National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Minutes of Meeting January 25, 2023

Via Videoconference

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH

> DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL INSTITUTES OF HEALTH NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

January 25, 2023

The 232nd meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on January 25, 2023, at 10:00 a.m., via videoconference. The meeting was open to the public from 10:00 a.m. until 2:14 p.m.; it was followed by the closed session for Council business and consideration of grant applications from 2:15 p.m. until adjournment at 3:13 p.m. Dr. Rena D'Souza presided as Chair.

OPEN SESSION

Members Present

Dr. Joel Collier Dr. Frank Ebetino Dr. Raul I. Garcia Dr. Lee A. Niswander Dr. Jacques Nor Dr. Wenyuan Shi Dr. Amy Smith Slep Dr. Axel Visel

National Institute of Dental and Craniofacial Research

Dr. Rena D'Souza, Director Dr. Jennifer Webster-Cyriaque, Deputy Director Dr. Lynn King, Executive Secretary, and Director, Division of Extramural Activities (DEA) Dr. Janice Lee, Clinical Director, DIR Ms. Alisa Machalek, Director, Office of Communications & Health Education Ms. Joy Postell, Acting Chief Diversity Office (detailee) Mr. John Prue, OD, Director, Office of Information Technology (OIT) Dr. Lillian Shum, Director, Division of Extramural Research (DER) Dr. Marian Young, DIR, Deputy Scientific Director Dr. Lorena Baccaglini, DER, Center for Clinical Research (CCR) Dr. Anissa Brown, DEA, Research Training and Career Development Branch (RTCDB) Dr. Preethi Chander, DER, Integrative Biology and Infectious Diseases Branch (IBIDB) Dr. Zhong Chen, DER, IBIDB Dr. Aiwu Cheng, DEA, SRB Ms. Alicia Chou, DER, Translational Genomics Research Branch (TGRB) Dr. Michelle Cortes, DER, IBIDB Mr. Bret Dean, OD, Office of Administrative Management (OAM) Mr. Jimmy Do, OD, Financial Management Branch (FMB) Dr. Alicia Dombrowski, DEA Dr. Olga Epifano, DEA, OD

Dr. Dena Fischer, DER, Director, CCR Dr. Melissa Ghim, DER, IBIDB Mr. Harry Grant, DIR Dr. Margaret Grisius, DER, CCR Mr. Joel Guzman, DER Ms. April Harrison, DEA, GMB Dr. Belinda Hauser, DIR, Office of Training and Education Ms. Jeannine Helm, DER Mr. Gabriel Hidalgo, DEA, GMB Dr. Tanya Hoodbhoy, DER, IBIDB Mr. Tem Ibidapo, OD, OIT Dr. Hiroko Iida, DER, Oral Health Disparities & Inequities Research Program Dr. Leila Khaki, DER, Behavioral and Social Sciences Research Branch (BSSRB) Dr. Wendy Knosp, OD, Office of Science Policy & Analysis (OSPA) Dr. Jamie Kugler, DIR Dr. Shuang Li, DIR (detailee) Dr. Orlando Lopez, DER, IBIDB Ms. Jayne Lura-Brown, DER Ms. Susan Macharia, DEA Dr. Tamara McNealy, DER, IBIDB Ms. Susan Medve, DEA, GMB Dr. Yun Mei, DEA, Scientific Review Branch (SRB) Dr. Amanda Melillo, DER, IBIDB Ms. Amy Mhatre-Owens, OD, Office of Clinical Trials Operations & Management (OCTOM) Ms. Mable Nee, OD, FMB Mr. Paul Newgen, DEA, GMB Ms. Michelle Nguyen, OD, OAM Ms. Anna Nicholson, OD, OCTOM Mr. Thomas O'Farrell, DEA, SRB Dr. Noffisat Oki, DER, Data Science, Computational Biology, & Bioinformatics Program Ms. Lisa Peng, OD, OIT Ms. Debbie Pettitt, DEA, GMB Dr. Elise Rice, DER, BSSRB Mr. Ben Rassuli, OD, OIT Dr. Melissa Riddle, DER, BSSRB Dr. Yasaman Shirazi, DEA, SRB Dr. Ashley Smith, OD, OIT Dr. Kathryn Stein, DER, TGRB Dr. Shoba Thirumangalathu, DEA, RTCDB Dr. Jason Wan, DER, IDIDB Dr. Lu Wang, DER, CCR Dr. Yan Wang, DIR Dr. Hongen Yin, DER, TGBR National Institutes of Health

Dr. Nihal Altan-Bonnet, National Heart, Lung, and Blood Institute (NHLBI)

Guests

Dr. Natalia Chalmers, Centers for Medicare and Medicaid Services (CMS) Dr. Dana Graves, Penn Dental Medicine, University of Pennsylvania Mr. Matthew Miller, Neal R. Gross & Co. Dr. Carla Shoff, CMS

NIH VideoCast of the National Advisory Dental and Craniofacial Research Council January 2023 <u>https://videocast.nih.gov/watch=48550</u>: 793 views as of 3/3/2023

I. WELCOME

Dr. Lynn King, Director of Division of Extramural Activities (DEA) and Advisory Council Executive Secretary, called the open session of the 232nd Advisory Council meeting to order at 10:00 a.m. and briefly reviewed the logistics for the virtual meeting.

II. APPROVAL OF MINUTES FROM PREVIOUS MEETING AND ANNUAL REVIEW OF COUNCIL OPERATING PROCEDURES

Dr. King asked if there were corrections or comments on the minutes of the September 13, 2022, Advisory Council meeting, hearing none the Advisory Council voted unanimously to approve the minutes. The Advisory Council was required to review and approve the Council's operating procedures on an annual basis. Dr. King noted that there were two changes made to the operating procedures since the last Council review. The first conformed the NADCRC's procedures with the updated NIH policy on special council review of research applications. In 2012, NIH issued a policy that required Institute and Center (IC) advisory councils to provide additional review of applications from principal investigators (PIs) who received more than \$1M per year in direct costs. The new NIH policy revised the \$1M threshold to \$2M, by expanding to include both direct and indirect funds. Dr. King stressed that this policy was not intended to represent a hard cap on NIH funding. The second change added cooperative agreements to the Public Health Service Act eligibility language. The Advisory Council voted unanimously to approve the operating procedures.

III. DIRECTOR'S REPORT AND DISCUSSION

Dr. Rena D'Souza, Director, NIDCR, opened by wishing a Happy New Year to the Council members and attendees, thanking them for their efforts in support of the NIDCR community. Dr. D'Souza's written Director's Report for the September 2022 Council meeting was provided to the Council members and is available on the NIDCR website (http://www.nidcr.nih.gov).

Dr. D'Souza began her remarks by reviewing the meeting's agenda. She informed the Council that Dr. Lawrence Tabak, former NIDCR Director and current NIH Principal Deputy Director, continues to serve as the NIH Acting Director until a permanent Director is nominated and confirmed, while Dr. Renee Wegrzyn has been named the first director of the Advanced Research Projects Agency for Health (ARPA-H). Dr. D'Souza then updated the Council on NIH and NIDCR's funding levels for FY 2023. NIH received a \$3B, or 6.5% increase, with slightly over \$1B of those funds earmarked for ARPA-H. NIDCR would receive \$19M more compared to 2022, representing a 3.8% increase. While NIDCR had seen increases in recent years, its purchasing power remained below 2020 levels, primarily because of inflation. Dr. D'Souza then illustrated how NIDCR's budget was distributed, with 78.7% of the funds going towards the Extramural Program, of which 79% was devoted to Research Project Grants (RPGs). Dr. D'Souza acknowledged that there was work to be done to maintain a proper balance between funding RPGs and sufficiently supporting other areas of NIDCR's purview. She expects the share of funds devoted to research training and career development for example, to increase in coming years. In FY22, 44% of NIDCR's extramural budget went towards dental schools, representing 65% of NIH's total funding to dental schools. Dr. D'Souza also discussed NIH's efforts in recent years to increase support for early-stage investigators (ESIs). NIH had set the goal of funding 1,100 ESIs; last year, NIH funded almost 1,600 ESIs.

Dr. D'Souza notified the Advisory Council of several proposed changes to the RPG review process being considered by the NIH following the Center for Scientific Review's deep dive into the NIH peer review process as part of its five-year strategic plan. Emphasis has been placed on facilitating identification of the strongest, most impactful scientific research. The proposed changes are intended to refocus the peer review process on scientific merit, to reduce administrative burden, and to mitigate reputational bias. Dr. D'Souza encouraged Council members to review the proposed changes and submit comments or suggestions by March 10. One of the most significant changes is the reduction from five to three criteria to be scored: importance of the research, rigor, and feasibility. The description of expertise and resources would no longer be scored. Another updated NIH policy in effect is the new Data Management & Sharing Policy, which aims to encourage more robust sharing of scientific data produced by NIH-funded research. NIH strongly believes that data sharing could help accelerate biomedical research discovery, enhance scientific rigor and validation, and foster large-scale integrative approaches to research. NIDCR intends to provide resources to assist researchers to comply with this new policy.

Dr. D'Souza shifted gears to expand on the mission of ARPA-H in greater detail. ARPA-H is modeled on the Defense Advanced Research Projects Agency (DARPA), which was designed to support high-risk, high-reward research and was responsible for numerous technological advancements, such as the internet and the GPS satellite system. The goal of ARPA-H is to lead to similarly game-changing advances in the field of biomedical research though its four initial mission areas: health science futures, scalable solutions, proactive health, and resilient systems.

Dr. D'Souza and the NIDCR leadership team had been busy visiting dental schools and delivering presentations at stakeholder gatherings across the country and virtually, working to develop new partnerships with the community and other NIH ICs. Internally, Dr. Sharon Jackson has been recently named the new NIDCR Deputy Clinical Director; Joy Postell has been appointed Acting Chief Diversity Officer, and Dr. Shoba Thirumangalathu has been promoted to Program Officer in the Division of Extramural Activities. Dr. D'Souza also took a moment to congratulate Dr. Jennifer Webster-Cyriaque, NIDCR Deputy Director, on several recent career achievements, including her election to the National Academy of Medicine and receiving the Distinguished Scientist Award in Oral Medicine & Pathology Research from the International Association for Dental Research (IADR).

Dr. D'Souza then briefly touched on NIDCR's 2023 Requests for Applications (RFAs), concepts approved by the Council over the last year, including the Practice-Based Research Integrating Multidisciplinary Experiences in Dental Schools (PRIMED) Funding Opportunity Announcement (FOA), and Notices of Special Interest (NOSIs). Dr. D'Souza also highlighted NIDCR's partnership with the American Association for Dental, Oral, and Craniofacial Research (AADOCR) on the MIND the Future program. Sixty percent of the first cohort from the program and 50% of the second cohort went on to achieve subsequent NIH funding. Dr. D'Souza presented some recent research highlights from NIDCR-funded studies. One study from McLean et al. looked at site specificity of bacteria in the oral microbiome, which could eventually lead to more targeted therapeutic interventions. Another paper from Heaton et al. presented results from this study could help inform ways to make the dental environment more welcoming for minority or historically underserved populations.

Dr. D'Souza then sketched out NIDCR's plans for the commemoration of its 75th anniversary this year. Rather than one big celebration, NIDCR will be holding a series of special events and symposia throughout the year, including sessions at stakeholder conferences and annual meetings. The flagship event will be the NIDCR Trainee Symposium, to be held October 10-11, 2023, and will include a keynote address by Nobel Laureate Dr. Ardem Patapoutian, a former NIDCR grantee. Finally, Dr. D'Souza announced the retirement of Dr. Tony Fauci from government service. She emphasized his incredible career of public service and his impact on the NIH and the scientific community.

Discussion

Dr. Axel Visel raised the topic of increased ESI support and noted that eventually ESIs would no longer be early-stage and would need to seek funding from a finite pool of resources, most of which was devoted to ESIs. Dr. D'Souza acknowledged that a risk-reward analysis came into play and said that ICs took different approaches in how much they wanted to reshape their portfolios. NIDCR looked at the needs and gaps in the dental research community and concluded that this was a good approach to kick-start or reinvigorate certain fields, for example, data science. It was a balancing act, and NIDCR would look to Council for continued input.

Dr. Jacques Nor asked what problem NIH was attempting to address with the proposed new [Research Project Grant] RPG review criteria, and what the timeline was for the implementation of the new policy. Dr. D'Souza said the goal of the policy was to focus the review to the science itself and limit perceived bias towards prominent or well-known institutions. Regarding the timeline, NIH is still soliciting public comment and no implementation schedule has been determined.

IV. DEPUTY DIRECTOR'S REPORT AND DISCUSSION

Dr. D'Souza invited Dr. Webster-Cyriaque, NIDCR Deputy Director, to present her report on diversity, equity, inclusion, accessibility, and belonging (DEIAB) activities at NIDCR and NIH. Dr. Webster-Cyriaque reminded the Council that in 2021, in the wake of the murder of George Floyd and subsequent nationwide social justice protests, then-NIH Director Francis Collins had issued a statement acknowledging NIH's insufficient efforts to improve diversity and pledging to begin earnest efforts to eliminate structural racism in the biomedical research enterprise. A series of listening sessions raised concerns in the areas of grants, career pathways, the state of workforce, health disparities and minority health research, and community partnerships. Dr. Webster-Cyriaque briefly described NIH's strategic response to address these concerns and highlighted a program that had emerged from these efforts; the Community Partnership to Advance Science for Society (ComPASS), which put the community at the forefront of health equity research. Two ComPASS FOAs had been issued so far for the planning and implementation phases. At the NIH level, one major outgrowth of NIH's DEIA efforts had been the UNITE Committee, a collection of five commutes with coordinated objectives in the arena of racial and ethnic equity in the NIH community.

Dr. Webster-Cyriaque then discussed efforts for promoting equity in the internal NIH and NIDCR workforce. At the NIH level, an Anti-Racism Steering Committee has been established and an initiative was underway to strengthen outreach about NIH job opportunities to as broad a range of applicants as possible. Other activities include the addition of IC-level racial and ethnic equity plans (REEPs), publication of demographic data on the NIH workforce, a review and reform of NIH achievement awards, and the creation of new career development programs. Dr. Webster-Cyriaque described NIDCR's decision to use its REEP as a foundation in the creation of a more comprehensive plan to build a sense of belonging at the Institute; meaning that everyone felt valued and comfortable bringing their authentic selves to work. The REEP plan addresses the acceptance of differences, increased transparency, improved access to NIDCR leadership, encouraging career development, and improved communication both internally and externally. To achieve these goals, NIDCR instituted monthly all-hands meetings, developed new training programs, and added new ways to meet with leadership, among other activities. NIDCR now has a Building Belonging at NIDCR website that includes related information and material. Dr. Webster-Cyriaque highlighted another example of NIDCR's Building Belonging activities, the Build, Relate, Inspire, Develop, Grow, Empower (BRIDGE) career development program. The program provides tools, skills, mentorship, and networking opportunities to help participants grow professionally and achieve their career goals. BRIDGE is open to non-supervisory staff and the initial cohort consists of 10-15 individuals.

Dr. Webster-Cyriaque moved on to talk about NIH's efforts to promote equity in the extramural community. Initiatives to support and retain a diverse and talented workforce include the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program and the Science Education Partnership Awards (SEPAs); NIDCR participates in both programs. NIH also sought comments and suggestions for a planned DEIA institutional excellence prize that would support institutions to conduct organizational climate and needs assessments. The extramural framework is centered around evaluation, stakeholder engagement, and timely actions responding to reports of harassment and/or discrimination. Along with the <u>AADOCR MIND the Future</u> program, NIDCR was also working with the Foundation for the NIH (FNIH) to build public-private partnerships promoting oral health workforce diversity. Dr. Webster-Cyriaque highlighted the Galvanizing Health Equity Through Novel and Diverse Educational Resources (GENDER) research education RFA. The goal of this RFA is to support educational activities that complemented and/or enhanced the training of a diverse workforce to meet the nation's

biomedical, behavioral, and clinical research needs. Courses and curricula designed under this RFA should help advance health-related research on sex as a biological variable and gender influences on health. NIDCR is committed to building career development programs and partnerships across the early career trajectory, from high school to postgraduate programs. The third DEIA-related topic Dr. Webster-Cyriaque briefed the Council on are the NIH and NIDCR efforts to promote health disparities and minority health research. It is known that structural racism and other social 1 determinants could create health inequities. To better understand and address these factors, NIH has dramatically increased funding in minority health and health disparities research in recent years, from 18 funding opportunity announcements (FOAs) in 2018 to 115 in 2022. Dr. Webster-Cyriaque noted that NIDCR has been at the forefront of this field, having established Oral Health Disparity Centers in the 1990s.

Dr. Webster-Cyriaque described some of the research topics of the 2022 FOAs, which cut across many disease areas and research approaches. These efforts were vital given the wide prevalence of oral diseases and conditions in the global population, and the proven disparities among racial and ethnic and other populations in the United States. NIDCR developed two research programs under the auspices of the All of Us Research Program that examine health disparities among older adults and assess electronic health record accuracy. Another NIDCR activity is hosting a two-part Oral Health Disparities Think Tank, which is underway and led by Dr. Hiroki Iida, the NIDCR Director of the Oral Health Disparities & Inequities Research Program. To develop a larger social determinants of health (SDOH) data set for secondary data analysis, NIDCR is partnering with ResDAC to access [Centers for Medicare & Medicaid Services] CMS data, as well as the Wisconsin Collaborative and OCHIN, to access their large patient data pools. Finally, NIH is working to improve the accuracy and transparency of racial and ethnic equity data via a request for information issued by the NIH UNITE Initiative, which received over 1,000 responses. UNITE also held a series of 14 listening sessions to gather more feedback on concerns from the community. NIH launched a public-facing Data Dashboard, and Ending Structural Racism website and internal NIH site for DEIA-related information.

Discussion

Dr. Nor commented that d it is important to recruit potential oral health researchers early and asked Dr. Webster-Cyriaque to expand on NIDCR's outreach efforts to high schools and colleges. Dr. Webster-Cyriaque provided additional information about how NIDCR has worked to include DOC research into scientific career groups, such as <u>Futurum Careers</u>, which focuses on introducing high school and early college students to a broad range of research careers, and noted that NIDCR and the dental research community need to work to advance inclusion among the many STEM programs that have arisen around the country. NIDCR strives to be present at large gatherings of students interested in careers in science, such as the Annual Biomedical Research Conference for Minoritized Scientists (ABRCMS). Dr. D'Souza stressed the importance of working with NIDCR's stakeholder community in these efforts. Council members also encouraged efforts to increase research capacity at Historically Black Colleges & Universities' dental schools and research opportunities for their students.

V. ENTERIC VIRUSES REPLICATE IN SALIVARY GLANDS AND TRANSMIT THROUGH SALIVA

Dr. King introduced Dr. Nihal Altan-Bonnet, a Senior Investigator, Laboratory of Host-Pathogen Dynamics, National Heart, Lung, and Blood Institute (NHLBI), to deliver a presentation of her research on the robust replication and transmission of enteric viruses in saliva. Dr. Altan-Bonnet began with a brief overview of her lab, which is multidisciplinary and focuses on the mechanisms of viral infection. Enteric viruses are RNA viruses, such as rotavirus, norovirus, and astrovirus. Enteric viruses can infect both humans and animals, together infecting approximately 1.5 billion people worldwide each year; small children and the elderly are particularly vulnerable. The viruses also had a significant economic impact due to outbreaks among livestock. It had been generally assumed that these viruses replicated primarily in the intestine and were transmitted via the fecal-oral route. Dr. Altan-Bonnet has been studying enteric viruses for many years and recently began using animal models to study pathogenesis and transmission. The common model to study viral transmission in mice is the suckling pup model, which Dr. Altan-Bonnet's lab uses to look at norovirus and rotavirus. The team found a correlation between viral clearance and an increase in intestinal secretory IgA loads. Secretory IgA is an important antibody, produced abundantly in saliva, but could not be produced yet by mice pups. The research team found that the sIgA was being received through the mother's milk, and the level of sIgA being produced in the milk increased with viral infection of the pups.

Dr. Altan-Bonnet's lab then worked to discover the mechanism through which the mother sensed her pups' infection. They found that the mother's mammary gland became infected with the virus through suckling. This was confirmed when they showed that oral inoculation of the mother did not lead to an increase of milk sIgA. The team then hypothesized that saliva might be issuing some signal during suckling, either via the virus itself or some other means. Dr. Altan-Bonnet noted that similar theories of transmission and response via human breastfeeding had been posited but remained controversial and lacked direct evidence. However, there had been studies showing increased pressure and dilation of milk ducts and corresponding reduction of pressure and backward flow as breastfeeding ends, suggesting the possibility of salivary transmission from the baby. Dr. Altan-Bonnet's group looked at the suckling pup saliva and confirmed the presence of the viruses in the saliva, and that a combination of milk and saliva could efficiently spread infection between infants and mothers. Examination of mouse salivary glands found robust and persistent replication of enteric viruses, and that norovirus could persistently shed in mouse saliva. The team found that norovirus tends to replicate in the acinar epithelial cells and rotavirus in the ductal epithelial cells. Since enteric viruses had been difficult to grow ex vivo, Dr. Altan-Bonnet's lab attempted to use salivary cells and organoids to grow norovirus and rotavirus ex vivo, which they successfully achieved.

The next step in this research was to look at enteric virus transmission among humans, and early findings confirmed the presence of norovirus in the salivary glands collected from autopsies of humans who died from enteric disease. Another open question is whether saliva promoted viral persistence in the gut. Preliminary results from mouse studies indicate that intestinal infections clear faster when salivary glands are absent. Dr. Altan-Bonnet's team is also investigating whether viruses could be shed asymptomatically via saliva. She noted that these

findings about saliva could one day lead to saliva-based diagnostics, which would be less unpleasant or laborious than the current fecal testing.

Discussion

Dr. Wenyuan Shi expressed excitement about this research in light of advances in salivabased diagnostics that have occurred as a result of the COVID-19 pandemic response. Dr. Webster-Cyriaque asked Dr. Altan-Bonnet if her team looked at oral mucosal immune response and susceptibility based on existing immunity. Dr. Altan-Bonnet said her lab is doing immune profiling of salivary glands. Dr. Webster-Cyriaque suggested exploring innate immune response and antimicrobial peptides as additional factors. Special populations worth considering as well include people living with HIV and people with Sjogren's syndrome. In response to questions from Dr. Joel Collier, Dr. Altan-Bonnet said her lab is looking to see if similar responses occur with other antibodies, as well as the potential for vaccine applications in the future.

VI. ORAL HEALTH: AN EVIDENCE- AND DATA-DRIVEN APPROACH TO ACHIEVE BETTER HEALTH, EQUITY, AND FISCAL RESPONSIBILITY

Dr. King next invited Dr. Natalia Chalmers, Chief Medical Officer at the Centers for Medicare & Medicaid Services (CMS) to present. Per the last enrollment numbers, Medicaid and Children's Health Insurance Program (CHIP) has over 90 million enrollees and Medicare has 65 million enrollees. CMS' vision statement is to "serve the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes." Dr. Chalmers briefly touched on CMS' strategic pillars, which are advancing equity, expanding access, engaging partners, driving innovation, protecting programs, and fostering excellence. Dr. Chalmers noted that advancing equity was intentionally listed first. CMS defines health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes." CMS has launched a Framework for Health Equity with five priority areas, including expanding data collection and reporting, examining the causes of disparities within CMS program, building capacity of healthcare organizations, improving language access and health literacy, and increasing access to care and coverage. Dr. Chalmers highlighted CMS was ensuring that its health equity efforts cut across the multitude of programs and types of coverage CMS provided. Dr. Chalmers then presented her vision for oral health CMS, which is to "improve beneficiaries' health by integrating oral health and transforming the healthcare system to advance health equity, expand coverage, and improve health outcomes." Dr. Chalmers emphasized the role of stakeholder engagement throughout this process.

This effort is extremely important given the deep disparities that existed in oral healthcare in America, with severe fiscal implications on top of the health consequences. Untreated minor oral health problems ultimately become serious health problems, and the burden often becomes shifted to emergency departments (EDs) and the broader care community, with all the added costs associated. Costs associated with treating severe dental issues in the ED could rise to tens of thousands of dollars. The health information technology divide is another major hurdle that needs to be overcome as it obstructs efforts to integrate and coordinate care. While the gap in care between children living above and below the federal poverty line has closed in recent years, the gap persists, and has not closed at all in working age adults and has widened among the elderly. Dr. Chalmers noted that wide geographical variation existed even among the child population which has seen improvements; in some states only 12% of children receive preventive dental services, but in others 60% did. One of the key factors in children receiving dental care is whether their parents receive dental care. Another significant gap exists between urban and rural populations; racial disparities also tend to be more pronounced among rural populations. Large racial disparities also persist in the elderly population.

Dr. Chalmers shifted focus to the financial aspect of oral health. Dental care represents approximately 4% of total healthcare expenditures. One major hurdle overcome was the large out-of-pocket costs for dental care compared to other services. CMS-related spending on dental services (including out-of-pocket costs) rose approximately 16% in 2021, to \$161.8B, after a decline of 3% in 2020. Despite this large amount of money, spending on oral health remained relatively low when compared to other disease or anatomical groups. Dr. Chalmers then presented data on the percentage of people seeking dental visits and medical visits, or neither, in a given year. In 2018, 37.1% of people had both a dental and medical visits, but 19.8%, or 64.7 million people, had neither. Interestingly, 28.2 million people had a dental visit, but no medical visit. This cohort of people could be leveraged by the dental community as part of its efforts to improve whole person health. Dr. Chalmers pointed to inflammation and maternal health as avenues to connect oral health conditions with medical conditions as a whole.

Circling back to the impact of ED visits for dental care, Dr. Chalmers presented a study on its consequences, showing that dental pain was one of the top conditions for opioid prescriptions, which contributes to the ongoing opioid crisis. The oral health community also grapples with the aftershocks of the COVID-19 pandemic, which has resulted in millions of people foregoing dental care for a year or more. CMS has also seen large jumps in enrollment, and the provider community will likely face the challenge of more patients along with postpandemic burnout and workforce shortages.

Discussion

Dr. Garcia asked Dr. Chalmers for her thoughts on how NIDCR could assist in the research response to the issues she raised in her presentation. Dr. Chalmers said collaboration would be vital, and NIDCR could be the leader on the research front. One example could be developing brochures on maternal and oral health that CMS could disseminate to the states. NIDCR's input would also be crucial in the development of CMS guidance. She also underscored the importance of eliminating the health IT divide. Dr. D'Souza raised the possibility of partnering with the National Institute on Drug Abuse (NIDA) to develop a grant program on the topic of ED visits for dental care and opioid prescription.

VII. DATA SCIENCE STRATEGY WORKING GROUP UPDATE

Dr. King invited Council member Dr. Visel to provide an update on recent activities of NADCRC's Data Science Strategy Working Group, which is co-chaired by Dr. Visel and Dr.

Amit Acharya of Advocate Aurora Research Institute. Dr. Visel reminded the Council that the Data Science Strategy Working Group was stood up to develop an NIDCR data science strategy to help achieve success in NIDCR's strategic priority areas. Specific areas of interest are evolving the DOC data ecosystem, application of data science methods, and strengthening research in health disparities. The work group is composed of a diverse group of experts and plan to provide short-term and long-term recommendations. The work group has met regularly since September 2022 and has been conducting an environmental scan, mapping the DOC data ecosystem, and developing a Request for Information (RFI) to help inform a proposed data science strategy. Dr. Visel presented the preliminary results of the environmental scan, which found a great deal of heterogeneity and complexity, with over 30 different databases, resources, and repositories regularly used by the DOC community. Additionally, there are a number of general repositories that contain DOC data. The working group also found significant variation in compliance with FAIR (Findable, Accessible, Interoperable, and Reusable) principles and use of common data standards.

The working group identified a lack of connectivity between data systems and data sets without a corresponding data system to host them. As Dr. D'Souza mentioned in her Director's Report, the NIH has a new Data Sharing and Management Policy that strongly encourages the sharing of research data, but the work group found hurdles vis-à-vis building the attendant data repositories and assisting researchers in ensuring FAIR compliance. The pending RFI is intended to solicit feedback from stakeholders on their interactions with data and their thoughts on the needs and gaps in areas related to data science. The group hopes to receive comments that address data science across the translational spectrum and is working to encourage a robust response... The results of the RFI would ultimately inform the working group's final recommendations to NIDCR.

Discussion

Dr. D'Souza asked Dr. Visel if the work group is looking at data systems used by the pharmaceutical industry and the role professional organizations could play helping to support big data initiatives. Dr. Visel said it is difficult to get a full picture of industry systems because they are often internal or closed; adding that it might not be possible to collect a truly comprehensive list of extant data systems. Dr. Nor encouraged the working group to look at the Journal of Dental Research's recent special issue on Data-Driven Analytics for Dental, Oral, and Craniofacial Health Care. Dr. Lillian Shum, Director, DER, asked Dr. Visel if the working group has explored whether the issues they identified apply to other research fields or are DOC-specific, as they might shape the group's final recommendations. Dr. Visel said they have not attempted a comparison to other fields to date, but thinks it is likely that some of them are trans-NIH in nature, while others are more DOC-specific.

VIII. ORAL HEALTH RESEARCH WORKFORCE WORKING GROUP UPDATE

Dr. King invited Dr. Dana Graves, Penn Dental Medicine and Oral Health Research Workforce Working Group Chair, to deliver the update for the work group. The charge of the Oral Health Research Workforce Working Group is to develop recommendations to NIDCR on evidence-based approaches to "sustainably recruit, train, and retain researchers who have knowledge to build a diverse DOC scientist and clinician-scientist research workforce." The working group has developed and issued an RFI to solicit feedback from the community and would be reviewing the responses soon. The working group has been seeking feedback on NIDCR's current research training opportunities and has held listening sessions with relevant stakeholders. These sessions included past and current NIDCR trainees, NIDCR and other training program directors, and leaders in the oral health field. Dr. Graves provided some of the findings from the listening sessions. Participants felt NIDCR training programs did not provide sufficient support and infrastructure needed to support trainees, highlighting the importance of supplementary assistance from non-governmental organizations. Trainees felt that dental school research culture needed improvement and lacked sufficient mentoring, particularly in the post-trainee phase, as well as a lack of networking opportunities at the local, regional, and national levels. These gaps were often exacerbated for individuals from underrepresented groups. Stakeholders also expressed the need for more diversity in early outreach programs and for expanded awareness of non-academic research career opportunities. In addition, there is a needto mitigate the uncertainty of establishing a successful research career, among other comments.

The working group's assessment of the NIDCR research training grant portfolio identified the need for a more granular examination of factors associated with training program success and individual trainee career success. The working group will be assessing means of promoting a more supportive research environment, enhancing successful mentoring, improving the quality of training, and strengthening diversity among trainees and early-career researchers. They will also work to identify factors associated with successful career progression and assess the potential for partnerships with professional associations, dental schools, and industry. The work group hopes to present its recommendations to the Council at its September 2023 meeting.

Discussion

Dr. D'Souza said she would like to hear the working group's thoughts on the feasibility and usefulness of developing a universal curriculum for DDS/PhD dual degree trainees. Dr. Graves said that program directors usually stress the importance of local control when the idea of a universal curriculum is broached, but trainees are often more critical of the current state of affairs. Dr. Hal Ebetino asked Dr. Graves to expand on the role of pharma when it came to strengthening the research workforce. Dr. Graves replied that industry could offer internships and externships, regulatory guidance, and advice on entrepreneurship. The working group has reached out to major companies and will be meeting with representatives from their oral health programs to get their input. Dr. Nor raised the topic of the growing gap between researchintensive and non-research-intensive dental schools and the role of the Commission on Dental Accreditation.

IX. CONCEPT CLEARANCE

Dr. King stated that NIDCR is required to present the purpose, scope, and objectives of proposed concepts for research initiatives to the Council in a public forum for the Council's review, discussion, and approval, and for public comment. Concepts approved by the Council are published on the NIDCR website (<u>future research initiatives</u>). NIDCR staff presented one concept, and designated Council members led the discussion, as summarized below.

Reissuance: NIDCR Prospective Observational or Biomarker Validation Study Cooperation Agreement

Dr. Lorena Baccaglini, Program Officer, NIDCR Center for Clinical Research, presented the concept. This initiative was designed to support research-intensive prospective observational and biomarker validation studies of up to five years in duration. Since 2017, this funding opportunity has received 29 new applications, 12 of which were successful, with another 6 are still pending. Of the 12 approved awards, 8 were prospective observational studies, 3 were biomarker validation studies, and 1 was both. Dr. Baccaglini discussed some of the approaches the PIs were taking and the types of data and specimens they were using, including clinical data, biospecimens, and imaging. Research under this funding opportunity has led to 37 publications, thus far. Dr. Baccaglini stressed that awardees were strongly encouraged to follow NIDCR's data sharing guidelines and follow the FAIR and TRUST principles.

The Council's lead discussants for the concept were Drs. Axel Visel and Raul Garcia. Dr. Visel expressed his support for the reissuance. He noted that well-validated biomarkers are critical for improving diagnosis and treatment. This program had been successful and holds continued promise going forward. Dr. Garcia concurred with Dr. Visel's remarks.

The Council unanimously approved the concept.

CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., and Section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014).

X. REVIEW OF APPLICATIONS

Total	Requested	Approved
Number	755	465
Dollars	\$ 284,049,213	\$175,613,360

XI. ADJOURNMENT

CERTIFICATION

I hereby certify that the foregoing minutes are accurate and complete.

/Rena D'Souza/

/Lynn King/

Dr. Rena D'Souza Chairperson National Advisory Dental and Craniofacial Research Council Dr. Lynn King Executive Secretary National Advisory Dental and Craniofacial Research Council