National Institute of Dental and Craniofacial Research

National Advisory Dental and Craniofacial Research Council

Minutes of Meeting May 22, 2024

Building 31 C Wing, 6th Floor, Rooms A & B National Institutes of Health Bethesda, Maryland

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

May 22, 2024

The 236th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on May 22, 2024, at 8:30 a.m., in Building 31, C Wing, 6th Floor, Rooms A & B, National Institutes of Health (NIH), Bethesda, Maryland. The meeting was open to the public from 8:30 a.m. until 3:00 p.m.; it was followed by the closed session for Council business and consideration of grant applications from 2:47 p.m. until adjournment at 4:30 p.m. Dr. Jennifer Webster-Cyriaque presided as Acting Chair.

OPEN SESSION

Members Present

- Dr. Joel Collier
- Dr. Terry Dickinson
- Dr. Luisa DiPietro
- Dr. Stephany Duda
- Dr. Frank Ebetino
- Dr. Michelle Hamilton, ex officio
- Dr. Hyun (Michel) Koo
- Dr. Paul Krebsbach
- Dr. Jacques Nor
- Dr. Amy Smith Slep
- Dr. Axel Visel

National Institute of Dental and Craniofacial Research

- Dr. Jennifer Webster-Cyriaque, Acting Director
- Dr. Lynn King, Executive Secretary, and Director, Division of Extramural Activities (DEA)
- Mr. Aubrey Callwood, Chief Information Officer; Director, Office of Information Technology (OIT)
- Dr. John (Jay) Chiorini, Acting Associate Scientific Director, DIR
- Dr. Sharon Jackson, Senior Advisor, Office of the 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
- Ms. Mehrnoosh Abshari, Combined Technical Research Core (CTRC), DIR
- Dr. Azeez Alade, DIR

- Ms. Alexandria Alfarano, DER, Center for Clinical Research (CCR)
- Dr. Hosam Alraqiq, OD, Office of Science Policy and Analysis (OSPA)
- Mr. Dandre Amos, OD, Office of Clinical Trials Operations & Management (OCTOM)
- Dr. Nicole Arroyo, OSPA
- Dr. Lorena Baccaglini, DER, CCR
- Dr. Alison Boyce, DIR
- Ms. Laurie Brenchley, DIR
- Ms. Beth Brillante, DIR
- Dr. Anissa Brown, DEA, Research Training & Career Development Branch (RTCDB)
- Mr. Christopher Brown, DEA, Scientific Review Branch (SRB)
- Dr. Thomas Bugge, DIR
- Dr. Christopher Campbell, DEA, SRB
- Dr. Preethi Chander, DER, Salivary Biology and Immunology Program
- Dr. Jingshan Chen, DEA, SRB
- Ms. Tiffany Chen, OD, Office of Communications & Health Education (OCHE)
- Dr. Zhong Chen, DER, Integrative Biology & Infectious Diseases Branch (IBIDB)
- Dr. Aiwu Cheng, DEA, SRB
- Ms. Jennifer Chi, OD, OCTOM
- Ms. Saranya Chitturi, DIR
- Ms. Alicia Chou, DER, Translational Genomics Research Branch (TGRB)
- Mr. Sean Choi, DIR
- Ms. Michelle Cortes, DER, IBIDB
- Ms. Mary Daum, DIR, Office of Communications & Health Education (OCHE)
- Mr. Jimmy Do, OD, Financial Management Branch (FMB)
- Dr. Bill Elwood, DER, Behavioral & Social Sciences Research Branch (BSSRB)
- Dr. Olga Epifano, DEA
- Dr. Luis Fernandez de Castro, DIR, Office of the Scientific Director (OSD)
- Dr. Dena Fischer, DER, Director, CCR
- Mr. David Fraser, DIR, OSD
- Dr. Kat Futrega, DIR, OSD
- Dr. Rachel Gafni, DIR, OSD
- Dr. Melissa Ghim, DER, IBIDB
- Dr. Ioana Ghita, DIR, OSD
- Ms. Angelica Gomez, Office of Administrative Management (OAM)
- Ms. Kim Gordon, DIR
- Mr. Harry Grant, DIR
- Dr. Margaret Grisius, DER, CCR
- Mr. Joel Guzman, DER
- Dr. Sue Hamman, OD
- Dr. Ashleigh Hanner, DIR
- Ms. April Harrison, DEA, GMB
- Mr. Gabriel Hidalgo, DEA, GMB
- Dr. Timothy Iafolla, OD, OSPA
- Dr. Hiroko Iida, DER, CCR
- Dr. Tomoko Ikeuchi, DIR, OSD
- Dr. Priyam Jani, DIR

- Ms. Christina Jones, DIR
- Dr. Dara Kessler, OD
- Ms. Leila Khaki, DER, BSSRB
- Dr. Zohreh Khavandgar, DIR, OSD
- Dr. Wendy Knosp, OD, OSPA
- Dr. Taishi Komori, DIR, OSD
- Dr. Jamie Kugler, DIR, OSD
- Dr. Ashok Kulkarni, DIR, Functional Genomics Section (FGS)
- Dr. Shuang Li, OD, DER
- Dr. Orlando Lopez, DER, IBIDB
- Ms. Alisa Machalek, OD, OCHE
- Dr. Michael Maio, DIR
- Dr. Jill Mattia, DER, BSSRB
- Dr. Vanessa McMains, DIR
- Dr. Tamara McNealy, DER, IBIDB
- Ms. Susan Medve, DEA, GMB
- Dr. Yun Mei, DEA, SRB
- Dr. Amanda Melillo, DER, IBIDB
- Dr. Randy Merling, DIR
- Dr. Eva Mezey, DIR
- Ms. Amy Mhatre-Owens, OD, OCTOM
- Dr. Hitomi Minagi, DIR
- Ms. Mable Nee, OD, FMB
- Mr. Paul Newgen, DEA, GMB
- Ms. Michelle Nguyen, OD, OAM
- Ms. Anna Nicholson, OD, OCTOM
- Dr. Thomas O'Farrell, DEA, SRB
- Dr. Noffisat Oki, DER, TGRB
- Ms. Marshelle Parker, DEA, GMB
- Dr. Vaishali Patel, DIR
- Ms. Eileen Pelayo, DIR
- Dr. Iriana Pena Manrique, OD
- Ms. Lisa Peng, OD, OIT
- Dr. Paola Perez, DIR
- Dr. Lilli Pinzon, OD, OSPA
- Dr. Fatemeh M. Pour, OD
- Mr. John Prue, OD, OIT
- Dr. Pam Robey, DIR
- Ms. Diana Rutberg, DEA, GMB
- Dr. Zubaida Saifudeen, DER, TGRB
- Dr. Nadine Samara, DIR, OSD
- Dr. Rachel Sare, DER, RTCDB
- Dr. Rachel Scheinert, OD, OSPA
- Dr. Yasaman Shirazi, DEA, SRB
- Dr. Maruska Silveira, OD, OSPA

- Ms. Jamie Sim, OD, OSPA
- Ms Ashley Smith, DEA, OD
- Dr. Roman Szabo, DIR,
- Dr. Ildiko Szalayova, DIR, OSD
- Dr. Kelly Ten Hagen, DIR
- Dr. Shoba Thirumangalathu, DEA, RTCDB
- Mr. Shawn Thomas, OD, AMB
- Dr. Scott Verbridge, DER, IBIDB
- Dr. Jason Wan, DER, IBIDB
- Dr. Lu Wang, DER, CCR
- Dr. Yan Wang, DIR, OSD
- Dr. Blake Warner, DIR
- Ms. Stacey Warr, OD, OIT
- Dr. Achim Werner, DIR
- Dr. Drake Williams, DIR
- Dr. Ken Yamada, DIR, OSD
- Dr. Hongen Yin, DIR, CCR

National Institutes of Health

- Dr. Monica Bertagnolli, Director, NIH
- Dr. Lindsey Criswell, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

Guests

- Dr. Christopher Fox, International Association for Dental Research (IADR)
- Dr. Dana Graves, Penn Dental Medicine; Co-Chair, Council Oral Health Research Workforce Working Group
- Mr. Matthew Miller, Neal R. Gross & Co.
- Dr. Jim Lipton

NIH videocast https://videocast.nih.gov/watch=54640 Views: 230 Live

I. WELCOME

Dr. Lynn King, Director of Division of Extramural Activities (DEA) and Advisory Council Executive Secretary, called the open session of the 236th Advisory Council meeting to order at 8:31 a.m. Members of the public may submit written comments and questions until February 8th at NIDCRCouncilMail@nider.nih.gov. Dr. King announced that this meeting will be the last for Council members Dr. Axel Visel, Dr. Joel Collier, and Dr. Frank Ebetino. Dr. King thanked them for their service to NIDCR and the community. She welcomed two new Council members, Dr. Michel Koo from the University of Pennsylvania and Dr. Stephany Duda from Vanderbilt University.

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

Dr. King asked the Advisory Council if there were corrections or comments on the minutes of the January 24th, 2024, Advisory Council meeting. There were no comments and the Council voted unanimously to approve the minutes.

III. OPENING REMARKS

Dr. Jennifer Webster-Cyriaque, Acting Director, NIDCR, welcomed Council members, staff, and other attendees to the Council meeting, and highlighted the presentations by the Director of NIH, Dr. Monica Bertagnolli, and the Director of NIAMS, Dr. Lindsey Criswell. Dr. Webster-Cyriaque's opening remarks included an overview of NIDCR's recent 75th anniversary celebrations and a selection of the Institute's past, current, and future research achievements and focus areas. She also discussed how NIDCR is working to leverage data and supporting efforts to integrate oral health into primary healthcare to improve health for all.

NIDCR's 75th anniversary was celebrated throughout 2023 and into this year, including events at the AADOCR annual meetings and a series of symposia and seminars at NIH that highlighted the Institute's scientific achievements and training and career development. NIDCR funds research across the United States and globally, and NIDCR-supported research has led to over 60,000 publications, including over 100 that have over 1,000 citations, and the development of over 175 drug products that span beyond NIDCR's mission areas. Dr. Webster-Cyriaque provided examples of the Institute's past and current work in the fields of autoimmunity, cancer, connective tissue, pain and neuroscience, and host-pathogen interactions, all of which underscore how NIDCRsponsored research has supported multidisciplinary and seminal fundamental science breakthroughs and advancements. Examples of collaborative, trans-NIH programs that NIDCR currently sponsors or participates in include the Accelerating Medicines Partnership on Autoimmune and Immune-Mediated Diseases (AMP AIM) Program's Sjögren's Team for Accelerating Medicines Partnership (STAMP), the Advancing Head and Neck Cancer Early Detection Research (AHEAD) consortium, TMD Collaborative for IMproving PAtient-Centered Translational Research (TMD IMPACT), and the Restoring Joint Health and Function to Reduce Pain (RE-JOIN) Consortium, which is part of the NIH Helping End Addiction Long-term (HEAL) Initiative.

Dr. Webster-Cyriaque also discussed NIDCR's data science-related research efforts. In 2009, NIDCR created the FaceBase data repository, the preeminent dental, oral, and craniofacial (DOC) research database. NIDCR is working to expand FaceBase to incorporate related data and data types relevant to the entire translational spectrum. FaceBase currently houses over 11,000 datasets, 45,000+ images, and over 7,400 sequence data files. In FY23, NIDCR funded 23 data science-related projects, representing \$4.4M in funding. Moving forward, the Institute is committed to leveraging cutting-edge data science modalities in areas of artificial intelligence (AI) and machine learning (ML). Supporting data science research and fostering a diverse cadre of DOC investigators trained in data science are key components of NIDCR's Strategic Plan. The Institute is also working to address the recommendations from the Advisory Council's Working Group on Data Science Strategy. The working group's five recommendations were to create data infrastructure tailored for DOC research; modernize DOC-specific data ecosystems; develop data management, analytics, and visualization; enhance data science workforce development with inclusive training; and promote

data stewardship and sustainable data policies. As part of the response, NIDCR plans to launch later this year the Data Driven Solution (DDS) Hub, which will be a central source of data science resources for DOC researchers.

NIDCR is also working to address the findings of the most recent Surgeon General's Oral Health in America report, particularly the finding that the needs of underserved and underrepresented communities remain unmet. The continued prevalence of preventable dental caries and treatable dental decay is one prominent example of this fact; although dental caries remain an issue among all populations, the rates remain higher among minority and rural populations. In 2001, NIDCR established NIH's first disparities research center and developed the first partnership between a research-intensive institution and a minority-serving institution in 1992. In FY23, NIDCR spent \$30.2M on health disparities and racial and ethnic minority health research and \$4.1M on rural health research. As one example of NIDCR's work in this area, Dr. Webster-Cyriaque described the Advancing DAta and Practice Transformation (ADAPT) for Caries Equity program. The ADAPT program will develop a research consortium and data hub "to support community-based participatory approaches to design, implement, and evaluate population-based intervention strategies for reducing dental caries disparities and inequities in target populations." ADAPT is intended to be collaborative program with the National Institute on Minority Health and Health Disparities (NIMHD) under the auspices of the Science Collaborative for Health disparities and Artificial intelligence bias Reduction (ScHARe).

Finally, Dr. Webster-Cyriaque discussed NIDCR's efforts to support primary healthcare research to further the Institute's broader goal of integrating oral health into whole person healthcare. Childhood caries is an example of where this would have the biggest impact, due to the condition's preventable nature, and to help reduce disparities. In addition, treatment of dental caries and periodontal disease in adults has been linked with reduction in risk in morbidity and mortality from other conditions. In FY23, NIDCR funded 35 research projects on primary healthcare research totaling \$18.1M. In connection to this effort, NIDCR supports the National Dental Practice-Based Research Network and the Practice-Based Research Integrating Multidisciplinary Experiences in Dental Schools (PRIMED) program. Primary care research is particularly important in the wake of the U.S. Preventive Services Task Force's conclusion last year that there is insufficient evidence to support oral health screening in the primary care setting. This presents an opportunity for national studies on how whole-person oral health approaches in the primary care setting can improve oral health outcomes and reduce health disparities. This work has already begun at the local/regional level.

Discussion

Dr. Janice Lee, NIDCR Clinical Director, asked Dr. Webster-Cyriaque to comment on the lack of integration of dental electronic health records (EHR) with medical health records and NIDCR's activities to confront this problem. Dr. Webster-Cyriaque noted that some EHR systems, such as Epic's Wisdom module, do allow for integration of records, for both clinical care and research, is an important part of achieving the Institute's goal of fully incorporating oral health into whole-person health. However, it is a challenging topic because of the wide variety of provider groups and EHR systems and software.

Council members discussed with Dr. Webster-Cyriaque the importance of improving the training and career pathways for researchers and the need to strengthen the diversity of the DOC research workforce. On the latter topic, Dr. Webster-Cyriaque said she hoped to see a greater percentage of Research Project Grants (RPGs) Principal Investigators (PI's) take advantage of available research supplements to promote diversity. She also stressed the importance of developing future researchers at the K-12 level through funding opportunities such as the NIH Science Education Partnership Award (SEPA).

IV. NIH DIRECTOR'S INTRODUCTION: TOWARD EVIDENCE-BASED HEALTHCARE

Dr. Webster-Cyriaque welcomed Dr. Monica Bertagnolli, Director of the National Institutes of Health, and invited her to introduce herself to NIDCR and Council and to discuss her vision of NIH's future. Dr. Bertagnolli began by thanking the Council members for their valuable service to NIDCR and NIH.

Dr. Bertagnolli grew up on a remote sheep and cattle ranch in Wyoming, and the experience of being raised in a place 100 miles from the nearest school, grocery store, and doctor's office has informed her career's work. After undergraduate studies at Princeton University, Dr. Bertagnolli returned west to attend medical school at the University of Utah, where she realized she wanted to be a surgeon. She did her residency at Brigham and Women's Hospital in Boston, where she received her first NIH funding and first became interested in familial adenomatous polyposis (FAP). Her later career involved collaborating on large-scale clinical trials and specializing in cancer surgery where she recognized the vital importance of translating research results from the bench to the clinical setting. Dr. Bertagnolli was inducted into the National Academy of Medicine in 2021 and she served for a year as Director of the National Cancer Institute (NCI) before being nominated by President Biden to be the NIH Director. She also shared her personal experience being diagnosed with early-stage breast cancer less than two months into her tenure as NCI Director, which has influenced her perspective towards the impact of the decades-long history of clinical research in the U.S.

In her position as NIH Director, Dr. Bertagnolli has to confront the worsening health trends among the American population, particularly in comparison to peer nations. One recent study found that Americans' life expectancy fell by 2.4 years between 2019 and 2021, a period that coincides with the COVID-19 pandemic. The numbers have recovered partially since then, but not completely. High rates of drug overdose and suicide and stalled progress in treating cardiometabolic diseases are some of the important factors in decreasing life expectancy. The U.S. continues to outspend peer nations on healthcare despite worse outcomes. The NIH must play a central role in producing the evidence-based research that is needed to better identify what is working and what isn't, to help rein in costs. This aligns with NIH's principle that its work does not end with scientific discovery but must extend to ensuring all people are living long and healthy lives. A second principle is that NIH research must encompass the laboratory, the clinic, and the community. NIH must also embrace the rapid progress in data analytics and scientific technology while ensuring that these new tools are applied to data that includes everyone, and that new discoveries are rapidly and equitably translated to the clinic. One way to achieve these

goals is to better integrate everyday clinical care with research. This includes primary care, and Dr. Bertagnolli explained that dental care is primary care. NIH can extend its influence beyond individual specialty networks to build national primary care networks that reach into all communities. This will require innovative study designs and a data-driven system where insights from research and clinical care are constantly integrated. At the national level, biomedical research data must be better integrated to support better data sharing and maintenance.

Dr. Bertagnolli emphasized that fundamental science remains at the core of NIH's mission. She provided some recent examples of highly impactful NIH-funded research, some of which began as relatively small projects, including the development of mRNA vaccines and gene therapy for sickle cell disease. The mRNA vaccine delivery system and gene therapy technologies hold significant promise for application across a wide array of disease conditions. Two sickle cell gene therapy treatments recently received FDA approval, and the Biden administration is working to make the treatment Medicaid-eligible to increase access. Dr. Bertagnolli concluded her remarks by highlighting several recent NIDCR research achievements and reiterating her support for integrating oral health into overall medical health.

Discussion

Dr. Paul Krebsbach asked Dr. Bertagnolli to comment on how NIH balances prioritizing clinical trials versus basic science, particularly in the context of the cost of translation and workforce limitations. Dr. Bertagnolli agreed that it is a balancing act, and it is something that is thought about by every NIH IC, with the principle of improving health at the forefront. She pointed again to the mRNA and gene therapy platforms as examples of what it looks like when things go right, and fundamental science unlocks applications that can be applied more broadly. Research on fundamental processes such as inflammation, the immune system, metabolism, infection response, and the senescence process are other examples where basic science research can have overarching impacts in the clinic. Dr. Webster-Cyriaque noted that oral health is a modifiable risk factor that impacts a number of conditions related to these processes.

Dr. Axel Visel asked if there were lessons to be learned from the career of Dr. Katalin Kariko, who received the Nobel Prize in Medicine for her work on the development of mRNA therapy but struggled early in her career to secure funding. Dr. Bertagnolli acknowledged the difficulty of knowing so far in advance what research will pan out and what won't. One lesson from the mRNA technology is that the fundamental elements of human biology are an important place to look for developing new therapeutics. Dr. Michel Koo asked Dr. Bertagnolli for her thoughts on how to overcome the silos between the bench and the clinic. Dr. Bertagnolli said that she has been fighting those silos her entire career and has seen significant improvement over the course of her career. Researchers are increasingly realizing that sustained integration on the clinical side can lead to greater long-term success. Dr. Bertagnolli pointed to the NIH All of Us Research Program as an example of a program in which basic science is a critical component of clinical research. Dr. Stephany Duda also raised the topic of data silos and efforts to connect the disparate data repositories in some kind of federated data ecosystem. Dr. Bertagnolli said that NIH does foresee a federated system in which databases housed at individual ICs can be seen as nodes. NIH is beginning this process by creating an interoperable data repository for all its clinical activities. This effort will be housed at the National Library Medicine, but Dr. Bertagnolli cautioned that a significant increase in funding will be needed to develop a comprehensive NIH-wide federated system.

Dr. Michelle Hamilton asked Dr. Bertagnolli to comment on ways to streamline the integration of research components into primary care to better support providers who might be interested in doing so. Dr. Bertagnolli said the most crucial aspect is the technological project of making EHR systems research-ready, but there also must be a concerted effort to work with front-line providers to find out what study designs would be most useful for them. Working with Federally Qualified Health Centers (FQHC) would be a good starting point, because they already incorporate many relevant activities, including dental practices, and because they operate in communities that NIH wants to reach.

Dr. Luisa DiPietro asked if NIH has a role to play regarding communicating discovery and providing general medical education to the general population. Dr. Bertagnolli said there is a cross-agency federal responsibility to communicate with the public, and that professional organizations have a role to play, too. She acknowledged that this task has been complicated by the rise of social media. Studies show that people trust their primary care doctors, pharmacists, and friends and family ahead of the government, which makes some amount of sense because those are the people they see in their day-to-day lives.

V. EXAMPLES OF NIAMS' COMMITMENT TO DENTAL AND CRANIOFACIAL RESEARCH COLLABORATIONS

Dr. Webster-Cyriaque welcomed Dr. Lindsey Criswell, Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), to deliver a presentation on the work of her Institute and the ongoing collaboration between NIAMS and NIDCR.

Dr. Criswell began her presentation by briefly describing her career before joining NIH. She was trained as a rheumatologist and has devoted her research career to the study of geneenvironment interactions, particularly the genetics and environmental risk factors of autoimmune diseases. Dr. Criswell has also been involved in Sjögren's disease research since 2003, which is an area of overlapping interest for NIAMS and NIDCR. Dr. Criswell maintains a research lab at the National Human Genome Research Institute (NHGRI) where she primarily focuses on systemic lupus and Sjögren's disease research. Dr. Criswell connected her research on Sjögren's to her participation in a program launched by NIDCR two decades ago called the Sjögren's International Collaborative Clinical Alliance (SICCA). The purpose of this program was to comprehensively phenotype patients from around the world in order to better define and understand Sjögren's disease, and it resulted in an internationally accepted classification of the disease. When Dr. Criswell arrived as the NIAMS Director, she had a number of goals for her tenure, which included engaging the NIAMS and NIH communities, increasing NIAMS' visibility, pursuing emerging opportunities in team and data science, continuing the Institute's support of early- and mid-career investigators, and enhancing workforce diversity and research to address health disparities.

Dr. Criswell provided the Council a short overview of NIAMS' mission statement, research focus areas, and budget situation, and then segued to discuss examples of the longstanding collaborative activities between NIDCR and NIAMS. In the field of bone biology and diseases, NIAMS and NIDCR worked together to convene a NIH Pathways to Prevention panel and workshop on the appropriate use of drug therapies for osteoporotic fracture prevention. The panel's recommendations included leveraging large clinical datasets to address knowledge gaps and to encourage study on the pathophysiology of atypical femoral fractures (AFFs). Following the panel, NIAMS and NIDCR worked together, along with the National Institute on Aging (NIA), to issue a Notice of Special Interest (NOSI) titled Promoting Research on Mechanisms of Pathogenesis and Pathophysiology of AFF and Osteonecrosis of the Jaw, which has funded five research projects to date. Dr. Criswell also discussed her Institute's participation in the Foundation for the NIH (FNIH) Biomarkers Consortium's Bone Quality Project, which resulted in FDA approval of a biomarker qualification plan for the first surrogate endpoint for anti-osteoporosis drug trials. She noted that this was the first surrogate endpoint approved under the 21st Century Cures Act. Dr. Criswell also went into further detail on the RE-JOIN Consortium, which is another program where NIDCR and NIAMS collaborate. As Dr. Webster-Cyriaque noted in her remarks, RE-JOIN is housed within the larger NIH HEAL Initiative, which is a trans-NIH initiative with the goal of addressing opioid misuse, addiction, and pain. The goal of the RE-JOIN Consortium is "to define the innervation of the different articular and peri-articular tissues that collectively form the joint by sensory neurons that mediate the sensation of pain", with a primary focus on the knee and temporomandibular joints (TMJ). Ultimately, RE-JOIN hopes to lead to the identification of new targets for intervention and more precise therapies. Of the five RE-JOIN awards issued thus far, three were for TMJ-focused research. Dr. Criswell stated that NIAMS, like NIDCR, believes in a whole-person approach to health.

Dr. Criswell next highlighted shared areas of interest and collaboration related to autoimmune diseases. One such example is research on the links between periodontal disease and rheumatoid arthritis. Patients with both conditions often present with more severe symptoms than those who only have one condition. In one example, NIAMS-supported researchers have found a direct immune response that causes rheumatoid arthritis flares when the lining of the mouth is injured. NIAMS and NIDCR were also both participants in a genome-wide association study that identified 10 new risk loci for Sjögren's syndrome. Dr. Criswell also touched on NIAMS' participation in AMP AIM, which has proven to be a highly successful public-private team science initiative and has been particularly impactful for early-career investigators. AMP AIM is a successor program to the AMP Rheumatoid Arthritis and Systemic Lupus Erythematosus Program that began back in 2014. The goal of AMP AIM is to index and map cells and pathways in autoimmune diseases and to identify which cells and pathways are specific or shared across diseases. Dr. Criswell stated that the STAMP program, mentioned earlier by Dr. Webster-Cyriaque, is recruiting very well thus far. NIAMS, in partnership with NIA and Sage Bionetworks, has established a knowledge portal, the ARK Portal, to provide data resources in support of AMP-related programs.

Regenerative medicine is another area of overlapping interest between NIDCR and NIAMS. In 2022, NIAMS held a Cartilage Preservation and Restoration in Knee Osteoarthritis Roundtable to discuss challenges, research gaps, and recent findings, with an eye towards eventually translating those findings to other joints. NIAMS was excited to see that one of the

first projects announced by the Advanced Research Projects Agency for Health (ARPA-H) is a research program called Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO), which hopes to develop injectable bone and cartilage technologies and replacement joints built from human cells. In 2023, NIAMS assumed leadership of the Regenerative Medicine Innovation Project (RMIP), which NIDCR participates in, and a workshop was held in November to discuss the future of the program, including lessons learned from RMIP and the potential for an NIH-wide regenerative medicine initiative, among other topics. Dr. Criswell discussed two other AMP-based regenerative medicine programs that NIDCR and NIAMS are both involved in, the Bespoke Gene Therapy Consortium, which is focused on rare diseases, and the newer, more broadly focused Cell-Based Therapy Consortium, which is currently in the design phase.

Dr. Criswell also briefly noted examples of collaboration between the two Institutes' intramural research programs on specific studies, participating in an intensive grant-writing workshop co-sponsored by the NIDCR Office of Training and Education, and the NIH Three-Minute Talks science communication competition. Dr. Criswell concluded her remarks by providing an overview of NIAMS' ongoing strategic planning efforts. She encouraged anyone interested in learning more about the Institute's funding opportunities to reach out for more information.

Discussion

In reference to earlier discussion topics, Dr. Criswell highlighted NIAMS' Research Innovation for Scientific Knowledge (RISK) for Musculoskeletal Disease, which encourages high-risk, high-reward research initiatives, and the Stephen I. Katz Early-Stage Investigator Research Project Grant, which explicitly does not allow applications for which preliminary data already exists. In response to a question from Dr. Krebsbach, Dr. Criswell discussed how NIAMS tries to minimizing competition over resources by seeking collaborative funding sources outside the Institute and by stressing to the program officers that the goal is for good research to get funded, irrespective of where that funding comes from. Dr. Terry Dickinson asked Dr. Criswell for her thoughts on how to move the field of TMJ dysfunction research forward. Dr. Criswell said that, in line with Dr. Bertagnolli's comments earlier, the field needs to get to a place where it is generating high-quality data and where the research and clinical communities and professional societies are working together towards the same goal. NIDCR's goal of fostering a whole-person medical approach that incorporates dental care will be also helpful in the overall effort of breaking down silos. Dr. Webster-Cyriaque pointed to the TMD IMPACT initiative as an example of a program trying to identify real-world solutions, and both NIAMS and NIDCR are involved in this effort. Similar lessons about community-wide coordination on research programs can be applied to other focus areas that NIAMS and NIDCR share, such as Sjögren's disease research and disease-specific regenerative medicine applications.

VI. NIDCR DIRECTOR'S REPORT

Dr. Webster-Cyriaque's written Director's Report was provided to the Council members and is available on the NIDCR website (http://www.nidcr.nih.gov).

Dr. Webster-Cyriaque opened her report by extending her thanks to the departing Council members on behalf of the Institute and welcoming the two new members, Drs. Duda and Koo. Dr. Webster-Cyriaque then provided an update on recent leadership changes elsewhere at NIH. Dr. Kathleen Neuzil was recently named the new Director of the Fogarty International Center and NIH Associate Director for International Research. Earlier this year, Dr. Sean Mooney was hired as the next Director of NIH's Center for Information Technology. Dr. Webster-Cyriaque also provided an update on staff changes at NIDCR since the last Council meeting. In the Office of the Director, Dr. Dara Kessler has been named Chief of Staff, Dr. Sharon Jackson has joined as a Senior Advisor within the Office of the Clinical Director, and Dr. Lu Wang has been named Senior Advisor for Data Science. Within the Division of Extramural Research, Dr. Amanda Melillo has been promoted to Deputy Director, Ms. Alicia Chou has been named Director of the Translational Genetics and Genomics Program, Dr. Jill Mattia has been named Director of the Behavioral and Social Sciences Research Program and Dr. Bill Elwood is now Chief of the Behavioral and Social Sciences Research Branch.

Dr. Webster-Cyriaque discussed noteworthy trans-NIH activities and updates. As touched on by Dr. Bertagnolli, the NIH Common Fund is developing a network aimed at improving health outcomes and research equity by integrating research into primary care settings. The basic structure of the network will be to expand enrollment of existing studies and eventually develop pilot studies that partner with primary care providers and community partners in under-resourced areas. The goals are to establish a disease-agnostic primary-care focused clinical research network, integrative innovative research with routine clinical care in real-world settings, and to create a foundation for sustained community engagement.

Dr. Webster-Cyriaque also updated the Council on NIH's new scientific peer review criteria framework. As has been discussed at previous Council meetings, NIH has implemented a simplified application peer review framework for Research Project Grants, reducing the number of main review factors from five to three. Those three factors are importance of the research, rigor and feasibility, and expertise and resources, the last of which is unscored. A similar simplification process is taking place for the review of training grants, and those changes will be implemented at the beginning of next year.

Dr. Webster-Cyriaque also informed the Council of the HEAL Initiative's PURPOSE Network (PURPOSE stands for "Positively Uniting Researchers of Pain to Opine, Synthesize, & Engage"), which is a digital platform that aims to act as a centralized community and resource hub for research trainees and researchers across the continuum of basic, translational, and clinical pain research. Dr. Webster-Cyriaque believes this is an opportunity where DOC researchers can and should be represented.

The President signed into the law the federal government's FY 2024 appropriations budget since the last Council meeting. In the final budget, the NIH received a \$300M increase from last year, to approximately \$47.08B, but NIDCR's budget remained essentially flat, at around \$520.16M. The President's budget request for FY 2025 calls for a small increase to the FY 2024 enacted level. As is typical, most of the budget will go towards funding extramural Research Project Grants. Dr. Webster-Cyriaque provided a snapshot of NIDCR's budget trends over the past decade. Although the funding level has continued to increase at a nominal level, when adjusted for inflation

the Institute has seen decreases in its budget over the last several years. Nevertheless, NIDCR has strived to keep its funding rates steady and has increased its early-stage investigator (ESI) funding rate in the last few years. NIH and NIDCR have also increased their funding to dental schools in recent years.

On the legislative outreach front, Dr. Webster-Cyriaque announced that the U.S. Senate passed a bipartisan resolution in March honoring NIDCR's 75th anniversary, and a companion resolution has been introduced in the House of Representatives. In April, the ACT for NIH Foundation held a 10th anniversary congressional reception celebrating the foundation's decade of advocacy. In May, AADOCR and Friends of NIDCR sponsored a congressional reception in recognition of the Institute's 75th anniversary. On June 14, NIDCR will present as part of the NIH Office of Legislative Policy and Analysis's bimonthly virtual Lunch and Learn series for congressional staffers. The topic of the webinar will be TMD and orofacial pain. NIDCR leadership has also been very active reaching out to the DOC community and related entities via participation in conferences, academic events, and NIH-wide activities.

Dr. Webster-Cyriaque highlighted three NIDCR NOSIs relevant to the themes that have been discussed at Council: Translating Biomaterials-Based Technologies to Commercially Viable Products (NOT-EB-24-001), Promoting Data Reuse for Health Research (NOT-OD-24-096), Women's Health Research (NOT-OD-24-079). She also noted funding opportunities for the Rare Disease Clinical Research Consortium and the NIDCR Mentoring Network to Promote a Diverse DOC Research Workforce, among others. Dr. Webster-Cyriaque also encouraged the community to consider applying for Common Fund-supported initiatives such as the NIH Director's Pioneer Award, New Innovator Award, Early Independence Award, and Transformative Research Award.

Dr. Webster-Cyriaque concluded the Director's Report by presenting research highlights from NIDCR-funded studies. These included work on nanozyme-based robotics approaches for targeting fungal infections, predictive modeling for TMJ osteoarthritis disease progression, a clinical trial to assess caries arrest by the use of silver diamine fluoride in children, a survival analysis of posterior composite restorations based on data from the National Dental Practice-Based Research, the use of hair biomarkers among Alaska Native children to identify variation in added sugar intake, and molecular mechanobiology approaches to the study of organogenesis.

Discussion

Council members discussed with Dr. Webster-Cyriaque NIDCR's efforts to incorporate general dentistry into its primary care integration initiatives, and how the Institute and NIH as a whole has made a commitment to prioritize support for ESIs. Dr. Shum pointed to the NIH's Next Generation Research Initiative as one of the drivers for ESI support at the NIH-wide level. Dr. DiPietro emphasized the importance of providing continued support for junior investigators, for example, at the continuing renewal application stage. Dr. Koo highlighted the post-training, postdoc phase as another area where additional mentoring and support can be particularly impactful in order to enable a "soft landing." In response to a question from Dr. Christopher Fox, IADR/AADR, Dr. Webster-Cyriaque discussed NIDCR's ongoing research on the topic of craniofacial defects, some of which she believes will be good candidates for CRISPR/Cas9

approaches. She also highlighted the importance of FaceBase and collaboration with other organizations in this arena.

VII. ORAL HEALTH RESEARCH WORKFORCE WORKING GROUP REPORT

Dr. King invited Dr. Dana Graves, co-chair of the Council's Oral Health Research Workforce Working Group, to deliver the report.

Dr. Graves first reminded the Council of the Working Group's charge, which was 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." The Working Group met on a near-monthly basis over the course of 21 months. To assess the current landscape and identify success factors and gaps, the Working Group issued a Request for Information (RFI) and conducted a robust series of listening sessions and discussions with stakeholders from the broader DOC research community.

The Working Group considered NIDCR's current research training and career development programs, which include individual awards, institutional awards, and participation in the NIH loan repayment program. The Working Group also reviewed NIDCR-supported trainee outcomes and noted that a large portion of dual degree candidates leave their training programs and enter private practice, and that less than 10% of T and F trainees who do complete their program received K awards or RPGs. However, three-quarters of dual degree K08 awardees remained employed in research. Feedback from the RFI and listening sessions indicated that individual level factors or strategies underlying successful outcomes for trainee outreach and recruitment, and the structure of successful training programs are unknown. Some trainees felt disconnected from the larger research community and expressed that mentorship is lacking during career transitions. There was also the belief that institutions do not incentivize or provide the support structure for mentors. Respondents also found there to be a wide variety in the quality of training and career development programs and a lack of academic positions that effectively combine clinical instruction and protected research time. Additional challenges for dual-degree scientists = included funding difficulties and lack of awareness of NIH/NIDCR funding opportunities. Financial constraints were another theme, both personal indebtedness and the uncertainty of sustained grant support. The pay disparity between private practice and academia was raised as another financial factor.

Dr. Graves presented the Working Group's recommendations, which prioritized improving mentoring, increasing trainee success rate, enhancing DOC training opportunities to make careers in DOC research more appealing, and increasing interdisciplinary research in emerging fields. At the programmatic level, the Working Group recommended that NIDCR develop funding opportunities that support collaborative research in which an ESI and experienced research serve as PI and co-investigator, respectively; expand loan repayment programs and increase awareness of these programs; and develop programs to assist dual-degree graduates in transitioning from training to faculty positions and help them stay in academia.

The Working Group's recommendations to enhance career opportunities were to promote and develop interdisciplinary training opportunities, develop additional research opportunities on

the connection between oral and systemic health, and increase collaboration with other organization to promote networking and awareness of research opportunities. Building off this last topic, the Working Group recommended that NIDCR establish an office to enhance collaboration with professional societies, foundations, dental schools, and industry. The Working Group found that professional societies, foundations, dentals schools, and industry were eager to collaborate with NIDCR but felt this process could be made more efficient and effective by establishing a dedicated office to facilitate such collaborations. These partnerships could be on research, mentoring, training, career development, product development, among other topics.

Dr. Graves noted that there were a number of areas that the Working Group felt that it could not make specific recommendations because of a lack of available data, such as what factors and characteristics lead to successful training programs and trainees, and why trainees choose to leave research. To address this, the Working Group recommended that NIDCR establish a center to assess research training and career outcomes. This center could develop and monitor outcome metrics, track trainees over time, and serve as a data repository. Data collected by this center could ultimately be used to inform future NIDCR programs and enable the Institute to make more efficient use of its training dollars. Finally, the Working Group also made a number of recommendations regarding recruitment and retention of clinician scientists. These included developing new programs to enhance mentoring across career stages, creating stronger financial incentives, and increasing training opportunities via collaborations with other organizations.

Discussion

Dr. Krebsbach observed that DOC research seems to overemphasize the need for dualdegree status in a way that other fields of biomedical research do not. There are many MDs who have gone on to successful research careers despite not obtaining a PhD because they have been provided several years of post-degree scientific training and mentoring. He asked if such a scenario in the field of DOC research was contemplated by the Working Group. Dr. Graves said that the recommendation to increase the variety of training programs was meant to include alternative, non-PhD pathways. Many stakeholder organizations are interested in participating in this space, which could be assisted by the proposed office to facilitate collaboration. Dr. Nor added that DDS/PhD candidates often feel they need to obtain specialty training to obtain research-intensive positions in dental schools. He also described a program at the University of Michigan School of Dentistry in which new tenure-track hires are supported by a three-member committee of experienced faculty to help them launch their careers. The Council also discussed how to rethink financial incentive structures in DOC research, particularly for clinician scientists and ESI. Dr. Graves suggested that NIDCR has a role to play in providing assistance for these individuals in situations where dental schools are constrained by their own budgets. Dr. Grave and Dr. DiPietro emphasized that the recommended NIDCR center for outcomes assessment could play an important role in answering some of the questions being raised by the Council about the optimal training path.

Dr. Webster-Cyriaque agreed with the Working Group's emphasis on collaboration but cautioned that NIDCR has to be cognizant about conflict-of-interest concerns. The Foundation for NIH is an important intermediary that can help facilitate the relationships the Working Group

has described. NIDCR staff discussed with Dr. Graves and the Council the recommendation for award program that partners an ESI with a senior investigator as co-investigator. Council members were in support of the recommendation and saw it as addressing an important gap, but staff sought clarity on the structure of the proposed mechanism. Dr. Nor pointed out that the recommended center for outcomes analysis could look into the effectiveness of comparable multi-PI programs. Council members debated whether the proposed program would need to be an RFA and concerns about how multi-PI studies are viewed by tenure committees. Dr. Graves said that the trend in research is towards increased collaborative and team science and tenure committees will have to account for that.

VIII. 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 (future research initiatives). NIDCR staff presented one concept, and designated Council members led the discussion, as summarized below.

Advancing Precision Imaging for Enhanced Diagnosis and Treatment of Oral Lesions

Dr. Zhong Chen, Director, Oral & Salivary Cancer Biology Program, DER, and Dr. Orlando Lopez, Director, Dental Materials & Biomaterials Program, DER, presented the concept, which is a reissuance of the Precision Imaging of Oral Lesions Notice of Funding Opportunity (NOFO that was first issued in 2018 and reissued in 2021. Dr. Chen provided a brief background of the concept. Histopathology remains the gold standard for the diagnosis and management of pathological lesions in the oral cavity and oropharynx, but is limited by lack of sensitivity and specificity, and by reliance on clinician judgment. NIDCR believes that recent advances in precision and digital imaging offer promising solutions to address unmet needs. The program has received over 100 applications since its creation, and it has funded 14 awards. Dr. Chen highlighted continued opportunities for research, including the use of imaging biomarkers for early detection, personalized treatment planning, assessing response to management, intraoperative imaging for precision surgery, and early disease recurrence detection, among others.

The Council's lead discussants for the concept were Drs. Nor and Visel. Dr. Nor said he believes the concept is timely and extremely important to addressing the subjectivity of current diagnostics methods. The concept also stimulates translational work on new imaging modalities and has potential impact beyond DOC research. Dr. Visel agreed that the concept is timely and well-justified. He also noted that the concept aligns with recommendations of the Council's Data Science Strategy Working Group, and he encouraged NIDCR staff to consult that report for data science-specific aspects of the concept, particularly with an eye towards ensuring AI readiness and reuse of data by future technologies. Dr. Lopez agreed that those considerations are important, and staff will work with the Working Group's report as it further develops the program.

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

IX. REVIEW OF APPLICATIONS

National Institute of Dental & Craniofacial Research

Council Applications Recommended for Further Consideration

May 22, 2024

Total	Requested	Approved
Number	899	582
Dollars	\$ 345,446,797	\$ 221,621,439

X. ADJOURNMENT

CERTIFICATION

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

Dr. Jennifer Webster-Cyriaque Acting Chairperson National Advisory Dental and Craniofacial Research Council Dr. Lynn King Executive Secretary National Advisory Dental and Craniofacial Research Council

ATTACHMENTS

I. Roster of Council Members

MEETING ROSTER

National Advisory Dental and Craniofacial Research Council NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH NADRC

Agenda Seq Num - 494054 05/21/2024 - 05/22/2024

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-22-044, including removal of the application from immediate review.

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