

National Institute of Dental and Craniofacial Research

National Advisory Dental and
Craniofacial Research Council

Minutes of Meeting
May 18, 2022

Via Videoconference

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

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NATIONAL INSTITUTES OF HEALTH
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH

MINUTES OF THE
NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL

May 18, 2022

The 230th meeting of the National Advisory Dental and Craniofacial Research Council (NADCRC) was convened on May 18, 2022, at 10:00 a.m., via videoconference. The meeting was open to the public from 10:00 a.m. until 2:18 p.m.; it was followed by the closed session for Council business and consideration of grant applications from 2:15 p.m. until adjournment at 4:30 p.m. Dr. Rena D'Souza presided as Chair.

OPEN SESSION

Members Present

Dr. Kathryn Marie Albers
Dr. Joel Collier
Dr. David J. Couper
Dr. Frank Ebetino
Dr. Raul I. Garcia
Dr. Lee A. Niswander
Dr. Jacques Nor
Dr. Wenyuan Shi
Dr. Amy Smith Slep
Dr. Clark M. Stanford
Dr. Joel Strom
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. Matthew P. Hoffman, Scientific Director, Division of Intramural Research (DIR)
Dr. Janice S. Lee, Clinical Director, DIR
Mr. John Prue, OD, Director, Office of Information Technology (OIT)
Dr. Lillian Shum, Director, Division of Extramural Research (DER)
Ms. Kathleen Stephan, OD, Associate Director for Management/Executive Officer
Mr. Jeff Ventura, OD, Director, Office of Communications & Health Education (OCHE)
Ms. Tamera Addison, OD, Office of Administrative Management (OAM)
Ms. Alexandria Alfarano, DER
Mr. Hosam Alraqiq, OD, OSPA
Dr. Lorena Baccaglini, DER, Center for Clinical Research (CCR)

Ms. Carol Beasley, OD, OAM
Dr. Nisan Bhattacharya, DEA, Scientific Review Branch (SRB)
Dr. Anissa Brown, DEA, Research Training and Career Development Branch (RTCDB)
Dr. Preethi Chander, DER, Integrative Biology and Infectious Diseases Branch (IBIDB)
Ms. Tiffany Chen, OD, OCHE
Dr. Zhong Chen, DER, IBIDB
Mr. Starsky Cheng, OD, FMB
Dr. Aiwu Cheng, DEA, SRB
Ms. Jennifer Chi, OD, Office of Clinical Trials Operations and Management (OCTOM)
Ms. Alicia Chou, DER, Translational Genomics Research Branch (TGRB)
Mr. Kevin Chu, OD, OIT
Ms. Vickie Contie, OD, OCHE
Ms. Michelle Cortes, DER, IBIDB
Ms. Mary Daum, OD, OCHE
Mr. Bret Dean, OD, OAM
Ms. Sharie Diggs, OD, OAM
Mr. Jimmy Do, OD, Financial Management Branch (FMB)
Dr. Alicia Dombrowski, DEA
Dr. Catherine Evans, OD, OCHE
Dr. Dena Fischer, DER, Director, CCR
Dr. Leslie Frieden, DEA, RTCDB
Dr. Melissa Ghim, DER, IBIDB
Mr. Harry Grant, DIR
Dr. Margaret Grisius, DER, CCR
Mr. Joel Guzman, DER
Dr. Sue Hamann, OD, OSPA
Ms. April Harrison, DEA, GMB
Dr. Marika Heinicke, OD, OCTOM
Mr. Gabriel Hidalgo, DEA, GMB
Dr. Tanya Hoodbhoy, DER, IBIDB
Mr. Tem Ibidapo, OD, OIT
Ms. Joy Jackson Farrar, OD, Events Management
Ms. Petronilla Joseph, DIR
Dr. Leila Khaki, DER, Behavioral and Social Sciences Research Branch (BSSRB)
Dr. Orlando Lopez, DER, IBIDB
Ms. Amber Lowery, OD, OMB
Ms. Jayne Lura-Brown, DER
Ms. Susan Macharia, DEA
Mr. Mike Martin, OD, OAM
Dr. Tamara McNealy, DER, IBIDB
Ms. Susan Medve, DEA, GMB
Dr. Yun Mei, DEA, SRB
Dr. Amanda Melillo, DER, IBIDB
Ms. Amy Mhatre-Owens, OD, OCTOM
Dr. Niki Moutsopoulos, DIR
Ms. Mable Nee, OD, FMB

Mr. Paul Newgen, DEA, GMB
Ms. Anna Nicholson, OD, OCTOM
Mr. Thomas O'Farrell, DEA, SRB
Ms. Linda Orgain, OD, OCHE
Mr. Conor O'Shaughnessy, OD, OAM
Ms. Lisa Peng, OD, OIT
Ms. Debbie Pettitt, DEA, GMB
Mr. Ben Rassuli, OD, OIT
Dr. Elise Rice, DER, BSSRB
Dr. Melissa Riddle, DER, BSSRB
Dr. Jose Ruiz, DEA, SRB
Ms. Diana Rutberg, DEA, GMB
Dr. Yasaman Shirazi, DEA, SRB
Dr. Ashley Smith, OD, OIT
Mr. Michael Somes, OD, OCHE
Dr. Katie Stein, DER, TGRB
Dr. Shoba Thirumangalathu, DEA, RTCDB
Dr. Jason Wan, DER, IDIDB
Dr. Lu Wang, DER, CCR
Dr. Hongen Yin, DER, TGBR

National Institutes of Health

Dr. Lawrence Tabak, Acting NIH Director
Dr. Susan Gregurick, Associate Director for Data Science; Director, Office of Data Science Strategy (ODSS)

Guests

Mr. Matthew Miller, Neal R. Gross & Co.
Dr. David Yule, University of Rochester

I. WELCOME AND INTRODUCTIONS

Dr. Lynn King, Director of Division of Extramural Activities (DEA) and Advisory Council Executive Secretary, called the open session of the 230th Advisory Council meeting to order at 10:00 a.m. and reviewed the meeting logistics. Dr. Rena D'Souza, Director, NIDCR, welcomed attendees to the Council meeting. She noted that the meeting was taking place in the aftermath of the horrific racially-motivated mass shooting in Buffalo, New York. Dr. D'Souza read the note NIDCR sent to its staff offering its support and intent to combat systemic racism throughout society in general, and the biomedical research workforce in particular.

Dr. D'Souza remarked that this meeting would be the final Council meeting for four members: Drs. Kathryn Albers, David Couper, Clark Stanford, and Joel Strom. She thanked them for their long-time service and looked forward to continue interaction on topics of shared interest to the community in the future. New Council members will be announced at the next meeting. Dr.

D'Souza also welcomed Dr. Anissa Brown as the new chief of the NIDCR Research Training and Career Development Branch.

Dr. D'Souza reviewed the agenda for the day's meeting. She also provided a brief update on the Council's working groups, which are just getting under way. There will initially be two working groups: one on the data science, chaired by Dr. Axel Visel, and a second on dental workforce training, chaired by Dr. Dana Graves of the University of Pennsylvania.

II. APPROVAL OF MINUTES FROM PREVIOUS MEETING

Dr. King asked Advisory Council members if there were corrections or comments on the minutes of the January 25, 2022 Advisory Council meeting. There were no comments and the Advisory Council voted unanimously to approve the minutes.

III. REMARKS FROM THE ACTING NIH DIRECTOR

Dr. D'Souza welcomed Dr. Lawrence Tabak, Acting NIH Director and former Director of NIDCR, and invited him to deliver his remarks to the Council. Dr. Tabak began by noting a series of personnel changes in NIH leadership. Dr. Francis Collins, long-time NIH Director, stepped down from that role late last year. Upon Dr. Tabak being named Acting Director, Dr. Tara Schwetz became Acting NIH Principal Deputy Director, Dr. Courtney Aklin was named NIH Acting Associate Deputy Director, and Dr. Lyric Jorgenson was appointed Acting Director of the NIH Office of Science Policy. Dr. Tabak spoke highly of this group's ability and skill in taking over these roles in this period of transition.

Dr. Tabak then provided an overview of NIH's funding trends over recent years. Since 2014, NIH has seen sustained growth in congressional appropriations per the Biomedical Research and Development Price Index (BRDPI). Congressional hearings have begun for the next federal budget and congressional support for NIH's mission remains strong. Dr. Tabak presented a pie chart indicating NIH's main funding areas, which showed that the majority of NIH's funds go towards research project grants. The Intramural Program represents approximately 10-11% of NIH's overall budget. Dr. Tabak noted that this data does not include the COVID-19 emergency supplemental funds that NIH has received since 2020. He then reviewed NIH's FY 2022 appropriations from Congress, which represented a 5.2% increase over FY 2021, while individual ICs saw a general increase of 3.4%. For FY 2023, the President's proposed budget includes a \$16.3 billion increase, which would be a 35.4% increase. This increase would include \$12.05 billion for pandemic preparedness and \$4 billion to stand up the Advanced Research Projects Agency for Health (ARPA-H). Despite this large overall increase, Dr. Tabak cautioned that some ICs might see flat budgets or decreased budgets compared to the FY 2022 omnibus bill in the President's proposed budget, but negotiations with the White House and Congress remain ongoing and Dr. Tabak is hopeful NIH ICs will see FY23 funding increases in line with recent budgets.

Dr. Tabak shifted to provide an update on NIH's response to the COVID-19 pandemic. In April 2020, NIH stood up the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership to speed up the development of COVID-19 interventions. Dr. Tabak reviewed the status of the numerous agents being developed and tested under the aegis of the ACTIV initiative. Despite only a couple of efficacious agents being discovered thus far, Dr. Tabak considers this initiative to be highly successful because finding out which interventions do not work is as important as finding out which ones do work. NIH has also created the REsearching COVID to Enhance Recovery (RECOVER) Initiative, which aims to rapidly improve the understanding of, and ability to predict, treat, and prevent post-acute sequelae SARS-CoV-2 infection (PASC), also known as Long COVID. Dr. Tabak also briefly described the ACTIV Tracking Resistance and Coronavirus Evolution (TRACE) initiative, which works to identify emerging variants of SARS-CoV-2, as well as NIH and NIAID's efforts to develop and maintain COVID-19 treatment guidelines.

Dr. Tabak then spotlighted some of the many NIDCR research highlights from the past year. In the extramural realm, NIDCR has played an important role in the Helping to End Addiction Long-term (HEAL) Initiative, and is supporting two important initiatives under the HEAL umbrella: Developing Quantitative Imaging and Other Relevant Biomarkers of Myofascial Tissues for Clinical Pain Management, and the Restoring Joint Health and Function to Reduce Pain (RE-JOIN) Consortium. On the extramural side, Dr. Tabak highlighted a recent study by Dr. Mark Hoon and colleagues on how sensory nerves respond to inflammation and cause the sensation of itch with therapeutic implications for severe dermatological conditions. He also discussed work of Drs. Kelly Ten Hagen and Nadine Samara, et al., on how certain enzymes are involved in homeostasis and adiposity in humans and mouse models show that silencing that enzyme leads to decreased adiposity, among other effects.

Dr. Tabak next provided an update on NIH's efforts to encourage and support diversity, equity, inclusion, and accessibility (DEIA) on its campus and in its workforce. Following a presidential executive order, a government-wide strategic plan on DEIA was released in late 2021, which called on all federal agencies to develop a DEIA strategic plan. NIH was already taking such a step before the executive order, which began with the Diversity at NIH Work Group and led to the founding of the NIH UNITE Initiative, which "aims to establish an equitable and civil culture within the biomedical research enterprise and reduce barriers to racial equity in the biomedical research workforce." Dr. Tabak noted that Dr. D'Souza serves on one of the UNITE committees and briefly reviewed some recent and ongoing UNITE activities, as well as existing NIDCR extramural funding opportunities to enhance diversity.

Finally, Dr. Tabak updated the Council on the planned Advanced Research Projects Agency for Health (ARPA-H), a new health research entity within the Department of Health & Human Services (HHS). The ARPA-H director will be a presidential appointee who will report to the HHS Secretary. Congress is still debating funding levels and whether ARPA-H will exist within NIH or as a separate organization within HHS.

Discussion

Dr. D'Souza invited Dr. Tabak to comment on the search for a new NIH Director and the recent increase in for-profit or proprietary dental schools. Regarding the latter, Dr. Tabak expressed the hope that these schools engage in scholarly activities while also training dental professionals. Dr. Raul Garcia asked whether NIH needs to update the 2019 Notice of NIH's Interest in Diversity to include the LGBTQ+ community, particularly in light of the 2021 executive order. Dr. Tabak agreed that would be a move worth considering. Dr. Tabak also went into further detail on the structure and mission of ARPA-H, which is designed to support more aggressive and fast-paced, high-impact, cutting edge research. Dr. Jennifer Webster-Cyriaque asked Dr. Tabak to opine on lessons learned from the COVID-19 for the medical research enterprise. Among other lessons, Dr. Tabak underscored the importance of team science.

IV. IMMUNITY AT THE ORAL BARRIER

Dr. King introduced Dr. Niki Moutsopoulos, an Investigator in the NIDCR Oral Immunity & Infection Section, to provide an overview of her group's work and some recent scientific highlights.

Dr. Moutsopoulos' lab's main focus is exploring fundamental aspects of barrier immunity. Barriers include the oral mucosa, skin, lung, intestinal mucosa, which are regularly exposed to the outside environment and have to protect the host and tolerate innocuous agents. Dr. Moutsopoulos' lab focuses on the oral mucosa, and while mammalian barriers share many traits, most of the diseases they are confronted with are very tissue-specific. The oral mucosal barrier, in particular, is a site of first encounters, whether by food or through airborne allergens, particles, and microbes.

In this context, Dr. Moutsopoulos' lab primarily focuses on periodontitis, which is considered a microbe-triggered inflammatory disease. Dr. Moutsopoulos' provided a brief overview of the symptoms and course of periodontal disease. Questions remain about the best pathogenic mechanism for targeting this disease and there is a lack of targeted therapies. Dr. Moutsopoulos highlighted access and other public health factors when it comes to periodontal disease; studies show that regular dental care can reduce the incidence of periodontitis. However, interventions and further mechanistic understanding of the disease is still needed. Discovery in this arena can also advance understanding of host microbiome biology in general.

Dr. Moutsopoulos' described how her team leverage's the NIH Clinical Center's expertise in rare genetic diseases that enables researchers to unify a bedside to bench approach. Her team focuses on a specific immune pathway called the Th-17 neutrophil axis. Dr. Moutsopoulos described the basic immunology of this pathway and the central role of neutrophils in antimicrobial defense. Dr. Moutsopoulos' teams work on patients with neutrophil deficiency and neutrophil overabundance has led her to believe that the proper balance of neutrophils is crucial to periodontal homeostasis.

Dr. Moutsopoulos focused her presentation on her lab's recent work, with other colleagues, on plasminogen deficiency, which is a rare syndrome with widespread mucosal immunopathology, including oral lesions, bone loss, and periodontitis. Plasminogen is the inactive version of plasmin, and its main role is to degrade fibrin, which is vital to maintaining tissue homeostasis and clotting. Plasmin degrades fibrin after clotting to enable tissue repair; lack of plasmin can lead to chronic inflammation. Dr. Moutsopoulos then described how her team used Dr. Thomas Bugge's plasminogen-deficient mouse model to study how plasminogen deficiency leads to mucosal immunopathology. These studies have shown that plasminogen deficiency results in spontaneous periodontal bone loss, that plasminogen-deficient mice have persistent fibrin deposits in gingiva, and that plasminogen deficiency-associated periodontal bone destruction is mediated by fibrin. Dr. Moutsopoulos described how a postdoctoral fellow in her lab, Dr. Lakmali Silva, conducted a series of assays that showed fibrin deposition and an accumulation of neutrophils surrounding the fibrin deposits. This led the research team to ask whether neutrophil-fibrin interactions are mediating tissue pathology, and if inhibition of fibrin-neutrophil interaction can prevent or treat oral disease. Further studies using a fibrin mutation showed that the inhibition of fibrin-myeloid cell interaction rescues bone loss in mouse models, and even resolve natural bone loss that would occur in wild-type mice. They also found that the fibrinogen-gamma domain is crucial for neutrophil engagement and activation. Dr. Moutsopoulos also briefly described Dr. Silva's investigations on the role of NETosis in periodontal immunopathology. Finally, Dr. Moutsopoulos discussed her lab's recent work on the role of neutrophils and fibrin in non-Mendelian periodontitis, and potential future work on implications for more common periodontal diseases.

Discussion

Dr. D'Souza asked if Dr. Moutsopoulos is looking at possible multigenic influences. Dr. Moutsopoulos said that was a possible complicating factor, but her team is looking for genes that might play a more dominant role. Dr. Jacques Nor asked for Dr. Moutsopoulos's thoughts about locally targeting the plasminogen pathway. Dr. Moutsopoulos said fibrin accumulation and fibrinolysis would be a bigger concern at the local level, perhaps via a fib-gamma binding antibody. Ideally, patients would be stratified by plasminogen variations and whether the variations have functional outcomes. In response to a question from Dr. Matthew Hoffman, Dr. Moutsopoulos said that looking at microbiome and periodontal pathogen interaction would be one of her teams' next steps.

V. REPORT OF THE DIRECTOR, NIDCR

Dr. D'Souza's written Director's Report for the May 2022 Council meeting was provided to the Council members and is available on the NIDCR website (<http://www.nidcr.nih.gov>).

Dr. D'Souza began her presentation by noting that 2023 will be the 75th anniversary of the founding of NIDCR, and the Institute is currently preparing for celebratory events, for which she encouraged Council input and participation. She briefly noted that NIDCR's budget outlooks strong and the Institute continues to strive to balance research and training programs. Within both fields, NIDCR also works hard to encourage and maintain diversity of programs and participants.

Dr. D'Souza then announced that she will be delivering a presentation to the upcoming NIH IC Directors meeting. She provided a brief overview of the remarks she plans to deliver at the meeting, which will emphasize the importance of integration and a systems approach to oral health.

Two key reports in recent years have helped shape the oral health community's approach to oral health: The Lancet Commission's 2020 report, "Oral Health at a Tipping Point," and the NIH's "Oral Health in America: Advances and Challenges," which was released in December 2021. The report was originally to be managed by the Office of the Surgeon General and was intended to be a follow-up to the 2000 Surgeon General's Report on Oral Health. However, the report was delegated to NIH and NIDCR in the aftermath of the COVID-19 public health emergency. Dr. D'Souza reviewed some of the key findings regarding the changing landscape of oral health since the Surgeon General's 2000 report, "Oral Health in America." One important conclusion is that different populations in America experience oral health differently. Demographics, delivery of services, disease trends, and technologies have all changed drastically in the past 20 years. Dr. D'Souza also highlighted negative trends or continued burden in minority populations, particularly American Indian/Alaska Native communities, as well as untreated early childhood caries. There is also a powerful connection between oral health, mental health, and the opioid crisis; dental conditions are the second highest reason for patients being prescribed opioids.

Dr. D'Souza then discussed the centrality of diversity, equity, inclusion, and accessibility (DEIA) to NIDCR's mission. She updated the Council on the Institute's 2021-2016 Strategic Plan, which tasks NIDCR with advancing research and training priorities with an overarching theme of translation. The plan sets a new mission, vision, and emphasis on core values and metrics. NIDCR has established a DEIA Public-Private Partnership Working Group to provide recommendations on how to increase participation and diversity at every level of the oral health training pipeline. Dr. D'Souza noted that NIDCR is one of the few ICs that trains fellows, and briefly discussed NIDCR's Clinical Research Fellowship and the Dental Public Health Residency & Fellowship. She described NIDCR's research training and career development leadership and the Institute's intramural and extramural programs.

Dr. D'Souza then reviewed the recent leadership changes at NIDCR. Dr. Jennifer Webster-Cyriaque is the new NIDCR Deputy Director and Dr. Renee Joskow has joined NIDCR as a Senior Advisor. She reviewed recent scientific highlights from NIDCR's Intramural Program, which is led by Dr. Matthew Hoffman and is comprised of 7 principal investigators, including Dr. Moutsopoulos, who the Council heard from earlier. Dr. D'Souza then shifted to NIDCR's Extramural Program, led by Dr. Lillian Shum, where the Institute emphasizes connecting the dots through a systems approach. Dr. D'Souza discussed how the Institute is thinking about leveraging the National Dental Practice-Based Research Network (PBRN) to enhance translation, perhaps through expanding further into community-based public health in the manner of NIH's Community Engagement Alliance (CEAL) Against COVID-19 Disparities. FaceBase and the Dental, Oral and Craniofacial Tissue Regeneration Consortium (DOCTRC) are other NIDCR entities that can be leveraged as part of the new focus on systems approach, as well as the NIH-wide Accelerating Medicines Partnership on Autoimmune and Immune-Mediated Diseases (AMP-AIM), which include Sjögren's disease as one of its focus areas. Oral HPV and

temporomandibular joint disorder (TMJD) are other disease areas, among others, that are ripe for engagement with sister ICs on collaborative, systems-based research efforts.

Dr. D'Souza concluded by discussing the charge of NIDCR's Council working groups, which will tackle the topics of data science and oral health research training. The overarching goal of the working groups is to give a voice to the extramural community on how NIDCR can help impact these crucial areas of the oral health research enterprise.

VI. CONNECTING DATA, ENHANCING SOFTWARE, AND CREATING A DIGITAL DATA HEALTH ECOSYSTEM

Dr. D'Souza introduced Dr. Susan Gregurick, NIH Associate Director for Data Science and Director of the Office of Data Science Strategy (ODSS), to deliver her presentation on data science initiatives and policy at NIH.

Dr. Gregurick opened her talk by outlining the NIH Strategic Plan for Data Science, which serves as a North Star for ODSS. In support of the Strategic Plan, ODSS provides strategic leadership and coordination, works to develop and implement NIH's vision for an integrated and modernized data ecosystem, strives to foster a diverse and skilled data science workforce, and grows strategic partnerships to discover and promulgate new data science technologies and methods.

Dr. Gregurick updated the Council on NIH's new data management and sharing policy. The final policy was announced in October 2020 and will become effective on January 25, 2023. The policy requires researchers to submit a Data Management and Sharing Plan that describes how their data will be preserved and shared. While NIH strongly encourages a maximal sharing policy, and does mandate the ways in which data must be managed, the policy does not require all data to be shared (e.g., lab notebooks, preliminary analyses, case report forms, etc., are excluded). It is expected that data should be made available no later than publication or end of award. Dr. Gregurick then briefly discussed the key elements of a Data Management and Sharing Plan, such as which repositories will be used and how the data will be monitored, among others.

NIH adheres to the principles that biomedical research data should be findable, accessible, interoperable, and reusable (FAIR) while emphasizing transparency, responsibility, user-focus, sustainability, and technology (TRUST). Dr. Gregurick discussed how ODSS provides support for existing repositories across NIH ICs to come into alignment with these principles. The Office also funds efforts to make NIH repositories ready for artificial intelligence and machine learning applications. Dr. Gregurick noted that NIDCR's FaceBase consortium has taken advantage of these ODSS awards to update its FaceBase Hub repository. She described other ODSS-supported initiatives to encourage FAIR and TRUST principles. Other related programs include the Data Repository and Knowledgebase Program, which helps fill scientific gaps, engage the research community in FAIR training efforts, and encouraging data reuse. ODSS also supports the Generalist Repository Ecosystem Initiative, which works with existing generalist repositories to make data sharing easier, improve discoverability, enhance reproducibility of research, and encourage secondary use of data.

Dr. Gregurick then discussed the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative, which is a public-private partnership to explore the use of cloud environments to streamline NIH data usage and ultimately modernize biomedical research by reducing barriers to making use of commercial cloud services. A related program is the NIH Cloud Lab, which serves as a testbed that allows researchers to try out various cloud services and offers trainings. Dr. Gregurick also briefly reviewed supplements to enhance existing software tools, improve engineering of reliable scientific tools, and make research tools useable across multiple computing environments.

Electronic health records (EHRs) are rich data sources, but these data are protected by HIPAA and patient consent is required to access and exchange EHRs for research use. Fast Healthcare Interoperability Resources (FHIR) standards are designed to enable data sharing and interoperability for EHRs. NIH is at the forefront of promoting FHIR and is working to develop a FHIR-complaint software for retrieving standardized phenotype data from several large population cohort studies and coordinating FHIR tools and resources to encourage translational research networks. ODSS has experience high demand for FHIR training. Since December 2021, ODSS has supported three trainings on FHIR and is working with ICOs to explore future training opportunities. Dr. Gregurick thinks these standards provide good opportunities for NIDCR to help leverage FHIR for integrating EHRs and dental records, and to engage DOC researchers in FHIR trainings. Finally, Dr. Gregurick discussed the NIH Data and Technology Advancement (DATA) National Service Scholar Program, which is a one- or two-year national service sabbatical for experts in data science to help advance NIH mission. The program supports five fellows per year and has led to exciting work on biomedical data science applications.

Discussion

Dr. D'Souza asked Dr. Gregurick to comment on European practices on data sharing. She replied that the European Union's ELIXIR program has been very successful and has begun to include some non-European countries. She noted that Europe's nationalized healthcare structures enable easier integration than the American system. Dr. Visel invited Council members interested in this topic to consider joining the Council's Data Science Work Group, which he will be chairing. Dr. Lu Wang emphasized the need for advanced data analytics that can evolve with the fast pace of technological advances; data sets that seem comprehensive now may be seen as incomplete in the future. Dr. Gregurick said her office has been in the process of developing the next strategic plan for data science, and the need to incorporate state-of-the-art techniques to confront Dr. Wang's point will be central to that effort. Dr. Stanford highlighted the need to encourage sharing of biological samples; data from biospecimens is only as good as the data techniques performed by the original investigator, and the development of new technologies can provide new approaches for old specimens. Dr. Visel said the importance of defining uniform data standards, particularly for metadata, is similarly important for providing reliable data.

VII. CONCEPT CLEARANCE

Dr. King, Director, DEA, noted that NIDCR is required to present the purpose, scope, and objectives of proposed concepts for research initiatives to the Council in a public forum for the

Council's review, discussion, and approval, and for public comment. Concepts approved by the Council are published on the NIDCR website ([future research initiatives](#)). NIDCR staff presented one concept, and designated Council members led the discussion, as summarized below.

HEAL Initiative: Oral Complications Arising from Pharmacotherapies to Treat Opioid Use Disorder

Dr. Dena Fischer, Director of the NIDCR Clinical Trials and Practice-Based Research Program, presented the concept. In 2018, an estimated 10.3 million people 12 years and older in the U.S. misused opioids. The HEAL Initiative is a trans-NIH research initiative to strengthen prevention and treatment strategies for opioid misuse and addiction and to improve pain management research and interventions. The FDA has approved three drugs to treat opioid dependence: buprenorphine, methadone, and naltrexone. An FDA Drug Safety Communication indicated that oral complications, such as caries, abscesses, and tooth erosion and tooth loss, can arise from use of buprenorphine formulations dissolved in the mouth. Despite these reported oral complications, the benefits of pharmacotherapies to treat opioid use disorders (OUD) outweigh the risks. The goals of this concept, which is being submitted through the HEAL Initiative, are to further understanding of the biology and natural history of oral complications associated with pharmacotherapies to treat OUD, and to help address access to care and other challenges that may contribute to OUD disease onset and progression in people with OUD. Dr. Fischer briefly discussed the knowledge gaps, opportunities, and specific areas of interest related to the concept.

The Council's lead discussants for the concept were Dr. Hal Ebetino and Dr. Joel Strom, who both expressed support for the concept. Dr. Ebetino said the concept addresses clear needs in the fundamental science and communication of oral complications for providers. Dr. Strom was excited by inclusion of the microbiome as an area of interest, and also underscored the importance of training the prescriber community. Dr. D'Souza asked if there are any studies underway to validate the findings of the FDA regarding buprenorphine. Dr. Webster-Cyriaque and Fischer said that their understanding was that the alert was prompted by data received through adverse event reporting. Dr. Fischer agreed that more confirmatory research was needed.

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 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

VIII. REVIEW OF APPLICATIONS

IX. ADJOURNMENT

CERTIFICATION

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

 /Rena D’Souza/
Dr. Rena D’Souza
Chairperson
National Advisory Dental and
Craniofacial Research Council

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

ATTACHMENTS

- I. Roster of Council Members