U.S. Department of Health and Human Services
National Institutes of Health (NIH)
National Institute on Minority Health and Health Disparities (NIMDH)
56th Meeting of the
National Advisory Council on Minority Health and Health Disparities

Virtual Meeting

February 2, 2021
Open Session
11:00 a.m. – 5:10 p.m. EST

Meeting Minutes

Council Members Present

Eliseo J. Pérez-Stable, MD, Chairperson; Director, NIMHD
Lisa L. Barnes, PhD, Rush University Medical Center
Neil S. Calman, MD, Icahn School of Medicine at Mount Sinai
Marshall H. Chin, MD, MPH, FACP, University of Chicago
Giselle M. Corbie-Smith, MD, MS, University of North Carolina at Chapel Hill
Kimberly S. Johnson, MD, Duke University Medical Center
Joseph Keawe'aimoku Kaholokula, PhD, University of Hawaii at Manoa
Matthew Lin, MD, Retired
Spero M. Manson, PhD, MA, University of Colorado Denver
Brian Mustanski, PhD, MA, Northwestern University
Amelie Ramirez, DrPH, MPH, BS, University of Texas Health Science Center
Joan Y. Reede, MD, MS, MPH, MBA, Harvard Medical School
Kenneth A. Resnicow, PhD, University of Michigan
William M. Southerland, PhD, Howard University
Carmen Zorrilla, MD, University of Puerto Rico

Council Members Absent

None

Ex Officio Members Present

Judith A. Long, MD, VA Center for Health Equity Research and Promotion
Donald Shell, MD, MA, Office of the Assistant Secretary of Defense for Health Affairs

Representatives Present

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

Executive Secretary
Thomas M. Vollberg, Sr. PhD

Presenters
Debara L. Tucci, MD, MS, MBA, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), NIH, Bethesda, MD
Spero Manson, PhD, Director, Centers for American Indian and Alaska Native Health, University of Colorado-Anschutz Campus, Denver, CO
Derrick Tabor, PhD, Program Official, Integrative Biological and Behavioral Sciences Research, NIMHD
Rina Das, PhD, Program Official, Integrative Biological and Behavioral Sciences Research, NIMHD
Jennifer Alvidrez, PhD, Program Official, Community Health and Population Sciences, NIMHD
Rada Dagher, PhD, Program Official, Clinical and Health Services Research, NIMHD

CALL TO ORDER AND WELCOME

Dr. Pérez-Stable, Director of the National Institute on Minority Health and Health Disparities (NIMHD), called to order the Open Session of the 56th meeting of the National Advisory Council on Minority Health and Health Disparities (NACMHD) at 11:00 a.m.

ROLL CALL, MINUTES REVIEW

Dr. Vollberg called the roll. Council members and others present introduced themselves and their affiliations. Dr. Vollberg brought the September 2020 meeting minutes before the Council, calling for a motion to approve them. The Council unanimously approved the minutes of the September 2020 Council meeting.

NIMHD DIRECTOR’S REPORT AND DISCUSSION

Dr. Pérez-Stable provided the report on activities relevant to NIMHD since the September 2020 meeting.

Dr. Pérez-Stable opened by thanking the NIMHD staff for their remarkable, commitment and passion to advance the agenda on minority health/health disparities in a historical year of crisis and opportunity for the country and the world. He then, began an update of some events from the past four months.

General Updates

- Dr. Francis Collins will continue in his role as the Director, NIH and Dr. Lawrence Tabak will continue as the Principal Deputy Director.
- The administration has announced designees and appointments that relate to science. Xavier Becerra is the designee for Secretary, Department of Health and Human Services. David A. Kessler, MD is the Director of Operation Warp Speed which is focused on vaccine distribution and development of new therapeutics to address COVID-19. Eric S. Lander, PhD will be Presidential Science Adviser and Director of the Office of Science and Technology Policy (OSTP) at a proposed, cabinet-level position and Alondra Nelson, PhD, a social scientist will serve as Deputy Director, OSTP. Vivek Murthy, MD, a former Surgeon General, is named to serve in that position again. Rochelle Walinsky, MD, MPH from the Massachusetts General Hospital where she was chief of infectious disease has started as the Director, Centers of Disease Control and Prevention (CDC). Rachel Levine, MD, the chief health officer for the Commonwealth of Pennsylvania is the designate to serve as the Assistant Secretary for Health.
- Hannah Valantine, MD, MRCP retired from NIH in September 2020 after spending six years as the inaugural chief officer for the Scientific Workforce Diversity Office. In that position Dr. Valantine was charged with addressing the crisis of lack of diversity in the biomedical workforce and did a spectacular job of creating programs, passionately advocating for these causes, and supporting different improvement for workforce diversity in both the intramural and the extramural programs. Marie Bernard, MD, who is the current deputy director of the National Institute on Aging and a geriatrician by training, is serving as the acting chief officer for scientific workforce diversity. An active search is ongoing.
- Harvey J. Alter MD, Senior Scholar at the NIH Clinical Center's Department of Transfusion Medicine won the Nobel Prize in Physiology or Medicine on October 5, 2020 for his contributions to the discovery of the hepatitis C virus. He shares the award with Michael Houghton, PhD from the University of Alberta Canada and Charles Rice, PhD from Rockefeller University. Dr. Alter’s research was systematic, a great example of a clinician scientist who went about asking important basic questions and gradually contributing to the answers. NIH held a physically distanced, in-person ceremony for presentation of the award on December 8.
- NIH continues to update its webpages related to COVID-19 and all are encouraged to use these as a reliable source for trusted, accurate, and up to date information about research, treatment, vaccines, and trials.
- Among the NIH COVID-19 initiatives programs, NIMHD has a considerable commitment with or investment in the Community Engagement Alliance (CEAL)

Against COVID-19 Disparities, which developed over August and September of 2020. CEAL responds to a need for greater inclusivity in the clinical trials that were being implemented, or carried out on the vaccines, and also therapeutics, but primarily is focused on the vaccines. Initially, enrolled participants in trials for the now-approved mRNA vaccines from Moderna and Pfizer were predominantly White and there was concern that the population most being affected by COVID-19 would not be included in these trials. Science-based messages delivered by trusted messengers are important at both local and national levels. CEAL went about trying to build and sustain trusting relationships through community engagement, appealing to many of you, trusted investigators who have been doing this work for years, and to re-orient the emphasis on information about science with emphasis on the importance of moving at the speed of trust. Groups and organizations are encouraged to rely on trusted local leaders to carry the message. NIH is willing and able to help provide context. At the time that CEAL was set-up, the pandemic was surging in the Sunbelt and coincided with a high proportion of cases in communities of color, African Americans, Latino/as, American Indians, and Asian Pacific Islanders. There are 11 different programs, focused primarily on the South, but including Arizona, California, and Michigan, and Texas and with a focus for full partnership with community-based organizations, including community health centers and clinicians, faith-based organizations, state and local government agencies, particularly the public health offices, and pharmacy networks.

- The Rapid Acceleration of Diagnostics (RADx) initiatives are funded through a special appropriation from Congress to the NIH with a focus on improving and promoting testing for SARS-CoV-2. NIMHD has a significant involvement in the RADx-Underserved Populations (RADx-UP) program to enhance testing in underserved and vulnerable populations across the U.S. RADx-UP in Phase I supports a consortium of 69 community engaged research projects, and a large coordination and data collection center. The program seeks to strengthen the data available on infection rates, disease progression and outcomes, and to identify strategies by which to reduce health disparities in COVID-19 diagnostics. Phase 2 will integrate new advances and is at an early stage of planning. The RADx-UP Coordination and Data Collection Center (CDCC) through its investigators at Duke University and University of North Carolina provides for four primary task areas in the RADx-UP program: administration and coordination, COVID-19 testing technical support, community engagement and data science and biostatistics. Dr. Micky Cohen-Wolkowitz is the Contact PI, Dr. Warren Kibbe is responsible for the data science and biostatistics aspects, and Dr. Giselle Corbie-Smith, who is on our Council, provides her expertise to support community collaboration with different groups. The CDCC serves as a liaison for the RADx-UP projects and NIH and NIMHD and works with the 53 testing projects and 16 projects that are focused on social, ethical and behavioral issues. These projects are distributed across 33 states, DC, and Puerto Rico and reach many minority and health disparity population groups. Projects are based at the University of Hawaii with a primary focus on Native Hawaiians and other Pacific Islanders, and at Puerto Rico, as well at Yale University, each, with their focus in Puerto Rico and the U.S. Virgin Islands. A project at Montana State University works with one of the Native American Research Centers for Health (NARCH), and a Stanford University project that is funded as a supplement to a NIMHD award is focused on South Dakota Sioux. Although the geographic distribution of RADx-UP projects across the country is broad, there are some gaps that may be addressed in RADx-UP Phase 2. In addition, Mississippi, Tennessee, and Michigan, which are not in RADx-UP, are part of CEAL. Some NIMHD awardees who received supplements for RADx-UP projects include: Dr. Dedra Buchwald at Washington State University for work with urban American Indian peoples, Dr. Eida Castro at Ponce School of Medicine in Puerto Rico, Dr. Mona Fouad at University of Alabama, Dr. Jerris Hedges who leads the University of Hawaii project, Dr .Robert Kirken at the University of Texas-El Paso, Dr. Deepak Kumar at North Carolina Central University, Dr. Yvonne Maldonado of Stanford University for a program that is focused on South Dakota Sioux people, Dr. Flavio Marsiglia at Arizona State University, Dr. Pearl McElfish at University of Arkansas, Dr. Marcella Nuñez-Smith of Yale University, Dr. Bill Southerland at Howard University and a member of this Council, Dr. Guangdi Wang from Xavier University of Louisiana, and Dr. Lilian Winsor from the University of Illinois at Urbana-Champaign.

NIMHD Updates

- Several NIMHD grantees have received recognitions that are worthy of note. Dr. Marcella Nuñez-Smith of Yale University is selected to serve on President Biden’s COVID-19 task force. Dr. Margarita Alegría, Harvard University, received the Rema Lapouse Award for Achievement in Epidemiology, Mental Health and Applied Public Health Statistics. Dr. Vickie M. Mays, University of California Los Angeles, was presented the Carl Taube Lifetime Achievement Award for Mental Health Services Research. Dr. Spero Manson, University of Colorado Denver, received the Society for Medical Anthropology 2020 Career Achievement Award.

Legislative Updates and Virtual Presentations and Activities

- In September 2020, Dr. Pérez-Stable participated in *The Atlantic online roundtable* entitled “What can policymakers, health care leaders and public health advocates do to achieve health equity for all?”, and briefed members of the Ad Hoc Group for Medical Research and the Coalition for Health Funding on NIMHD's work to address health disparities in the COVID-19 epidemic.

- On September 30, 2020, NIH Director Dr. Francis Collins with Dr. Anthony Fauci, NIAID Director, Dr. Gary Gibbons, NHLBI Director, Dr. David Wilson, Tribal Health Research Office Director, and Dr. Pérez-Stable met to brief members of the Asian, Black, Hispanic and Native American Caucuses on diversity in clinical trials, the CEAL initiative and the RADx-UP initiative award recipients.
- Dr. Pérez-Stable briefed staff members of the House Energy and Commerce Committee on RADx-UP and CEAL in October, together with Dr. Gary Gibbons, and in November on how data from COVID -19 testing studies could be used to help the U.S. utilize COVID-19 testing capacity more effectively to contain outbreaks and reopen the economy with Dr. Richard Hodes, NIA Director, Dr. Bruce Tromberg, NIBIB Director, and Dr. Tara Schwetz, NIH Associate Deputy Director.
- In January NIMHD Deputy Director Dr. Monica Webb-Hooper spoke at a Texas townhall organized the Texas CEAL group with U.S. House Representative Sheila Jackson Lee to discuss national efforts of the CEAL initiative.

Budget

- The Fiscal Year (FY) 2021 Appropriation that was passed and signed by the President in December provided an allocation of $391,586,000 to NIMHD. This represents a 17% increase above last year's allocation and is a larger percentage change than the increase in allocation to other NIH Institutes and Centers. Most of the increase to NIMHD is targeted to support legislated programs.
- In FY 2020, NIMHD allocated 44 percent of its funding to Research Project Grants, 22 percent to Research Centers in Minority Institutions (RCMIs), nine percent to non-RCMI Centers, seven percent to Research Management and Support, eight percent to Other Programs and Training, five percent to Research and Development Contracts (*i.e.*, NHLBI's cohort studies, Jackson Heart and the Hispanic Community Health Study/Study of Latinos), three percent to Small Business Innovation Research and Small Business Technology Transfer, and two percent to the Intramural Program.
- Submission of R01 applications in FY2020 to NIMHD approached 450 applications and approximately 10% were funded. Success rates for R21 applications remain lower than what is seen for R01s. STTR (R41/R42), SBIR (R43/R44), and career-development (K) awards saw increased numbers of applications and awards. R13 applications and awards represent a very small part of the research project grants portfolio.

- The scoring distribution for FY2020 R01 applications and awards reflects our Institute's select pay process which examines program priorities and in which top scored applications are not always funded.
- K applications (K01, K08, K23 and K99) saw 63 submissions in FY2020 and 23 were funded. The funding of K awards has increased over the past 3 years and exceeded $5 million in FY2020. These applications represent the scientific future and the increase in numbers of applications and increase to 36 percent success are gratifying.

NIMHD Staff Updates

- Dr. Tilda Farhat was selected as the Director of the Office of Science Policy, Planning, and Evaluation. Dr. Farhat is a behavioral and social epidemiologist who came from the North Carolina School of Public Health and has been a steady, wonderful force in the office that she now leads.
- Dr. Yujing Liu was recruited as the new chief of Scientific Review in the Office of Extramural Research Administration. Dr. Liu is a physician and PhD in molecular genetics. He served as the deputy director in the Division of Receipt and Referral at the Center for Scientific Review and prior to that led the peer review team at the National Institute of Nursing Research.
- Dr. Joyce Hunter who filled the role of executive secretary of NACMHD retired at the end of calendar year 2020 with more than 31 years of NIH service at NHLBI, NIDDK and NIMHD. Joyce served as Deputy Director of NIMHD beginning in 2007 and stepped away from that position in 2018 to continue support of NIMHD in other roles.
- Dr. Courtney Ferrell Aklin, who was chief of staff in the NIMHD Director's Office since 2015, moved to work in the NIH Office of Director with Dr. Tara Schwetz, NIH Associate Deputy Director.
- Dr. Rina Das received, in a virtual ceremony, an NIH Director's Award for sustained, exceptional leadership in promoting scientific innovation in NIMHD's extramural research program. Dr. Das spearheaded novel research in the areas of social epigenomics, liver disease, cancer and lung cancer and provided support for "Speaking Up About Mental Health! This is My Story Essay Challenge."
- Dr. Monica Webb Hooper together with Samuel and Marsha Hooper, her father- and mother-in-law, participated in a "COVID-19 Vaccine Family Interview". Mr. and Mrs. Hooper discussed their experience as volunteers in the Moderna vaccine trial. It is hoped the interview will be shared across networks and resonate with those who might be hesitant about accepting the opportunity for vaccination.

- NIMHD is sponsoring a challenge award, “Envisioning Health Equity Art Challenge”. The goal is to raise national awareness about health disparities through art, any kind of art, paintings, drawings, photos, digital art that represent our vision. The challenge, which was planned to coincide with the 10-20-30 NIMHD Anniversary celebration last year and was interrupted by the COVID-19 shutdown, is happening now. Persons who have questions or suggestions are encouraged to contact Dr. Gina Roussos who is leading this for NIMHD at NIMHD2020@mail.nih.gov.

Program Highlights

- The 2021 NIMHD Health Disparities Research Institute (HDRI) is scheduled for August 9-13, 2021 and as a “virtual” week-long training experience. The decision for a virtual rather than an in-person program was made to not delay planning. The 2020 HDRI was by necessity conducted virtually and was successful. The virtual format provides some advantage for the availability of scholars and presenters to participate in the HDRI without travel. In the past, the pool of HDRI applicants and selected scholars has had representation of about 60% from underrepresented minority groups.
- A recently issued NIMHD Notice of Special Interest highlights the need for research strategies and interventions to address vaccine hesitancy, uptake, and implementation among populations with health disparities. Under this NOSI, the first applications will be due beginning on February 5, 2021.
- A NIH Common fund initiative, Faculty Institutional Recruitment for Sustainable Transformation (FIRST), was developed in the NIH Office of Workforce Development under Dr. Hannah Valantine and will receive applications in March 2021. The intent is to support the hiring of minority scientists as a cohort to foster building a community among them at the institution. The initial funding opportunity for U54 awards seeks to fund development of these cohorts at both low- and high-resource institutions and the awards will be managed at the National Cancer Institute. A second RFA will seek to fund a U24 Coordination and Evaluation Center and this award will be managed by NIMHD.
- The NIMHD Director’s Seminar Series opens in 2021 on February 4 with a presentation from Dr. L. Ebony Boulware “Where the Cloud Meets the Ground: Democratizing Health Data to Improve Community Health Equity”. Other recent presentations in the series included Ricardo Muñoz in October 2020 and a special NIH-only lecture by David Williams in December on structural racism.

Scientific Advances.

- NIMHD funded an examination of the effectiveness of lay counselors for telehealth depression treatment for older homebound adults. This telehealth study was initiated prior to the onset of COVID-19. Almost 277 homebound low-income adults with depression were referred through the Meals on Wheels program and randomized to receive either video problem-solving therapy with licensed clinicians, video behavioral activation therapy with lay counselors, or telephone support. The investigators provided the subjects with tablets on which to view the video therapies. The study demonstrated that lay counselors are effective in delivering telehealth mental health treatment.

- A project, funded through the Navajo Epidemiology Center and Community Outreach and Patient Empower Project and with NIMHD grant support, partners the investigators with the Navajo Tax Commission and the Division of Community Development and Tribal Council delegates and local chapter leaders to assess a 2% junk food tax for impact in improving the health of the Navajo people. Although the study is not yet complete, the partnership of the researchers and tribal representatives assisted with a reauthorization of this tax in 2020.
- Another NIMHD-funded study examined religious denomination, church attendance and religious coping effects on hypertension risk among African-American young adults. The Add Health cohort study, consisting of over 1900 adolescent enrollees who are followed as they age, began with funding from NICHD and has now is managed by the National Institute on Aging. The cohort is interesting in that representation of middle-class individuals is not insignificant. Pentecostal religious affiliation was associated with observed increased risk in women and church attendance was associated with significant risk reduction for hypertension in women. Religious coping was also associated with decreased risk of hypertension among women. For men in this study, these factors did not cause a significant change in risk
- Uptake or use of pre-exposure prophylaxis (PrEP) for the prevention of HIV transmission in adolescent males was the focus of one study. The idea of 13- or 14-year-old individuals engaging in sexual activity, regardless of orientation causes pause, but it is something that requires management when it occurs. PrEP is potentially lifesaving and so to study its use and barriers that impede its use in adolescents is important. In a cohort of 491 racially/ethnically diverse adolescent men who have sex with men (MSM), 55% of the participants had heard of PrEP but only 4% had every taken it. A concern for parental discovery was the most reported reason for non-use (32%) and most of these individuals (61%) cited a belief that their parents would not be supportive. Understanding this as a barrier points to improving parental knowledge of PrEP and encouraging parents to initiate conversations about PrEP as an important step if we are to succeed in fighting the HIV epidemic.
- COVID-19 has had a negative impact on use and access to colonoscopy screening for colorectal cancer and one study investigated the use of mailed

fecal immunochemical tests as a solution in medically underserved populations to ameliorate the impact of missed colonoscopy screening. While not a substitute for colonoscopy screening, the findings encourage the use of noninvasive screening, increased use of mailed fecal immunochemical tests (FITs), identification of partners to improve coordination of care, and prioritization of patients with early and abnormal FIT results.

- A Massachusetts study showed COVID-19 disparities for incidence in Black and Latino populations. Both groups experienced greater incidence for COVID-19. The association between the Latino population and COVID-19 rates was attenuated after adjustment for several factors, proportion of foreign-born noncitizens living in a community, mean household size, and the share of food service workers. In contrast, the association between the Black population and COVID-19 rates persisted and may be due to other systemic inequalities.
- A study examined barriers in the referral and transplant evaluation process in kidney transplantation and demonstrated a need for policies to promote and better evaluate referrals for kidney transplantation.
- In a large study examining environmental, built-environment exposures, and socioeconomic predictors of birth weight, lower birth weight was significantly associated with lower greenness and higher temperature, walkability, noise, and income segregation.
- From Dr. Forde in our intramural program, analysis from the Multi-Ethnic Study of Atherosclerosis, a longitudinal study on perceived discrimination and hypertension risk among 3,300 African-American, Latino, and Chinese, and White adults, ages 45 to 84 years, showed an increased hazard risk for development of hypertension among Black participants who experienced any lifetime discrimination. Among Latino participants, who were mostly foreign-born and primarily Mexican in this study, reporting of high everyday discrimination scores was not associated with increased risk of hypertension. In fact, it was associated with a lower risk of hypertension which is interesting.
- Dr. Sherine El-Toukhy of our intramural program completed a study to examine barriers to patient portal access and use, by analyzing data from the Health Information National Trends Survey. The large nationally representative sample completes a self-administered survey for a variety of factors including public perceptions and use of the electronic health record and patient portals. Race/ethnicity was not significantly associated with access or use of the portal. It was associated with socioeconomic status as measured by educational attainment, and whether the survey participant reported that they had an identified primary care clinician. Women were more likely to use the portal. Internet access and mobile device ownership were independently associated with accessing personal electronic health records. Once access was achieved,

use of patient portal functionalities was generally uniform across demographic segments.

- Dr. Montiel Ishino of the intramural program examined over 18,000 records from the Tennessee Department of Health cancer registry from 2005 to 2015 for adults ≥18 years, including age, marital status, race, county of residence (non-Appalachian or Appalachian), and health insurance type to study a disparity in prostate cancer treatment delay between Black and White men in Tennessee. Even with health insurance coverage, Black persons living in non-Appalachian counties had the highest treatment delay, which was almost double that among White persons in the lowest delay profile. These disparities in prostate cancer treatment delay may explain differences in health outcomes among Black persons, who are most at-risk.
- An annual report from the American Cancer Society for statistics of various cancers shows that prostate cancer continues to be much more common among African American men, almost double any other group. Lung cancer has dropped in incidence among African Americans but remains higher among African Americans than among any other group. Colon cancer also remains higher among African Americans, and liver cancer is higher among all racial/ethnic minority groups. But the good news from the cancer statistics is that mortality for cancer has continued to drop and has been dropping steadily now for the last five years, and believed to be in large part to better therapies as well as better management and detection of early disease.
- A report from Dr. Sandro Galea and colleagues examined cardiovascular disease prevalence in NHANES data against the metric of family income to poverty ratio. The top 20 percent of income or higher resources showed steady decreases in cardiovascular disease whether it was measured as heart attacks, heart failure, or stroke. The poverty level would be about $25,000 for a family of four, so this higher resourced group was five times that. Individuals who were in the lower-resources category included a higher proportion of women, more African American and more Latino individuals. The lower 80 percent in this study experienced a disproportionate, reduced benefit with slight decreases in heart attacks, and slight increases in heart failure and stroke. The disparate benefit in the context of 40-plus years of remarkable advancements in prevention and therapeutics of cardiovascular disease shows the need for increasing attention on our part from a health disparity perspective.
- COVID-19 mortality and morbidity in persons who identify with racial/ethnic minority and populations with health disparities were the subject of a systematic review in the Annals of Internal Medicine last year that examined results in 37 studies, including CDC reports. African American and Latino persons suffered from higher rates of infection and hospitalizations and mortality overall, but in-

hospital mortality was not different. Persons who identified as Asian in this analysis were not different than White persons. There was insufficient data to make any statements about American Indian, Alaska Native, or Native Hawaiian and other Pacific Islander individuals.

- Dr. Pérez-Stable addressed several questions. Concerning the progression of career development (K) awardees to attaining research project (R01) grants. it is too early to assess applicant success for NIMHD's participation in funding opportunities for K grants. The HDRI program began tracking scholar progress in recent years, and there are several successes for K award applicants and at least one scholar who received a R01 research project award. Regarding the results showing a treatment delay among African American men with prostate cancer, this kind of study that involves a large registry of cancer patients does not lend itself to providing causality. The factors that influence and led to the observed differences are undetermined and in need of further study. The RADx-UP program under its allocation must involve testing for COVID-19 and may not focus on vaccination alone.

PRESENTATIONS

Minority Health and Health Disparities Research at the National Institute on Deafness and Other Communication Disorders: Debara L. Tucci, MD, MS, MBA, Director, NIDCD

The NIDCD mission is to provide research and training for research in hearing, balance, taste, smell and language disorders. The burden and prevalence of these disorders is significant. Hearing loss is the third most prevalent disorder worldwide, will affect almost half of all Americans by age 75 and occurs congenitally in 2-3 of every 1000 U.S. births. Balance problems, observed in 15% of adults, are not mechanistically understood and contribute to falls in older adults for which medical costs are approximately $50 million annually. Taste and smell contribute to nutrition and overall health status. Voice, speech, and language disorders affect a person's emotional and social life and can compromise educational and job opportunities.

Unaddressed hearing loss has significant public health ramifications. Hearing loss is also associated with higher risk of depression, anxiety, and social isolation in adults, and there's associated higher costs of healthcare. As a result, NIDCD is interested in funding research that reduces cost and increases accessibility of hearing healthcare for adults and for addressing barriers to hearing healthcare, include the high cost of devices such as hearing aids, the stigma associated with hearing loss and use of hearing aids, the complexity and difficulty in accessing hearing health services and the lack of insurance coverage for hearing health services. A National Academies study on affordability and accessibility of hearing healthcare for which NIDCD was a sponsor in

2016 recommended over the counter availability of hearing devices to make them less expensive and more available to people. Subsequent to this and other reports, the Warren-Grassley bill mandated that the FDA create a regulatory structure for over-the-counter sales of hearing devices. Although it is now three years, it is hoped that guidelines will be released, this year.

Several studies in the NIDCD portfolio address minority health and health disparities in various ways. Healthy People is a national program of the U.S. Department of Health and Human Services that every ten years sets new goals to improve health and well-being, and NIDCD participated in Health People 2020 for objectives on hearing and other sensory or communication disorders. Epidemiologic tracking of these objectives noted disparities in symptoms reported to healthcare providers. American Indian and Alaska Native populations had the highest rate for adults bothered by tinnitus during the past year. Asian and Hispanic/Latino population groups had the highest rates in adults seen for evaluation of problems with balance or dizziness. Hispanic Latino populations had the highest rate for persons with disorders of voice, swallowing, speech, or language who have been seen by a specialist for treatment. The highest rate for young children with phonological disorders, language delay, or other developmental language problems who participated in speech and language therapy was seen among African Americans.

Some programs that have been developed by NIDCD extramural investigators address some of these disparities. These programs have in common that: they serve underserved, rural, or urban populations; all involved the community in developing interventions that are important to the community, community-based participatory research; and all use care delivery models that rely on trained community health workers who are supervised by hearing health professionals.

- *Oyendo Bien,* which means Hearing Well, is a pilot study that was developed in the state of Arizona. The researchers determined that persons who do not live near Phoenix or Tucson may need to travel 100 miles to see an audiologist. Six metropolitan counties in Arizona have no audiologist, Santa Cruz County which is near the Mexican Border has no hearing healthcare providers, became the focus of the study. The intervention began with community input through a needs assessment to determine the barriers to care and developed into a program that is described as a five-week Spanish language culturally relevant hearing health outreach program for older adults with hearing loss, facilitated by community health workers supervised by an audiologist. Comments collected in focus groups following the program revealed increased self-efficacy and decreased stigma because of the program. At one year later, most participants had sought some sort of hearing healthcare intervention.

- The Hearing Equality through Accessible Research and Solutions (HEARS) pilot study in inner city Baltimore is designed to address a population that is inner city and underserved. Hearing aid use in Americans who are 70 plus years of age demonstrates a disparity for Black and Mexican American individuals where uptake is 10%, half of that seen in White individuals. The two investigators, Frank Lin and Carrie Nieman of Johns Hopkins University, developed a hearing care intervention program delivered by community health workers in an at-risk minority, urban dwelling, low-income population. This program was so successful that Dr. Nieman received the 2020 National Academy of Medicine's Healthy Longevity Catalyst Award which is awarded through an international competition to investigators who are making breakthrough interventions to improve the physical, mental, and social well-being of people as they age.
- A third study, just recently funded and will start shortly, is a community-based participatory research study which endeavors to address lack of services in rural Alabama. The target is to address mild to moderate hearing loss in a setting of no access to hearing healthcare using a state-of-the-art mobile audiology clinic and to mitigate the negative effects of hearing loss. The community-based participatory research will use a needs assessment to develop an effective community health worker-led rehabilitation training program. Through the mobile clinic they will assess the effectiveness of personal sound amplification products for decreasing hearing handicap and improving speech perception. Hopefully over the counter devices will be available by the time the study assesses products and can be implemented in an aural rehabilitation program.

In addition to studies that address hearing loss in aging, NIDCD funds studies of hearing disorders in infants and children.

- “Helping the Hearing of Infants by Reaching Parents: The CHHIRP Navigator Trial” from Matt Bush and his colleagues at the University of Kentucky targets children in rural Appalachia in Kentucky. Universal newborn screening was mandated by law in 1999, and amazingly 98 percent of newborns in the U.S. are screened within three months of life, most of them while in the hospital. However, 36 percent of children, particularly in underserved areas, are lost to follow-up care and do not receive definitive testing and intervention which should have occurred within 6 months. Hearing loss in the first years of life can be particularly impactful on language development. This program is studying the use of a patient navigator to decrease non-adherence to follow-up by parents. The investigators provided data on predictors of hearing loss in these newborns and minority race is the highest predictor of hearing loss among these factors.
- Dr. Susan Emmett of Duke University, a NIDCD investigator, in a study funded by the Patient Centered Outcomes Research Institute (PCORI) made use of

infrastructure built from her NIDCD grants to improve upon delayed hearing care follow-up in remote parts of Alaska which are centered around Nome, “Hearing Norton Sound”. The researchers worked closely with the Native Alaska community to create interventions that are meaningful to the community, shape the research questions, the outcomes to be measured, and the procedures for completing the project, such as participant recruitment. hearing screening of school-aged children with a mobile health referral process for early childhood intervention, and a cell phone-based screening process for adults. An existing strong system for telemedicine was strengthened further by this study to provide treatment of hearing loss and ear disease.

- Dr. Emmet in another study is leveraging a NICHD-funded prospective cohort study in northern and western Alaska to investigate the possible role of the CPT1A arctic variant in childhood infections and childhood hearing loss. The high prevalence of this genetic variant is thought to result from positive genetic selection, originally conveying beneficial effects to people who live in a cold environment and consume a traditional fish-based diet. Changes in diet and in living conditions such as overcrowding and in-home fires may alter the benefits and risks from the variant. Dr. Emmett is evaluating rates of otitis media in children who bear the genetic variant. The research demonstrated a disproportionately high rate of otitis media for children under one year of age among Native American and Alaska Native children which is almost three times greater than for other U.S. infants and which correlates with a disproportionately high prevalence of childhood hearing loss. This knowledge of the incidence of otitis media will help us, hopefully, to develop future interventions to reduce this important health disparity in Alaska Native children.

Taste is an area of study for NIDCD. Tobacco companies add menthol to make cigarettes seem less harsh and more appealing, especially to new smokers and young people. Seven out of ten African-American youth, ages 12 to 17 years, who use cigarettes use menthol cigarettes and almost 80 percent of non-Hispanic Black adults who smoked usually used menthol cigarettes compared to 35 percent of Hispanic adults and 25 percent of White adults. Additionally, quit rates for smoking behavior are lower in individuals who smoke menthol cigarettes.

- Dr. Dennis Drayna of the NIDCD intramural program and his research team conducted the first multi-ethnic study to look across all genes to identify genetic vulnerability to menthol cigarettes. The researchers showed a significant association for the odds of menthol cigarette use, five- to eight-fold increase, and the presence of coding variants in the gene MRGPRX4. A variant haplotype of MRGPRX4 was seen exclusively in African American participants. This very high impact finding can be very useful in public health messaging and regulations.

In the area of voice, speech, and language, there is a need for reliable user-friendly tools to help parents determine if their baby may have a communication disorder. Infants from lower income, African-American and rural families may receive a diagnosis of a communication disorder up to one and a half years later than children from other groups, delaying intervention with effective intervention strategies. Black and Hispanic children continue to be less likely to be identified with autism spectrum disorder than White children. These differences suggest that Black and Hispanic children may face socioeconomic or other barriers that lead to a lack of or delayed access to evaluation, diagnosis, and services.

- The Baby Navigator and the Autism Navigator are two programs to improve parental awareness for earlier diagnosis. The web-based interactive platforms show extensive video footage to illustrate early milestones and responsive parenting. They maximize the use of mobile technology for community implementation and scientific advances that can rapidly scale up to reach children and families anywhere, allowing access as needed at a younger age and with the potential to reach families who are underserved and underrepresented in research.

NIDCD is either currently participating in or planning to participate in programs to promote diversity and inclusiveness within the scientific workforce and a more inclusive environment within NIDCD and at the NIH.

- NIDCD participates in NIH-wide initiatives. The F31 Diversity Fellowship program is intended to increase the number of scientists from diverse population groups who do research in our mission areas. The scientific review team strives to expedite the peer review process and the award process by providing very quickly after the review the summary statement so that these can be revised and resubmitted on the next round.
- NIDCD workforce diversity and R01 awards use a high program priority process to award R01 applications that fall outside of the NIDCD automatic pay line. Additionally, NIDCD uses a R56 high priority short-term project award to provide funds to allow investigators to continue promising lines of research while revising and resubmitting an initially unsuccessful R01 application.
- NIDCD recently published a funding opportunity announcement to support cooperative agreements for clinical trials in communication disorders and incorporated new language in the funding opportunity to strengthen the involvement of underrepresented minority participants in clinical trials.
- Together with NIDCD Advisory Council, NIDCD is exploring ways to effectively engage underrepresented minority scientists throughout their careers and support training, mentoring, and leadership development programs to ensure a

robust workforce. The intent is to provide recommendations around training and engagement of scientists, including those from diverse backgrounds, identifying and supporting research related to health disparities and inequities within the NIDCD mission areas, and then finally creating opportunities for scientists with disabilities.

- NIDCD plans for further programming to help in promoting a diverse workforce, such as providing a two-day mentoring experience for candidates at various career stages who have submitted unsuccessful applications, continued support for an extramural program in one of the related professional societies and developing new approaches and mechanisms to better support the training, mentoring, leadership, and engagement of underrepresented minority scientists.
- Within NIDCD, an internal Diversity Working Group has great enthusiasm of staff volunteer representatives from every level and spanning all NIDCD divisions to help ensure that the NIDCD's own federal workplace is diverse, respectful, and inclusive. They meet monthly to identify opportunities to improve inclusion, equity, and respect within the institute, and foster an informed community that is welcoming to everyone. Recruitment is planned for a chief diversity officer who will help focus NIDCD efforts and strengthen accountability in this area both internally and in extramurally directed programs.
- The NIDCD continues to co-sponsor and participate in trans-NIH initiatives, such as: MOSAIC, the FIRST program, SCORE, and RADx-UP. NIDCD is considering providing supplements to FIRST program awards.

Dr. Tucci thanked the Council for the opportunity to present and addressed a few questions and comments.

Integrating Behavioral Health and Primary Care: Screening, Brief Intervention, and Referral to Treatment (SBIRT) in Native Healthcare: Spero M. Manson, PhD, Distinguished Professor of Public Health and Psychiatry, Director, Centers for American Indian and Alaska Native Health, Colorado Trust Chair in American Indian Health, University of Colorado-Anschutz, NACMHD Member

Dr. Manson made a presentation of his work that began almost 20 years ago with the first of a succession of awards for the NIMHD Centers of Excellence program. The NIMHD-funded center which sought to examine integration of behavioral health into primary care began with a focus on alcohol and substance abuse, that evolved more broadly to encompass trauma and suicide, recently. Suicide as a leading cause of death among American Indian/Alaska Native ranks higher for this population than for any other segment of our population. In addition, rates of suicide in American Indian/Alaska Native population groups escalates earlier in life, and prior to age 40 outpaces the rates of suicide in other population groups. The burden of suicidal behavior extends to hospitalizations due to suicide attempts; suicide attempts themselves, and individuals who seriously considered suicide represent a growing platform of concern in regard to this particular set of behaviors and emotional and psychological challenges.

In the historically largest psychiatric epidemiologic study of American Indians and Alaska Natives in three of the largest reservation-based tribal communities in the country in the late 1990s and early 2000s, Dr. Manson's work showed that stigmatization due to suicide and related mental health problems in American Indian/Native Alaska communities is second only to that which accompanies HIV/AIDS diagnosis, and the primary care clinical encounter is one of the few settings where Native patients feel sufficiently assured of confidentiality to disclose suicidal ideation and intent.

That observation led to the development of an evidence-based practice, termed Screening, Brief Intervention and Treatment (SBIRT), that represented a formalization of many of the detection and management procedures that have long been a part of screening in primary care, but in this instance a focus on behavioral health disorders, initially alcohol and substance abuse, and more recently with respect to suicide. This evidence-based practice was initially introduced, promoted, and heavily funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and with input from Dr. Manson was adapted for use in Native communities. SBIRT is a two-step process, which detects individuals at risk of suicide in a very efficient, simple, culturally relevant means, and then, through the co-location of a baccalaureate or master's level clinician among the primary care team members in recognition that suicidality can be subject to change, provides individuals at such risk the tools to engage in such change. In 2012, the National Strategy for Suicide Prevention identified SBIRT as a highly likely tool to be able to use in the early detection, triage, and management of young people at high risk of suicide. In the context of Indian healthcare, stigmatizing conditions such as suicidality are more readily discussed by patients in primary care than virtually any other setting, and SBIRT was the perfect vehicle to be partnering with primary care practitioners. Co-locating a behavioral health clinician in the primary care team requires adjustments in organizational climate and brings benefits for more timely intervention by a trained professional and relieving the already burdened primary care provider by providing the means to address suicidality and other comorbid conditions.

The co-location of this baccalaureate or master's level clinician in the team raises patient awareness of suicide as a plausible concern rather than something to deny, and enhances the individual's readiness to change, usually accelerated using motivational interviewing in the first exchange. Typically, the approach provides a contract between patient and the co-located clinician to pursue the next steps in addressing this risk to ensure that the patient knows not only that his or her concerns regarding confidentiality and stigmatization will be respected, and to identify concrete steps by which he or she can move forward in engaging and committing to this contractual relationship beginning with education and motivation. Dr. Manson's work has clearly indicated repeatedly that these elements of the SBIRT process can be readily adapted to the patient organizational culture in Native healthcare settings, rendering them particularly suitable for early identification and treatment of American Indian and Alaska Native people not only at risk of suicide, but often in many of the comorbid associated conditions such as alcohol, substance use, and other forms of trauma.

Over 72 percent of all American Indian and Alaska Native individuals across the developmental lifespan live in cities in America, and this hidden tribe is largely ignored. The Urban Indian Health Programs receive approximately one percent of the federal Indian Health Services budget. Urban American Indian/Alaska Native youth and young adults experience attempted suicide at rates nearly comparable to their Native counterparts in the rural and reservation areas, and which exceed by three times the risk of their non-Native counterparts in urban America. Although some risk factors are in common with those who live in rural and reservation counterparts, gang activity, teen pregnancy, interpersonal violence and abuse are more commonly factors for suicidal risk among urban American Indian/Alaska Native youth and young adults. The 34 Urban Indian Health Organizations in 19 states are poorly equipped to deal with the problems, both in terms of financial resources and provider preparation. Dr. Manson's team is working with 12 Urban Indian Health Organizations to examine use of SBIRT as a solution.

At the Southcentral Foundation located in the Alaska Native Medical Center in Anchorage, Alaska, Dr. Denise Dillard, an early mentee for Dr. Manson, began in 1999 to collaborate in looking at how SBIRT could be introduced into this extremely large primary care center hosted, operated, and supported by the Southcentral Foundation. Thirty-six primary care teams treat approximately 65,000 patients. The work began with support from SAMHSA to identify, hire and integrate three master level clinicians focused on behavioral health and co-locate them within primary care teams. In 2000 and 2001 these teams began screening patients with SBIRT at first with a focus on depression and alcohol abuse and substance abuse and for the past eight years with respect to suicidality. The opportunities for triage and management include not only behavioral health, but referral and the provision of traditional healing resources as well as the integration into other ancillary recovery programs available and supported through and by the Southcentral Foundation. In 2004 with NIMHD support, using the center of excellence grant under Dr. Manson's direction, they demonstrated that for the 27 percent of the individuals screened during that three-year period who were at high risk, over 72 percent of these at-risk individuals were referred successfully in-house to appropriate follow-up services. A cost of care analyses showed that SBIRT reduced the overutilization of primary care services with substantial savings in dollars and cents to the Southcentral Foundation and the state Medicaid funding system. These findings led in 2004 to the state of Alaska revising their CPT codes so that from that point on they now reimbursed the Southcentral Foundation for the provision of SBIRT-related services and an expansion in the number of masters-level clinicians from three to thirty-six.

Dr. Manson and colleagues translated this work into yet another large primary care setting in the interior of Alaska, the Chief Andrew Isaac Health Center of the Tanana Chiefs Conference in Fairbanks. The Chief Andrew Isaac Health Center has a similar mission the Southcentral Foundation but differs in that the patients are fewer but with much greater geographic spread across 37% of the landmass of the state of Alaska. Establishing SBIRT within this setting was quite similar in structure and process with respect to the introduction and the implementation. Ultimately evaluation and sustaining of the SBIRT model yielded similar results to what was seen for primary care services at the Southcentral Foundation.

In addressing Urban Indian Health Organizations in the lower 48 states, Dr. Manson’s team began with the First Nations Community Healthsource located in Albuquerque, New Mexico. With structure and process similar to that which was followed in Alaska, SBIRT was introduced to the First Nations Community Healthsource in Albuquerque, New Mexico which serves nearly 57,000 American Indian, Hispanic and other disadvantaged residents. With three distinct clinic locations, collocated master’s level clinicians began screening a substantial number of unique patients in their service population and based on the evidence collected in collaboration with Dr. Manson’s team these clinics were able to attain certification for SBIRT and are fully funded to provide SBIRT services by the state of New Mexico through their Medicaid expansion.

Dr. Manson presented experiences with the Seattle Indian Health Board located in Seattle, Washington, an Urban Indian Health Program that serves many unique patients each year. The Seattle Indian Health Board provides a wide range of comprehensive services that are biomedical and recovery in nature and include traditional healing resources. Their SBIRT program, which was initiated more recently here than at the other three in this presentation, focused initially on alcohol abuse and dependence, and since then it has expanded to include substance abuse and suicide risk. The Seattle SBIRT program is supported now by the state of Washington's Medicaid expansion program, based on the evidence that Dr. Manson and colleagues were able to marshal in support of the impact of its services on reducing costs of over-utilization and on the effectiveness of the services. The family medicine residency program at this site and the presence of the SBIRT program provides a training opportunity to show residents how to bring behavioral healthcare into a primary healthcare practice.

Quarterly dashboards were developed for each site and provide ongoing updates in terms of the differential rates of screening, rates of positive endorsement and associated risks. Engagement requires transformation of the organizational climate and culture of a primary care setting which occurs at different levels in each organization. As a result, there are differential saturation and coverage rates for behavioral health screening at the various clinics in these Urban Indian Health Programs, ranging all the way from 66 percent coverage all the way up to 82 percent coverage. Data for screening coverage feeds efforts in quality improvement procedures for the primary care providers across the teams, across these locations, and with supportive personnel to ensure that the patient is engaged at the time he comes into the clinic for his or her appointment. Another part to the dashboard demonstrates the various behavioral risks which are monitored and the reporting that occurs in the screened population for each risk. The clinics are also able to follow over time at 6- and 12-month intervals how this SBIRT process works from the moment of identification through follow-up and ultimately triage, thinking through management which ancillary treatment resources to which patients are referred, how are they followed up, what's the effectiveness of those resources, either individually or in combination, in reducing the risk of suicide.

Medical records analysis using multilevel regression models in a study published in 2012 with Dr. Denise Dillard examined at one year after implementation of this detection initiative the associations between patient and provider factors and administration of the Patient Health Questionnaire-9 and revealed that 47% of patients were screened with women somewhat more represented in the screened group. The study demonstrated a need to improve coverage and saturation for the SBIRT approach. The odds of being screened had strong associations with older age, increased service use, and chronic disease, but not with substance abuse disorders, or prior anti-depressant dispensation.

Information across these Urban Indian Health Programs have brought the research to consciously and deliberately focus on how to engage eligible patients, how to minimize the stigma, how to ensure confidentiality, and thus increase both the recruitment and the retention in treatment. Challenges that call for continuing work include maintaining implementation fidelity within the clinical workflow and ensuring patient transition through this process of care and maximize the transition. This requires a continuing feedback loop that is rigorous and empirically informed through publication. Success of the entire effort is through a team-based approach that requires community-based participation in partnership.

Dr. Manson accepted some comments and questions and thanked the audience for their attention.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program Working Group Report

Dr. William Southerland was introduced to speak on behalf of the Working Group. The SBIR/STTR Working Group was established in October of 2019 to review the NIMHD SBIR/STTR program, and to produce recommendations for the NIMHD Director on ways to maximize the program's potential to advance minority health and reduce health disparities. The review of the program focused on three priority areas: advancing the science of minority health and health disparities through scientific innovation and dissemination, leveraging other funding opportunities to advance the agenda, and advancing outreach efforts to expand opportunities for participation in the program by the extramural community. The programs are established by Congress and the NIH Institutes are required by law to allocate 3.2% of their yearly extramural R&D budget for SBIR awards and 0.45% of their yearly extramural R&D budget for STTR awards. Applicants must be qualified for-profit, majority-US-owned, small business concerns (SBCs). Awards are structured to support the first two of three phases; a shorter-term Phase I award for feasibility work (6 months for SBIR and 1 year for STTR) and a multi-year Phase II award to support development that leads to full commercialization in an unfunded third phase. In FY 2019, NIMHD allocated $9.3 million for SBIR awards and $1.3 million for STTR awards, prioritizing R&D activities designed to empower communities to achieve health equity through health education, disease prevention, and partnering in community-based, problem-driven research. From FY 2003 through FY 2019, NIMHD made nearly 200 competing SBIR and STTR Phase I and Phase II awards to 104 small businesses based in 28 states and Puerto Rico. Until 2013, applications to these awards came in response to a NIH Omnibus solicitation. NIMHD added its own RFAs in 2014 on topics relevant to NIMHD’s research interests and these applications were reviewed by Special Emphasis Panels convened by NIMHD’s Scientific Review Branch. The Special Emphasis Panels for the RFAs provided a greater percentage of applications which were scored and with a greater concentration of grants related to NIMHD objectives, reviewers were more focused on significance to the NIMHD mission.

Going forward, the working group noted a need for enhancements to application quality in terms of significance, scientific rigor, and feasibility, and to review panel composition and orientation for representation of behavioral and social sciences, ensuring expertise in mixed methods approaches and community-engaged research and consideration of social return on investment (social entrepreneurship). A focus on financial “bottom line” may overlook the needs of disadvantaged communities and the U.S. small business ecosystem may benefit from a wider view of opportunities for “social entrepreneurship” in the service of community health and well-being.

The working group formulated recommendations in four categories. Under Scientific Gaps and Opportunities, NIMHD should identify opportunities for product development and sustainable social ventures to benefit communities, issue NIMHD Small Business funding opportunities that align to the NIMHD research framework and assist SBCs in considering the interconnecting factors in the framework and issue SBIR/STTR Notices of Special Interest on select and emerging minority health topics. Under Program Outreach, NIMHD should cultivate connections between small businesses and NIMHD-funded researchers and investigators to foster partnerships that can translate NIMHD-funded research findings into products and services that benefit communities, and should offer workshops, resources and activities covering business basics in social media events, blogs, webinars and virtual workshops for academic investigators, SBCs and community groups. The working group recommends Technical Assistance for Applicants and Reviewers in the form of webinars, workshops, and links to grant writing resources for applicants, orientations for peer reviewers that promote concepts of social return on investment and value to the community, and post-award commercialization strategies and resources including the NIH Niche Assessment Program and NIH Commercialization Accelerator Program. Lastly, recommendations for Implementation Strategies support robust program management with a knowledgeable point-of-contact to coordinate and oversee SBIR/STTR program promotion, outreach and technical assistance, NIMHD website and social media enhancements that focus on the role of small businesses for improving minority health and reducing health disparities, and convenings that bring SBCs into NIMHD meetings of minority health and health disparity researchers.

In discussion, the importance of peer review orientation was recognized. An evaluation component to measure or show social impact from the program was suggested and a response noted that this had not been a topic that was discussed in the working group.

A motion to accept the Working Group Report was seconded and passed unanimously by the council members.

CONCEPT CLEARANCES

Small Business Program Concept Clearance - Small Business Innovation Research (R43/R44) and Small Business Technology Transfer (R41/R42): Derrick Tabor, PhD, Program Official, Integrative Biological and Behavioral Sciences, NIMHD

The objective of this initiative is to support Small Business Innovation Research proposing to develop a product, process, or service for commercialization with the aim of improving minority health or reducing and ultimately eliminating health disparities. Appropriate technologies should be effective, accessible, affordable, and culturally acceptable.

The initiative seeks to engage small business concerns (SBC) in developing technologies and products which engage, empower, and motivate individuals, and communities, including providers and healthcare institutions and which sustain health promoting activities, and in developing interventions which lead to improved health, healthcare delivery.

The NIMHD has developed the Minority Health and Health Disparities Research Framework that conceptualizes multiple domains and levels of influence for the promotion of minority health and for the understanding and reduction of health disparities. Applicants to this program will asked to show how their work is informed by this framework.

Dr. Tabor presented examples for technologies of interest while emphasizing that other possibilities could exist and be brought forward by applicants. The examples included: patient-centered technologies for identifying and leveraging racial and ethnic specific sociocultural protective factors and areas of resiliency (*e.g.*, community support); disrupting or preventing the impact of discrimination, bias, and indifference on mortality and morbidity outcomes for racial and ethnic minorities, and populations experiencing health disparities across systems of care and levels of influence; technologies leveraging multiple digital technologies, for example, Fast Healthcare Interoperability Resources, PhenX Toolkit, personalized medicine, and electronic health records for preventing mortality and morbidity disparities; technologies for predicting mortality and morbidity risk, and for identifying preventive interventions, and; technologies leading to equal access, effective continuity of care, and provision of quality care through disruption of the limitations resulting from factors like insurance coverage, socioeconomic status, access to community resources, and site of care.

Dr. Tabor paused to note that two of the examples had included the term “disruption” which reflects interest in technologies that might disrupt some of the factors, or processes, or pathways that lead to health disparities. He then cited a product, Meducation, that developed from a 2005 SBIR grant to improve medication adherence among patients with limited English proficiency. The product’s success had even led to some laws for multi-lingual prescription labeling in California and is an example of technology that has disrupted pathways that normally would lead to lack of adherence. Another project supported “mobile internet directly observed therapy” to enhance adherence for the delivery of tuberculosis therapy. The approach, now called video-directly-observed-therapy, was successful as an enhancement to adherence and is employed across the country.

The presentation continued with additional examples for technologies of interest: innovative products or services that facilitate or enhance self-management, and, products to promote communication or care coordination between primary care providers, hospital emergency department staff, specialty physicians, dental health professionals, nurse practitioners, providers of mental health and behavioral health services, or patient navigators in medically underserved communities and regions.

Last, he noted that disasters, such as catastrophic storms and the COVID-19 emergency, demonstrated a need for technologies that prevent and minimize adverse exposures and health risk, or that promote health, well-being, resilience, and recovery resulting from disasters or the threat of disasters. Such technologies may include new tools, apps, education, curricula, or other technologies to detect, screen, treat, or prevent or otherwise mitigate adverse health outcomes or to leverage community and or population resilience and prevention efforts.

Comments from Council: Council members were very supportive for the initiative. The concept is important for altering the focus on dealing with a disease problem to achieve financial profitability that would favor application in a prevalent population to a focus that brings consideration for the needs of minority health and health disparity. The concept serves to align the SBIR program to the NIMHD mission, to educate on the value in using the NIMHD framework to identify novel opportunities, and to promote social entrepreneurship. While partnership is a part of the SBIR/STTR program, it is suggested that funding opportunities related to the concept should be explicit in encouraging partnership with not-for-profit entities. This concept is timely in that COVID-19 showed many of technology difficulties that occur in many of our underserved communities.

Dr. Vollberg called for a motion to move the concept forward to Funding Opportunity Announcement (FOA) development. The motion was made, seconded and passed unanimously.

Clinical Research Education and Career Development (CRECD) Program (R25) Renewal: Rina Das, PhD, Program Official, Integrative Biological and Behavioral Sciences, NIMHD

Dr. Das noted that a co-author on this concept is Ms. Phuong-Tu Le, Integrative Biological and Behavioral Sciences, NIMHD. The objective of this initiative is to enhance diversity of the research workforce in clinical and translational research through the support of research educational activities in lower resource institutions that offer doctoral degrees in health professions or in health-related sciences. Lower resource institutions are those institutions which have received less than $50 million of NIH funding per year on an average in the last three years.

Data from Association of American Medical Colleges and the National Academy of Sciences demonstrate a need to increase and diversify the U.S. research workforce, especially the clinical research community. To help meet this need, the program began at the National Center for Research Resources in 2002, and since 2011 NIMHD has supported the Clinical Research Education and Career Development (CRECD) program using R25 Research Education Program awards. Over time the program evolved from being a didactic education program alone to one that combines didactic education and mentored research experiences. Initially, awards were made to institutions that were funded by the Research Center in Minority Institutions, the RCMI programs, and subsequently 2017 the program expanded to other lower resource institutions, with awards around $500k direct costs per year for five years..

The R25 awards are intended to support educational activities to develop skills for postdoctoral candidates with clinical degrees, and to develop clinical researchers who can conduct minority health and health disparities research. Each award consists of two educational components, Phase 1 with a didactic curriculum leading to a master's degree, and Phase 2 to provide for mentored research experiences with protected time. Currently funded programs are at Morehouse School of Medicine, University of Puerto Rico Medical Science Campus, Charles Drew University of Medicine and Science, and University of Oklahoma Health Science Center. These institutions, all with accredited master's level program for clinical researchers, have established curriculum to enhance their knowledge and skills in minority health and health disparities research with courses that include community-based participatory research (CBPR), implementation science and quantitative/qualitative methodologies. Under CRECD awards, more than 200 Scholars for whom the vast majority (over 90%) are from underrepresented groups have been enrolled for MSCR or MPH degrees, mainly African American, Hispanic/Latino, and American Indian trainees. CRECD-supported scholars upon completion continue to do research and complete their careers by receiving grant funding from NIH (K01, K08, R21, SC1/2/3, G08, K99/R00, R34, R25 awards), other federal agencies (DOJ, AHRQ, PCORI), state and local agencies and private foundations. Contributions in clinical and translational research are seen in over 400 papers in peer-reviewed journals. These institutions have also partnered with many other existing NIH funded programs and with other academic institutions to enhance their capacity to support these scholars and provide the necessary mentorship. Some scholars are invited to present their work and interact with NIH staff, program staff at an annual scholar meeting that is planned in conjunction with the Association for Clinical and Translational Sciences (ACTS) annual meeting.

The majority of scholars have MD degrees, a few with PhDs in psychology, nursing and others with degrees in dentistry and other areas. The varied topic areas of research include cancer disparities, HIV, and promoting PrEP use among Latino men, diabetes, cardiovascular disease, oral health, and mental health disparities.

The CRECD program combines didactic courses with mentored research experiences for scholars with clinical degrees at the postdoctoral level, with salary support to conduct research not available through formal NIH training mechanisms. There is a need for such a program to increase the diversity of research workforce to address health disparities.

This concept seeks to renew the CRECD program, PAR16-350, to continue to promote and support research educational activities, to enhance the diversity of the research workforce who can conduct clinical and translational research in the field of minority health and health disparities. Some changes are proposed for addition of an evaluation of the program for measuring the accomplishments, assess how well the program is meeting its goal, track the scholars' progress and retention of the scholar with its impact on overall capacity at the institution. It also proposes increased flexibilities for the phase 2 option: to remove a requirement for completing the master's degree in phase 1, as long as there are the necessary skills to conduct research; and more latitude in the requirement of 75 percent protected time, which may be a barrier for some clinicians. Lastly, it is proposed that eligibility expand to other low resource institutions, besides the RCMI funded institutions.

Comments from Council: Council members gave enthusiastic support for the CRECD concept. The significance of the CRECD is recognized for its focus on clinician scientists and the record of success. Evaluation as a component in moving forward is supported. There are suggestions for consideration in four areas. First, increasing interactions among scholars across institutions through virtual forums is suggested to expand opportunities for collaboration, new role models and potential peer mentors, and making available additional avenues for obtaining and sharing information. A second consideration might involve establishing and coordinating an evaluation center to ensure more robust evaluation both within and across programs. Racial and ethnic discrimination and biases, isolation and the lack of network and mentors with similar backgrounds, clinical and community obligations can be barriers and building support strategies into the program that mitigate these challenges would increase the likelihood of success. The fourth area for consideration involves possible alternative vehicles or opportunities for training to support scholars who do not receive phase 2 support.

Dr. Vollberg called for a motion to move the concept forward to Funding Opportunity Announcement (FOA) development. The motion was made, seconded and passed unanimously.

Community-Level Interventions to Improve Minority Health and Reduce Health Disparities: Jennifer Alvidrez, PhD, Program Official, Community Health and Population Sciences, NIMHD

This concept for reissuance of an existing program proposes to support research to develop and test community-level interventions to improve minority health and reduce health disparities. Community-based participatory research is of longstanding interest to

NIMHD and the NIMHD Community-Based Participatory Research (CBPR) program was established in 2005. The intent in the coming period is to move from a focus to support research based on use of CBPR principles to emphasize research priorities that can be addressed through community-engaged research to provide community interventions that address the social and structural environment.

In this initiative, “communities” is defined as place-based communities, within some set of parameters or boundaries. Some examples include neighborhoods, cities, counties, school districts, reservations, or tribal communities, military bases, and college campuses. A “community level intervention” modifies community characteristics, norms, or behaviors in a way that modifies health in the community. Using the National Institute on Minority Health and Health Disparities Research Framework, community level interventions could act upon community level determinants (*e.g.*, community functioning like community cohesion, community social capital), the physical/built environment of resources (food stores, green space) or exposures (air pollutants, local contaminants), the social-cultural environment of community norms, traditions and social climate and the availability and quality of healthcare services. In addition, the objective in this concept is an opportunity to look health outcomes of communities in aggregate.

The expectations are that research in response to this initiative will include community level intervention projects involving collaboration with community partners to improve health outcomes or reducing health disparities in one or more NIH-designated health disparity populations in the US with a focus on either the entire community or a subgroup and with a community level of analysis using either cluster randomized designs, or rigorous quasi-experimental designs. Multilevel interventions that target community level determinants as well as individual level, family, organizational determinants will also be encouraged. Outcomes can be at the interpersonal or organizational level (*e.g.*, the number of families living in households that are smoke-free in a community or the proportion of students within the school system who meet fitness goals), or at the community level (*e.g.*, community rates of vaccine uptake, or changes in the food purchasing practices within the community).

Dr. Alvidrez presented several examples of interventions that would not be considered community-level interventions under this initiative: interventions that are community-based but do not target community-level determinants of health, interventions to help individuals to address or cope with community-level determinants without operating directly on those community-level determinants, interventions that include community-wide elements but intervention effects are tested only at the individual or interpersonal/organizational level, and community-wide outreach and recruitment of participants into interventions that are not community level.

Some examples of topics of special interest for community level interventions could, along with others, include: increasing healthy food options and opportunities for physical activity outside the home, changing community norms and reducing structural barriers related to health promoting behaviors (*e.g.*, breastfeeding, vaccination, physical activity and preventive health screening), promoting detection, help-seeking, and self-management related to acute or chronic illnesses (*e.g.*, COVID-19, stroke, diabetes, cardiovascular disease, depression, substance use disorders), enhancing the ability of community-dwelling older adults to age in place or individuals with disabilities to live independently and maintain health and well-being, and promoting community re-integration and health of individuals returning to the community after incarceration, hospitalization, or institutionalization.

Comments from Council: Council members were very supportive of the concept and complimentary for the presentation as a timely and well-argued enhancement of the original program. The concept recognizes appropriately that since the previous FOA in 2015, community-based participatory research has moved from being itself a central focus of research and practice to a well-established critical method in the toolkit. The emphasis on academic public partnerships, and deep equitable involvement of all relevant partners is admirable. Several suggestions were provided. The responses should be encouraged to include long-term partnerships with real collaboration, not opportunistic ones and evidence that the community level intervention is at least co-designed with the community. Projects should be encouraged to demonstrate fidelity with community-based participatory research practices as they are relevant to and apply in all aspects of conceptualizing the intervention design, its implementation, and interpretation of results, and their dissemination and have a clear theory-of-change to undergird the community level intervention and tie the nature of this work back into the health disparities research framework. Projects should be encouraged to include in their design strategies or plans that might sustain the intervention. The separation between community and societal level in the NIMHD Research Framework in the initiative could benefit if given greater clarity either for a distinction between those two, or for expanding the understanding and operational definition of community level interventions to allow extension to certain logical aspects of the societal level of influence. Intervention within the community and societal dimensions suggests that policy level interventions may be appropriate for incorporation. Methodological issues deserve special attention that acknowledges the strengths and weaknesses of the different kinds of methodological approaches and frameworks that may be mobilized in addressing this concept.

Dr. Vollberg called for a motion to move the concept forward to Funding Opportunity Announcement (FOA) development. The motion was made, seconded and passed unanimously.

The Role of Work in Health Disparities in the U.S.: Rada Dagher, PhD, Program Official, Clinical and Health Services Research, NIMHD

Dr. Dagher presented the concept on behalf of herself and co-author Dr. Nancy Jones (Program Official, Community Health and Population Sciences, NIMHD) and provided an acknowledgement for the assistance of Ms. Ligia Artiles for portfolio analysis. The objective in this initiative is to support research to understand and address the role of “work” as a social determinant that contributes to health disparities. It seeks to answer the extent to which “work” as a social determinant of health can explain health disparities for racial/ethnic minority groups, sexual/gender minority groups, socioeconomically disadvantaged populations, and underserved rural residents. “Work” as a social determinant of health may function as a social class marker, as a source of beneficial social and economic resources such as income, social metrics, healthcare access, as well as a source of exposures and risk factors.

“Work” is a factor in health outcomes, and a primary source of health insurance and access to health services. The experience of ““work”” among U.S. adults is strongly patterned by social identities that we usually consider when we study health disparities, race/ethnicity and Immigrant status, socioeconomic status, rural/urban and sexual minority status. The literature or studies that have been done in the United States support that those social identities are associated with differences in workplace exposures and workplace benefits. “Work” influences life trajectories for differences in access or in achieving social status, differences in access to workplace related resources, and differences in access to social networks. Structural racism/discrimination may explain geographic patterns and extent of occupational and workplace segregation. “Work” is amenable to intervention; it can be modified.

Most occupational health/health disparities research has mainly focused on “work” as a source of hazardous exposures and population-based health disparities research has rarely considered “work” as an explanatory factor for health disparities in the United States. A few studies have ascertained that unequal distribution of work exposures by race and ethnicity may explain disparities in certain health outcomes such as all-cause mortality rates and cognitive function. The extent to which “work” functions as a social class marker and as a source of beneficial economic and social resources and the extent to which that contributes to health disparities remains largely unstudied.

A NIMHD workshop in September 2020 brought together 17 interdisciplinary speakers from academia and from government to identify priority research areas to understand and address the role of “work” as a social determinant that contributes to health disparities. The workshop covered theoretical and conceptual foundations for “work” as a social determinant of health, and also measures, and indicators, and (audio interference) approaches, and key mechanisms and pathways through which “work” contributes to health disparities.

With this information for identified gaps, research objectives were developed: determine the extent to which “work” as a SDOH explains health and health care disparities, and determine the modifiable mechanisms and pathways by which “work” contributes to health and health care disparities. Research is needed to examine mechanisms influenced by structural racism such as occupational segregation and workplace segregation (*i.e,* unequal distribution of exposures and resources across occupations and within workplaces by social identities), and to examine pathways such as life course and intergenerational transmission and system-level Influences. Also, studies are needed to address the diseases, conditions and overall health quality where “work” as SDOH contributes significantly to health disparity. Lastly, research is needed to evaluate upstream policies, regulations, and system-level trends that exacerbate or mitigate “work’s” contribution to health and health care disparities.

Comments from Council: Comments were very supportive of the concept. The concept development is seen as a nice example of how a social factor can be thought about in all of its complexity regarding the web of relationships, the causal relationships, and then potential mechanisms for intervention. The concept looks within employed people at the nuance of the effects of employment and application, specifically looking at the physical and cognitive demands of various occupations, looking at the physical environment and safety, and then looking at the social environment and is seen as greatly moving the field. The depth and complexity make clear communication critical to foster the new and avoid those that propose to do the usual. Graphics with a clear conceptual model and text that describes then the richness of the multilevel factors are suggested. Upstream factors, and regulations, for example, in policies are noted and could benefit from expansion regarding barriers to implementation and to explaining “the why” for mechanisms, such as issues of racism, classism, economics, business case, who has the power. An additional consideration might be for ethics raised by various issues such as social justice versus individual freedom. Under-employment and its effects on job satisfaction and productivity and wellbeing may be a worthy area to include for relation to self-determination theory. The attention given in the initiative to the effect of immigration status, documentation and how that impacts the social setting at work and other aspects of interacting with people at work could be expanded. Policy and interventions at the individual, the work site and the policy levels are mentioned, and an area for study might be for implementation of diversity, equity and inclusion policies at the workplace and whether the policy leads to increased satisfaction and concomitantly health.

Dr. Vollberg called for a motion to move the concept forward to FOA development. The motion was made, seconded and passed unanimously.

PUBLIC COMMENTS

There were no public comments.

Dr. Pérez-Stable took the opportunity to inform NACMHD on a recent legislatively mandated program for the multiple chronic disease centers and health disparities. The legislated appropriation in FY2021 provided funding to NIMHD, to work in concert with NIDDK, NHLBI, NCI and NCATS, to establish a comprehensive center initiative aimed at identified chronic diseases and their links to health disparities. NIMHD was encouraged to consider funding mechanisms that would support regional multi-institutional consortiums that produce collaboration, research, and translational science on a wide scale, and $45 million was added to the NIMHD base for this targeted initiative. NIMHD is developing Requests for Applications (RFAs) to support new centers that will include an integration of prevention, intervention, testing, and management strategies for at least two chronic co-occurring conditions and co-occurring risk factors for chronic disease that lead to health disparities. The applications must have a regional focus and include a partnership of at least two institutions. They will require what we have required of all our centers which is to have a community engagement core and an investigator development core with allocated support for pilot grants for ESI or senior post docs level investigators. A P50 mechanism will be used for awards under this initiative.

CLOSING REMARKS

With no further business to attend to, Dr. Pérez-Stable adjourned the meeting at 5:10 p.m.

END NOTE:

REVIEW OF GRANT APPLICATIONS_ CLOSED SESSON

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

Dr. Pérez-Stable called the Closed Session to order at 1:00 pm, February 1, 2021.

Dr. Vollberg led the second level review of grant applications submitted to NIMHD programs. Council Members and Staff were instructed on conflict of interest and confidentiality regulations. Members and Staff absented themselves from the meeting room and discussions for which there was a potential conflict of interest, real or apparent.

The Council considered 437 competing applications requesting an estimated $250,976,255 in requested total costs for year 1 for non-fellowship grants. Funding recommendations for all applications submitted in response to funding opportunity announcements were reviewed. Applications submitted in response to program announcements and special program review announcements were considered by the Council through *En Bloc* voting.

Eliseo J. Pérez Stable, MD Director National Institute on Minority Health and Health Disparities, NIH	Date

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Thomas M. Vollberg, Sr., PhD Designated Federal Official National Institute on Minority Health and Health Disparities, NIH	Date