National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Minutes of Meeting January 24, 2024

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 24, 2024

The 235th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on January 24, 2024, at 10:09 a.m., via videoconference. The meeting was open to the public from 10:01 a.m. until 2:10 p.m.; it was followed by the closed session for Council business and consideration of grant applications from 2:20 p.m. until adjournment at 3:54 p.m. Dr. Rena D'Souza presided as Chair.

OPEN SESSION

Members Present

Dr. Joel Collier

Dr. Terry Dickinson

Dr. Frank Ebetino

Dr. Paul Krebsbach

Dr. Jose Moron-Concepcion

Dr. Jacques Nor

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. Indu Ambudkar, Acting Scientific Director, Division of Intramural Research (DIR)

Mr. Aubrey Callwood, Chief Information Officer; Director, Office of Information Technology (OIT)

Dr. John (Jay) Chiorini, Acting Associate Scientific Director, DIR

Dr. Sharon Jackson, Deputy Clinical Director, DIR

Dr. Janice Lee, Clinical Director, DIR

Ms. Joy Postell, Chief Diversity Officer, Office of the Director (OD)

Dr. Lillian Shum, Director, Division of Extramural Research (DER)

Dr. Shaun Abrams, DIR

Dr. Azeez Alade, DIR

Ms. Alexandria Alfarano, DER, Center for Clinical Research (CCR)

Mr. Dandre Amos, OD, Office of Clinical Trials Operations & Management (OCTOM)

- Dr. Marit Aure, DIR
- Dr. Lorena Baccaglini, DER, CCR
- Dr. Alison Boyce, DIR
- Dr. Anissa Brown, DER, Research Training & Career Development Branch (RTCDB)
- Dr. Christopher Brown, DEA, Scientific Review Branch (SRB)
- Dr. Christopher Campbell, DEA, SRB
- Dr. Preethi Chander, DER, Integrative Biology & Infectious Diseases Branch (IBIDB)
- Dr. Jingshan Chen, DEA, SRB
- Ms. Tiffany Chen, OD, Office of Communications & Health Education (OCHE)
- Dr. Zhong Chen, DER, IBIDB
- Dr. Aiwu Cheng, DEA, SRB
- Ms. Jennifer Chi, OD, OCTOM
- Ms. Alicia Chou, DER, Translational Genomics Research Branch (TGRB)
- Mr. Kevin Chu, OD, OIT
- Dr. Michelle Cortes, DER, IBIDB
- Mr. Brett Dean, OD Financial Management Branch (FMB)
- Mr. Jimmy Do, OD, FMB
- Dr. Olga Epifano, DEA, OD
- Dr. Catherine Evans, OD, OCHE
- Dr. Luis Fernandez de Castro, DIR, Office of the Scientific Director (OSD)
- Dr. Dena Fischer, DER, CCR
- Dr. Melissa Ghim, DER, IBIDB
- Dr. Margaret Grisius, DER, CCR
- Mr. Joel Guzman, DER, OD
- Ms. April Harrison, DEA, GMB
- Dr. Belinda Hauser, DIR, OSD
- Ms. Jessica Henry, OD, OSPA
- Mr. Gabriel Hidalgo, DEA, GMB
- Ms. Yu-Ling Huang, OD, OSPA
- Dr. Timothy Iafolla, OD, OSPA
- Dr. Hiroko Iida, DER, CCR
- Dr. Tomoko Ikeuchi, DIR, OSD
- Dr. Dara Kessler, OD
- Dr. Leila Khaki, DER, BSSRB
- Dr. Wendy Knosp, OD, OSPA
- Dr. Jamie Kugler, DIR, OSD
- Ms. Payal Rajender Kumar, OD
- Mr. Robert Kuska, OD, OCHE
- Dr. Bikash Lamichhane, DIR, OD
- Dr. Shuang Li, DER, OD,
- Dr. Jiwon Lim, DIR
- Dr. Orlando Lopez, DER, IBIDB
- Mr. William Martin, OD, Administrative Management Branch (AMB)
- Dr. Tamara McNealy, DER, IBIDB
- Ms. Susan Medve, DEA, GMB
- Dr. Yun Mei, DEA, SRB

- Dr. Amanda Melillo, DER, IBIDB
- Dr. Eva Mezey, DIR
- Ms. Amy Mhatre-Owens, OD, OCTOM
- Ms. Mable Nee, OD, FMB
- Ms. Suzanne New, OD
- Mr. Paul Newgen, DEA, GMB
- Ms. Michelle Nguyen, OD, Office of Administrative Management (OAM)
- Ms. Anna Nicholson, OD, OCTOM
- Dr. Thomas O'Farrell, DEA, SRB
- Dr. Noffisat Oki, DER, TGRB
- Dr. Robert Palmer, DIR, OSD
- Ms. Marshelle Parker, DEA, GMB
- Dr. Iriana Pena Manrique, OD
- Ms. Lisa Peng, OD, OIT
- Dr. Fatemeh M. Pour, OD
- Mr. John Prue, OD, OIT
- Mr. Ben Rassuli, OD, OIT
- Ms. Diana Rutberg, OD
- Dr. Zubaida Saifudeen, DER, TGRB
- Dr. Rachel Sare, DER, RTCDB
- Dr. Rachel Scheinert, OD, OSPA
- Dr. Yasaman Shirazi, DEA, SRB
- Dr. Maruska Silveira, OD, OSPA
- Ms. Shirley Simpson, DIR
- Dr. Ashley Smith, DEA, OD
- Dr. Shoba Thirumangalathu, DEA, RTCDB
- Mr. Shawn Thomas, OD, AMB
- Dr. Vidhya Venkateswaran, DER
- Dr. Scott Verbridge, DER, IBIDB
- Dr. Jason Wan, DER, IBIDB
- Dr. Lu Wang, DER, TGRB
- Dr. Blake Warner, DIR
- Ms. Stacey Warr, OD, OIT
- Ms. Denniese Wright, OD

National Institutes of Health

- Dr. Rick Woychik, Director, National Institute of Environmental Health Sciences (NIEHS)
- Dr. Heather Maldonado, NIEHS
- Dr. Joe Nguyen, National Cancer Institute (NCI)

Guests

- Dr. Amit Acharya, President, Advocate Aurora Research Institute
- Dr. Alonso Carrasco-Labra, Penn Dental Medicine
- Dr. Lucia Cevidanes, University of Michigan School of Dentistry
- Dr. Richard D'Souza
- Dr. Dana Graves, Penn Dental Medicine; Co-Chair, Council Oral Health Research Workforce Working Group
- Dr. Carl Kesselman, University of Southern California (USC) Viterbi School of Engineering
- Dr. Juan Prieto, University of North Carolina (UNC) School of Medicine
- Dr. Robert Schuler, USC Information Sciences Institute
- Ms. Cristina Williams, USC Information Sciences Institute
- Mr. Matthew Miller, Neal R. Gross & Co.

NIH Videocast https://videocast.nih.gov/watch=54023

Total Views (as of 3/15/2024) 233 (160 live, 73 On-demand)

I. WELCOME

Dr. Lynn King, Director of Division of Extramural Activities (DEA) and Advisory Council Executive Secretary, called the open session of the 235th Advisory Council meeting to order at 10:01 a.m. Members of the public may submit written comments and questions until February 8th at NIDCRCouncilMail@nider.nih.gov.

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

Dr. King asked Advisory Council members if there were corrections or comments on the minutes of the September 13th, 2023, Advisory Council meeting. There were no comments and the Council voted unanimously to approve the minutes.

Dr. King reminded the Council that it is required to review and approve the Council operating procedures on an annual basis. The Institute may propose additions and revisions to the procedures during this annual review period. This year, NIDCR has recommended a revision to the NIH Special Council Review (SCR) policy. This policy requires special consideration and/or additional review of NIDCR grant and cooperative agreement applications from principal investigators (PIs) who receive more than \$2 million in total direct and indirect costs per year from active NIH awards. In order to manage its resources more effectively, NIDCR proposes to revise its policy to include all pending NIH applications to the \$2 million SCR eligibility and to include multi-PI grants when any one PI exceeds the \$2 million threshold. The Advisory Council voted unanimously to approve the updated Council operating procedures.

III. DIRECTOR'S REPORT, NIDCR

Dr. Rena D'Souza, Director, NIDCR, welcomed Council members and guests to the virtual Council meeting. She remarked on how invigorating it was to see everyone in-person at the September meeting, and she looks forward to leveraging future gatherings, both in-person and virtual, to increase Council engagement with NIDCR staff and stakeholders. Dr. D'Souza reviewed the day's agenda and the purpose of her report, which is to disseminate knowledge about NIDCR's research mission, both intramurally and extramurally. Dr. D'Souza's written Director's Report was provided to the Council members and is available on the NIDCR website (http://www.nidcr.nih.gov).

Dr. D'Souza noted the recent passing of Dr. Harold Slavkin, the 6th Director of NIDCR from 1995-2000. During Dr. Slavkin's tenure, the Institute broadened its portfolio to include craniofacial research, at which point the Institute was changed from the National Institute of Dental Research to its current name. Dr. Slavkin also spearheaded efforts to recruit a diverse research workforce and develop a strategic plan to reduce health disparities, among achievements as Director. Dr. D'Souza shared some of her personal memories of Dr. Slavkin and led the Council in a moment of silence in memory of Dr. Slavkin's life. Dr. D'Souza noted that Dr. Slavkin's career will be honored at events throughout the year.

Dr. D'Souza updated the Council on recent leadership changes at NIH. In November, the Senate confirmed Dr. Monica Bertagnolli as the new Director of the National Institutes of Health, following a short tenure as Director of the National Cancer Institute (NCI) and a highly successful career as a clinician-scientist. Dr. D'Souza noted that Dr. Bertagnolli has expressed interest in delivering remarks to the NIDCR Council at its May in-person meeting. Dr. Larry Tabak, former NIDCR Director, returned to his role as NIH Principal Deputy Director after ably serving as interim NIH Director following Dr. Francis Collins' retirement. As Dr. D'Souza announced at the previous meeting, Dr. Jeanne Marrazzo is the new Director of the National Institute of Allergy and Infectious Diseases (NIAID). Dr. D'Souza and Dr. Webster-Cyriaque plan to meet with Dr. Marrazzo in the near future to discuss partnership opportunities between the two ICs. Dr. W. Kimryn Rathnell was appointed to succeed Dr. Bertagnolli as NCI Director. Ms. Kate Klimczak was named Associate Director for Legislative Policy & Analysis, the NIH's primary liaison with Congress. In her short tenure, Ms. Klimczak established a lunch-and-learn series that brings together NIH representatives with congressional staffers.

In November, President Biden established the White House Initiative on Women's Health Research within the Office of the First Lady to advance women's health research in the U.S. The Initiative will be led by Dr. Carolyn Mazure. Among its key actions will be to set research priorities, improve coordination, develop data-related policy recommendations, address health disparities and inequities, and to strengthen and diversify the research workforce. The NIH Office of Research on Women's Health (ORWH) will play a key role in the Initiative and serve as its coordinating office. NIDCR plans to leverage its existing collaborations with ORWH to participate in the Initiative as it progresses.

Dr. D'Souza updated the Council on the progress of the NIH All of Us Research Program. As of 2023, the program consented over 750,000 individuals over its five-year existence and has collected over 530,000 participant bio-samples. She encouraged Council members and attendees to take advantage of opportunities to use the All of Us database in their research activities and to reach

out to NIDCR staff for more information. She noted that the program is working to increase the collection of saliva samples. Twenty-seven NIH IC Directors have co-authored an article on the opportunities provided by the All of Us Research Program to enhance biomedical research diversity, which has been accepted for publication in an upcoming article of *Nature Medicine*.

Dr. D'Souza briefed the Council on recent NIDCR personnel news. At the executive level, Mr. Aubrey Callwood is the new Director of the Office of Information Technology (OIT) and Dr. Rachel Scheinert was appointed Director of the Office of Science Policy and Analysis (OSPA). At the program level, Dr. Scott Verbridge joined NIDCR as the new Program Director of the Tissue Engineering and Regenerative Medicine Program and Dr. Bill Elwood serves as Acting Chief of the Behavioral and Social Sciences Research Branch within the Division of Extramural Research (DER). Dr. D'Souza announced that NIDCR has expanded its Dental Public Health Research program and has engaged other ICs to identify interdisciplinary projects that can benefit from an oral health component. Dr. D'Souza thanked Dr. Matthew Hoffman for his service to the Institute as he winds down his lab prior to his departure for his home country of New Zealand. Dr. Hoffman previously served as NIDCR Scientific Director (SD) for five years. Dr. D'Souza particularly lauded Dr. Hoffman for his focus on mentoring and his work to restructure the NIDCR intramural program during his tenure as SD. Dr. Indu Ambudkar serves as Acting SD as the search continues for Dr. Hoffman's permanent successor, and Dr. John (Jay) Chiorini fills the role of Acting Deputy SD.

Dr. D'Souza briefly noted NIDCR leadership's outreach activities among stakeholder groups and other events in recent months, including NIDCR's 75th anniversary activities. Dr. D'Souza said NIDCR is willing to meet with academic institutions or other groups who express interest. In her comments since coming onboard as NIH Director, Dr. Bertagnolli has said she does not believe in the "big" and "small" Institute terminology and that she hopes to encourage greater integration among NIH ICs. One of her guiding principles is that scientific discovery is not the end of NIH's work; rather, NIH's work is finished "when all people are living long and healthy lives." She also believes in the principle that patients are partners in the research enterprise and that NIH needs to address barriers to participating research across the demographic spectrum. Dr. Bertagnolli is also eager to leverage advancements in data science and artificial intelligence/machine learning in furtherance of NIH's mission.

On the budget front, NIH will likely be operating under a flat budget in FY24. The NIH budget is operating under a continuing resolution that expires in early March. In the longer term, NIH is also preparing for the likelihood of another flat budget in FY25. Dr. D'Souza noted that NIDCR's intramural program is particularly sensitive to budget constraints, and emphasized that stakeholder partnerships become even more important in tight budget climates. As Dr. D'Souza has noted in the past, a flat budget has significant negative impacts. NIDCR hopes to engage the Council and other stakeholders on how to prepare for this constrained budget outlook so that NIDCR continues to fulfill its mission. Dr. D'Souza provided further details on how NIDCR's budget is functioning under the continuing resolution. During this period, non-competing Research Project Grants (RPGs) will be funded at 90%. Modular R01 early-stage investigator (ESI) grants will see no reduction in funding, but competing non-modular ESI R01s will experience a 10% cut. There will be no cuts to career training and research development grants. Other R01s and R01-equivalents will be seeing reductions of 9-15%, and competing renewal applications will be limited to no more than 20% budget increase over the last non-competing award. NIDCR strives to be

intentional and science-driven in its decision-making related to budget reductions, and Dr. D'Souza encouraged PIs and others to reach out to NIDCR staff with questions. It is likely that this interim funding policy will be like the final FY24 budget once a federal budget has been negotiated and signed into law.

In light of Dr. Bertagnolli's guiding principles, Dr. D'Souza shifted gears to discuss NIDCR's strategic goals for the coming years and the need for further translational advances to confront longstanding issues, such as continued disparities in prevalence of dental caries. Other important questions for the Institute are how it can address significant gaps in evidence to guide clinical care, and how it can better serve the needs of every community through an expansion of clinical research capabilities. One example Dr. D'Souza highlighted is the potential of engaging and integrating primary dental care communities. NIDCR can also explore coordinating and integrating its clinical research networks with other existing trials and expand its participation in global health research, which would align with Dr. Bertagnolli's desire to foster greater integration between NIH ICs. Dr. D'Souza plans to engage the Council on these questions, particularly at its May in-person meeting.

NIDCR will also continue its efforts to expand its data science and data sharing capacity and capabilities, which is also a priority of the NIH Director. The Council will hear more on this topic later in the meeting during Dr. Axel Visel's presentation on the recommendations of the Council's Data Science Strategy Work Group. Dr. D'Souza announced that, in response to the Work Group's recommendation, NIDCR will be creating an Office of Data Driven Solutions (DDS) to drive this effort. Other steps underway include educating executive staff on the latest data science applications, evaluating NIDCR investments and needs, developing a vision for the DDS office, and finalizing an NIDCR data science strategic plan by June.

Dr. D'Souza updated the Council on NIDCR's signature initiatives and other extramural research activities. The Practice-Based Research Integrating Multidisciplinary Experiences in Dental Schools (PRIMED) aims to foster a culture of scientific inquiry during dental education by leveraging faculty and student mentorship opportunities and institutional collaborations in patient-oriented clinical research, thereby germinating future clinical research relationships among program participants. Thus far, 10 colleges and universities across the country have been funded via PRIMED, including several previously under-resourced schools. Dr. D'Souza hopes to see this program form the groundwork for a dental school-based clinical trial network of the future. NIDCR is collaborating with NCI on the Advancement of Head and Neck Cancer Early Detection Research (AHEAD) program, which aims to confront the lack of effective early detection methods for head and neck cancers by developing and validating biomarkers. AHEAD is funding seven PI research groups across the nation, which themselves collaborate with other institutions. Dr. D'Souza expressed excitement about the Temporomandibular Disorder (TMD) Collaborative for IMproving PAtient-Centered Translational Research (TMD IMPACT), which is a trans-NIH initiative, administered by NIDCR, which recently issued its first nine awards.

Dr. D'Souza described examples of extramural research highlights from NIDCR-funded studies in recent months. These included studies on secretory phenotypes in salivary intercalated duct cells; high-throughput bioprinting of pre-vascularized injectable microgels for tissue regeneration; the potential of *C. gingivalis* for antimicrobial phage transportation through

biofilm; the relationship between social support and dental outcomes; the acceptance of mobile dentistry and virtual hygiene examinations during the COVID-19 pandemic; the use of large-scale, multi-ancestry genome-wide association studies and data reuse studies to explore cranial vault genetics; the development of a growth model for predicting craniosynostosis phenotypes; and examining electronic health record data to better characterize Sjögren's disease.

NIDCR currently has three bioethics and ethical, legal, and social implications (ELSI) funding opportunities available: ELSI Exploratory/Developmental Research Grant (R21), ELSI Small Research Grant (R03), and Administrative Supplement for Research and Capacity Building Efforts Related to Bioethical Issues. NIDCR has an open Notice of Special Interest (NOSI) entitled Applications of Data Science in Translational Dental, Oral, and Craniofacial Research. Dr. D'Souza informed the Council of an NIH Request for Information inviting input on an NIH-wide strategic plan for autoimmune diseases, which is open for comments until March 1st.

Dr. D'Souza closed her remarks by highlighting NIDCR's 75th activities over the past year. The anniversary year comes to a close in June. NIDCR held a Virtual Trainee Symposium in October, which was a great success. The two-day symposium included a poster session, presentations, panel discussions, networking opportunities, and a keynote speech by Nobel Laureate Dr. Ardem Patapoutian. NIDCR will be holding a 75th Anniversary Symposium Series at the IADR/AADOCR/CADR annual meeting in New Orleans, from March 13-15. One of the final anniversary events will be an NHLBI and NIDCR Joint Symposium on May 16th on the topic of "The Science that Unites Us: Celebrating our Past and Creating a Future of Health Equity."

Dr. D'Souza invited Dr. Webster-Cyriaque, NIDCR Deputy Director, to provide remarks on NIDCR's efforts to address oral health disparities and to foster diversity, equity, inclusion, accessibility, and belonging (DEIAB) in the dental, oral, and craniofacial (DOC) research workforce. In order to achieve the goal of oral health for all, the DOC research community needs to build belonging, break barriers, and build the evidence base. For NIDCR, this means focusing on three areas: the internal workforce, the external workforce, and oral health disparities research. Dr. Webster-Cyriaque briefly discussed the policy background of these activities and NIH's goal to end structural racism at NIH and in the biomedical research workforce at large. Internally, NIDCR takes a systematic approach to this effort via the Racial and Ethnic Equity Lens (REEL) Framework. NIDCR's Chief Diversity Officer is Ms. Joy Postell and Dr. Webster-Cyriaque encouraged Council members to contact her for further information. Dr. Webster-Cyriaque then described NIDCR's Building Belong Collaborative, which is composed of NIDCR staff volunteers and involves working groups on policies, practices, and procedures, accessibility, and storytelling. The goals are to change habits and structures to improve transparency, trust, accountability, and awareness.

For the external workforce, NIDCR aims to foster a diversity of thought and racial and ethnic diversity within the workforce itself. One mechanism to achieve this is pathway development where NIDCR has established an Oral Health Pathway Task Force. In addition to its training programs, NIDCR also is working to increase outreach to the academic research community, dental schools, and K-12 students, and to develop outreach and education resources for others to use. NIDCR's research training programs also play an integral role in this effort, led by Drs. Belinda Hauser and Anissa Brown.

Finally, Dr. Webster-Cyriaque discussed NIDCR's activities related to oral health disparities. The goals are to provide researchers with tools to ensure their studies are inclusive and optimized for translation, to build the health disparities research evidence base, and to encourage whole-person health approaches that incorporate oral health. NIDCR is developing preclinical and clinical training modules for translation and implementation. NIDCR is also creating a translation browser to assess its portfolio in this regard. Dr. Webster-Cyriaque described how this health disparities work aligns with the Institute's five strategic priorities of integrating oral and general health, precision dental medicine, translation and implementation, diverse research pipeline, and partnerships and collaboration. Dr. Webster-Cyriaque described several health disparities-related initiatives that NIDCR is involved with. In one example, NIDCR is partnering with the National Institute on Minority Health and Health Disparities (NIMHD) and its Science Collaborative for Health disparities and Artificial intelligence bias Reduction (ScHEMe) for the Advancing DAta and Practice Transformation (ADAPT) for Caries Equity program. The ADAPT program will use a community-based participatory approach to "design, implement, and evaluate population-based intervention strategies for reducing dental caries disparities and inequities in target populations." NIDCR is also working with a number of sister federal agencies on health disparities and medicaldental integration projects. Dr. Webster-Cyriaque noted that NIDCR is developing a NOSI on health disparities focused on co-located sites and is working with other ICs to view oral health as a modifiable risk factor and incorporate oral health-related questions into existing trial efforts.

Discussion

Dr. Paul Krebsbach asked if NIDCR and/or the NIH are concerned about the effects of the anti-DEI backlash that is hitting academia and other segments of the country. Dr. Webster-Cyriaque replied that NIDCR is aware of this sentiment and said that the Institute frames these activities as benefiting human health for all. Dr. Krebsbach also noticed that NIDCR seems to fund considerably more data science R03s as compared to R01s, and asked if this was an intentional strategy. Dr. Lilian Shum, Director, Division of Extramural Research, said that many of the R03s are for secondary analysis of existing databases, which the Institute views as a good entry point for researchers to become involved in data science. As the field matures, NIDCR hopes to see more R01s. Dr. Jacques Nor asked if NIDCR anticipates a second round of funding for the PRIMED program. Dr. D'Souza said NIDCR will assess the first round as it progresses but she hopes to be able to issue a second round focused more on clinical trials. In response to a question from Dr. Jose Moron-Concepcion, Dr. D'Souza discussed NIDCR's participation in the NIH Helping to End Addiction Long-term (HEAL) Initiative and the fact that dentists remain one of the top prescribers for opioids.

IV. RESEARCH PRIORITIES OF THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. D'Souza introduced Dr. Rick Woychik, Director of the National Institute of Environmental Health Sciences (NIEHS), to deliver a presentation on the work of his Institute and opportunities for collaboration between NIEHS and NIDCR.

Dr. Woychik opened his remarks by seconding the theme of collaboration that echoed through Dr. D'Souza's Director's Report and Dr. Webster-Cyriaque's discussion of health disparities. NIEHS is in Durham, North Carolina, and is the only NIH Institute that is headquartered outside of the greater Washington, D.C. area. The Research Triangle provides NIEHS direct access to the world-class public health, environmental health, and toxicology sciences programs run by the University of North Carolina, Duke University, and North Carolina State University, respectively. NIEHS' budget is approximately \$1B and the Institute is structured much like other NIH ICs with intramural and extramural programs. One unique feature of NIEHS is it manages the interagency National Toxicology Program (NTP), of which Dr. Woychik also serves as director. NIEHS's mission is "to discover how the environment affects people in order to promote healthier lives," and its vision is "to provide global leadership for innovative research that improves public health by preventing disease and disability."

As part of the planning for NIEHS's next strategic plan, the Institute has solicited input from its stakeholders on emerging scientific priority areas. The top six are the exposome, precision environmental health, climate change and health, environmental justice and health disparities, computational biology and data science, and mechanistic and translational biology/toxicology. For the purposes of this presentation, Dr. Woychik will focus on NIEHS's activities in the first two priority areas: the exposome and precision environmental health.

The exposome refers to the totality of exposures, both internal and external, across the lifespan. The idea is that to fully understand the influence of environmental exposures, one must consider the totality of exposures, rather than studying a single exposure. This should also include lifestyle, ecosystem, and social variables, in addition to the physical-chemical exposures. There are challenges to the effort of defining the exposome, including the need for an operational definition and the need for technological tools to study it. The basic question is: how can one do an exposomics study? In this early stage of this field, "pragmatic" exposome research can utilize existing tools, such as high-resolution mass spectrometry. Dr. Woychik noted particular interest in going beyond just measuring exposures into studying how the body reacts to exposures, how exposomic influence can affect the epigenetic status of an individual's genome. In general, Dr. Woychik believes a path forward for exposomics is to model itself on the field of genomics, which started with a big vision back in the 1980s but had to wait for significant technological advances to truly take flight. As part of the effort to operationalize the field of exposomics, NIEHS has developed a concept titled "Global Exposome Research Coordination to Accelerate Precision Environmental Health." The goal of the concept is to develop an agreed upon framework for the field, promote data collection and data sharing best practices, and to build a diverse and inclusive international global exposome research community. NIEHS believes creating a global research community is of central importance, which is a lesson learned from the history of genomics. On this front, NIEHS has issued a NOFO, "Center for Exposome Research Coordination to Accelerate Precision Environmental Health," which it hopes to fund this summer.

Dr. Woychik is also excited about NIEHS's activities in the precision environmental health (PEH) priority area. The goal of this field of research is to address complex traits associated with individuals' responses to environmental exposures. This effort aligns with the NIH Precision Medicine Initiative, which primarily consists of individual genome sequencing and correlating findings with disease outcomes. In the PEH, this entails studying the gene-

environment interactions, integrating genetics, epigenetics, and omics data. One of the challenges in the field of environmental health, and genomics as a whole, is that phenotypes of environmental exposure and other conditions are generally not caused by single gene variants, meaning they are so-called complex traits, which involve the interplay of multiple genes and gene variations. One of the collaborative efforts to address this challenge here at NIH is the All of Us Research Program, which aims to collect health data from over one million people living in the United States to accelerate health research breakthroughs and enable individualized prevention and treatment of disease. The All of Us database gives researchers access to large and diverse datasets, including from participants historically underrepresented in biomedical research. NIEHS is working with All of Us to incorporate geolocation and environmental exposure data to lay the foundations for future exposomics studies using the All of Us database.

Dr. Woychik concluded his presentation by talking about environmental exposures and DOC health and possibilities for future collaborations between NIEHS and NIDCR. As one example where the two ICs' mission areas overlap, Dr. Woychik noted that gene-environment interaction research has shown that maternal smoking is associated with an increased risk of cleft lip and palate. Similarly, maternal exposure to particulate matter and certain industrial emissions also leads to increased risk of cleft lip and palate. Potential areas for collaboration between NIDCR and NIEHS could include incorporating exposomics and PEH data into existing NIDCR cohorts, developing a data repository framework to foster data sharing, and partnering on projects to confront the challenges of climate change and health, health disparities, and environmental justice.

Discussion

Dr. Webster-Cyriaque noted that the oral cavity and saliva would seem to be obvious locations of study for exposomic exposures. The federal health disparities research projects that NIDCR is involved with could be a valuable place to incorporate geolocation data to facilitate future exposomics work with those cohorts. Dr. Woychik said those were terrific suggestions. Saliva also has important connections to the microbiome, a central part of the exposomic framework. Dr. Visel asked Dr. Woychik if he sees the exposomics community following the tradition of the Human Genome Project of pre-publication data sharing. Dr. Woychik replied in the affirmative and added that one of the early operationalizing objectives has to be to develop that data sharing framework and common data elements. Dr. D'Souza noted the important role teeth play as a repository of exposures, which can be traced back to their initial development as hard tissue in utero.

V. CONCEPT CLEARANCE

Dr. King stated that NIDCR is required to document the clearance of concepts by presenting 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 Small Grant Program for New Investigators (R03)

Dr. Preethi Chander, Director, Salivary Biology and Immunology Program, DER, presented the concept. The goal of the concept is to support early-career investigators whose proposed research addresses any of the goals described in the NIDCR Strategic Plan in order to help build a robust investigator pipeline. Research projects may take the form of feasibility studies or developmental research in the realms of basic science and/or clinical, behavioral, or population science. The end goal is to obtain enough preliminary data from this research to ultimately support a future R01 or equivalent application. The program is limited to New Investigators as defined by NIH and the award budget is \$100,000 per year for two years. Analysis of the past decade of this program has shown that its awardees are 1.6 times more likely to apply for R01s and 2.4 times more likely to be awarded an R01 compared to unsuccessful applicants.

The Council's lead discussants for the concept were Drs. Nor and Krebsbach. Dr. Nor expressed full support for the reissuance and noted that it addresses an urgent need to foster early careers in DOC research. The data shows that the program has been successful thus far, and the amount of funding provided in the award is appropriate. Dr. Krebsbach seconded Dr. Nor's comments. One of the features that he particularly likes is that the program encourages awardees to make research plans for after the award is over. He noted that the research environment is critical for junior investigators and asked if there was a mentoring component to the program. Dr. Chander said many applicants have independent appointments and that the program does require a letter of support from their program chair. Council members discussed the importance of formal mentoring structures at academic institutions. Dr. Moron-Concepcion suggested incorporating a networking component for awardees to get to know each other and foster relationships that could become valuable later in their careers.

The Council unanimously approved the concept.

VI. ORAL HEALTH RESEARCH WORKFORCE WORKING GROUP UPDATE

Dr. King invited Dr. Dana Graves, co-chair of the Oral Health Research Workforce Working Group, to deliver an update on the Working Group's activities

The Working Group's charge is to "develop and recommend evidence-based approaches to sustainably recruit, train, and retain researchers who have knowledge to build a diverse DOC scientist and clinician-scientist research workforce." Dr. Graves focused his update on two primary considerations that the Working Group has been focusing on as it drafts its recommendations. These are how to enhance the efficiency of training programs to make dollars go further, and how to make a lasting impact in the context of data on training program outcomes. To that end, the Working Group will be proposing that NIDCR create two new offices: one to focus on facilitating enhanced collaborations with professional organizations, academia, foundations, and industry; and a second office dedicated to analysis of trainee outcomes, programs, and workforce needs.

While all NIDCR stakeholders have expressed interest in increased collaboration, some professional societies have expressed frustration in not knowing how to achieve these goals. Dr. Graves described some challenges that were raised during the Working Group's listening sessions that the proposed new office for collaborations could address, such DOC trainees and Early Stage Investigators (ESIs) feeling disconnected from the research community and lacking knowledge about the broad spectrum of available career opportunities, and the need for more robust mentoring support and peer networks. An example of a successful collaboration in this arena is the NIDCR supported AADOCR MIND the Future mentoring and networking program for early career investigators. Dr. Graves listed some other ideas for collaboration that could be facilitate by NIDCR, such as working with dental schools to develop programs to support hybrid faculty positions that involve clinical teaching and clinical research with more evenly split amounts of time devoted to each. A research training program assessment office proposed by the Working Group would help address gaps in knowledge about the efficacy and outcomes of training programs. Developing metrics and collecting data on training programs would help NIDCR identify factors that lead to success, determine what portions of the workforce need to be targeted, and tailor its training programs for the greatest impact. More general questions that could be addressed are what types of mentoring programs are most successful and what is the ideal length of training for a DOC researcher.

Discussion

Dr. Webster-Cyriaque asked whether industry and professional societies had expressed interest in providing support at the level of clinical research components of training programs. Dr. Graves said they are interested in funding at the level of supplements, which could take the form of clinical research programs, or, for example, loan repayment programs. One of the pressing concerns for these groups was the need for a specific contact at NIDCR. Dr. Moron-Concepcion noted that his medical school uses T32 grants and support from professional societies to help cover additional research expenses for clinician-scientists. Dr. D'Souza said she looks forward to bringing specialty societies to the table to discuss ways of partnering in support of dentists who want to build a research career. Financial constraints may limit NIDCR's ability to establish new offices in the near future, but Dr. Graves clarified that the important part of the collaborations was to at least create a dedicated point of contact. The Council also discussed the student loan debt burden as an obstacle to careers in research. Dr. Nor expressed the hope that MIND the Future could be used as a model to extend to specialty societies and other DOC professional organizations. Dr. Amy Slep observed that some of the programs being suggested sound similar in structure to the field of clinical psychology, where clinical work is balanced with research training, and NIDCR might want to consider reaching out to those organizations for advice on how to design combined specialty/PhD training programs.

VII. DATA SCIENCE STRATEGY WORKING GROUP UPDATE

Dr. King invited Council member Dr. Visel, co-chair of the Advisory Council's Data Science Strategy Working Group, to present the Working Group's final report and

recommendations. The written report has been provided to NIDCR and the Council for comments, after which the report will be revised and publicly released.

Dr. Visel provided an overview of the report's structure and contents, including sections on NIDCR-specific opportunities in data science and the Working Group's recommendations. Dr. Visel briefly described the recent history of data science-related activities at NIH and NIDCR and the Working Group's charge and activities since its establishment. The Data Science Strategy Working Group was tasked with developing recommendations "for a well-informed and well-reasoned NIDCR data science strategy to enable NIDCR to realize the potential of data science in advancing the full translational spectrum of DOC research, reducing health disparities, and improving overall health." Dr. Visel noted that the role of data science is implicit throughout NIDCR's strategic pillars as denoted in its current strategic plan, and that the development of an NIDCR data science strategy will align the Institute with the NIH Strategic Plan for Data Science. Dr. Visel reviewed the Working Group membership, and highlighted that members have expertise across the research and translational continuum. He thanked NIDCR staff for their support throughout the process.

Dr. Visel reviewed the Working Group's activities and focus areas during its tenure. Since its establishment, the Working Group has held a series of meetings, issued an RFI to solicit feedback from the community, and has held a series of listening sessions to gather additional input from the stakeholder community on how people from across the research spectrum interact with data. After receiving the stakeholder feedback, the Working Group synthesized the comments into five general observations about the existing data ecosystem: the complexity, multiplicity, and heterogeneity of data resources and repositories, fuzzy boundaries between DOC-specific systems and other databases that contain DOC-relevant data, a lack of connectivity between resources and systems, lack of sustained and dedicated resources for data science projects, and hurdles to compliance with FAIR (Findable, Accessible, Interoperable, and Reusable) data principles.

The Working Group subsequently identified four NIDCR-specific opportunities for data science in DOC research: addressing oral health disparities, artificial intelligence (AI) and machine learning (ML) readiness of DOC data, converting data to applications, and leveraging DOC data diversity. Dr. Visel discussed examples of how data science can be brought to bear on each of these topics. For health disparities, data science can be used to facilitate the integration of social determinants of health and to apply advanced data methods to gain novel insights into oral health disparities. Data science applications hold potential for uncovering and addressing biases in data; however, NIDCR and the field as a whole must work to ensure AI applications do not themselves perpetuate biases and that the tools are used ethically. Data science workforce development should also be a priority in order to create a pipeline of researchers using data science in population oral health. NIDCR should work to prepare itself for the many AI/ML uses in the realm of biomedical research by establishing data governance best practices, developing quality assurance metrics, working to integrate and harmonize data from diverse sources, laying the infrastructure groundwork for the scaling up of AI/ML capabilities, and establishing a robust data security and compliance framework. Advanced AI/ML applications are already shaping patient care via rapid and enhanced diagnostic imaging, clinical records analysis, device optimization, and for precision medicine, among numerous other applications. Dr. Visel

emphasized that the current challenges of the complexity and heterogeneity of DOC data provide a significant opportunity for the field to leverage innovative data science methodologies to glean significant new insights.

To inform a future NIDCR data science strategy that successfully leverages these opportunities, the Working Group developed the following five recommendations:

- 1. Establish a robust data infrastructure tailored for DOC research that interfaces with NIH data systems,
- 2. Modernize data ecosystems specific to DOC research,
- 3. Foster the development of data management, analytics, and visualization tools for DOC research,
- 4. Enhance data science workforce development within the DOC research community, and
- 5. Promote data stewardship and sustainable data policies in DOC research.

Dr. Visel again directed the Council to the written report for additional details and encouraged Council members to provide feedback.

Discussion

Dr. Visel noted that several Working Group members were in attendance for the Council meeting: Working Group co-chair Dr. Amit Acharya, Dr. Carl Kesselman, and Dr. Lucia Soares Cevidanes. Dr. D'Souza opened the discussion by asking for thoughts on NIDCR establishing a federated DOC data repository, particularly given the resource constraints that would limit the feasibility of creating a centralized repository. Dr. Kesselman said that creating a DOC-specific repository will hold significant value to the community, and the challenge will be to find the right balance of coordination in how it is structured. Dr. Cevidanes agreed that the federated repository is likely to be more realistic given the cost considerations, among other factors. Dr. Acharya posited a hub-and-spoke model. Dr. D'Souza also raised the question of how to incorporate older data sets that were not designed with modern technologies in mind. Dr. Kesselman it is possible to re-curate old data in many cases, but the question is whether that task is worth the time and expense.

Dr. Nor thanked the Working Group for their superb work and emphasized the importance of the fourth recommendation. He noted his personal experience at his institution when they tried to recruit a data scientist and found the task to be very difficult due to the short supply of DOC-focused data scientists.

Dr. D'Souza thanked the Working Group for their report and their hard work. The next steps are for NIDCR to review and discuss the report internally and seek advice from other NIH offices, such as the National Library of Medicine and the NIH Office of Data Science Strategy. NIDCR will then come back to Council at a future meeting to present its vision for data science at the Institute.

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. Code and Section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014).

X. REVIEW OF APPLICATIONS

National Institute of Dental & Craniofacial Research Council Applications Recommended for Further Consideration

Jan 24, 2024

Requested	Approved
1044	653
\$ 347,074,945	\$ 225,601,701
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XI. ADJOURNMENT

CERTIFICATION

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

Jennifer Y.

WebsterCyriaque
Digitally signed by Jennifer Y. Webstercyriaque -S
Date: 2024.04.11
18:36:07 -04'00'

Dr. Rena D'Souza Chairperson National Advisory Dental and Craniofacial Research Council Lynn M. Digitally signed by Lynn M. King -S
Date: 2024.04.11
08:49:42 -04'00'

Dr. Lynn King Executive Secretary National Advisory Dental and Craniofacial Research Council

ATTACHMENTS

I. Roster of Council Members

