the clinical workflow can this data have the most utility to impact outcomes for vulnerable patients: a) Evaluation of how addressing EHR-based SDH risks impacts health; b) Implementation models of delivering CDS in diverse settings (e.g. small, rural, safety net clinics) and the usability of these tools to determine what is working & what is missing in reducing disparities in quality of care and outcomes; c) The effects of EHR use on patient - physician communication, relationships, and patient health outcomes and the impact on underserved populations; d) Disparities in adoption rates of patient portals/PHRs among older minority users, rural residents, low-income patients, persons with LEP, and race/ethnic minority patients; and e) The types of personalization needed to foster patient engagement of patient portals/PHRs in a sustained and relevant way for underserved populations. A supportive discussion of the Concept by Council followed the presentation. Dr. Hunter requested a motion to move the Concept forward to FOA development. Approval was moved and seconded. Members voted in favor of the motion.

Public Comments

Dr. Pérez-Stable opened the floor for public comments and questions.

Closing Remarks and Adjournment

Dr. Pérez-Stable adjourned the meeting at 3:15 p.m.