NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS

ADVISORY COUNCIL

September 8 and 9, 2022

National Institutes of Health

Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on September 8 and September 9, 2022, via videoconference at the National Institutes of Health (NIH) in Bethesda, MD. Dr. Debara L. Tucci, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: September 8, 2022, 10:00 a.m. to 12:00 p.m. for review of individual grant applications; and,

Closed: September 9, 2022, 10:00 a.m. to 11:00 a.m. for review of the Board of Scientific Counselors report.
Open: September 8, 2022, 1:00 p.m. to 3:38 p.m. and September 9, 2022, from 11:00 a.m. to 12:50 p.m., for the review and discussion of program development needs and policy.

Council members in attendance[1]:

Dr. Emily Buss
Dr. Nirupa Chaudhari
Ms. Vicki Deal-Williams
Dr. Ruth Anne Eatock
Mr. Richard Einhorn
Dr. Carol Espy-Wilson
Dr. Lisa Goffman
Dr. Andy Groves
Dr. Argye Hillis
Dr. Robert Hillman
Ms. Barbara Kelley
Dr. Anil Lalwani
Dr. Cynthia Morton
Ms. Lynne Murphy Breen
Dr. Ben Strowbridge
Dr. Margaret Wallhagen

Council Members Absent:
Dr. Dan Sanes

Ex-Officio Council Members in attendance:
Ms. Christa Themann (CDC)
Dr. Jeremy Nelson (DOD)
Dr. Judy Schafer for Dr. Lucille Beck (VA)

Ad Hoc Council Members in attendance:
Ms. Katherine Bowton
Dr. Daniel Merfeld
Dr. Melinda Pettigrew
Dr. Susan Thibeault

The complete Council roster can be found in Appendix 1.
NIDCD staff and other NIH staff in attendance list can be found in Appendix 3.

[1] For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to "*en bloc*" actions.

CLOSED SESSION September 8, 2022

Call to Order and Opening Remarks ..... Dr. Debara L. Tucci

The meeting was called to order by Dr. Tucci, Director, NIDCD, who expressed appreciation to the entire Council for their service and advice.

Council Procedures.....Dr. Becky Wagenaar-Miller

Procedural Matters

Dr. Becky Wagenaar-Miller discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members to avoid any conflict of interest and the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Wagenaar-Miller announced that the Council meeting would be closed for consideration of grant applications during the morning session and would be open to the public at approximately 1:00 p.m. via Videocast.

Council Consideration of Pending Applications .....Dr. Judith Cooper and Staff

Research Project Grant Awards

Consideration of Applications: On the Council's agenda was a total of 108 investigator-initiated R01 grant applications; 97 applications had primary assignment to NIDCD, in the amount of $37.6 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to R01 applications scoring up through the 14th percentile.

Special Program Actions

1. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council voted to support of one application.
2. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council voted to support of three applications.
3. NIH Pathway to Independence Award (K99/R00): The Council voted to support three applications.
4. NIH Support for Conferences and Scientific Meetings (R13): The Council voted to support two applications.
5. NIH Exploratory/Development Research Grant Award (R21): The Council voted to support seven applications.
6. NIDCD Early Career Research (ECR) Award (R21): The Council voted to support eleven applications.
7. NIH Small Business Innovation Research Awards (SBIR): The Council voted to support two Phase I (R43) applications.
8. RFA-DC-20-002 NIDCD's Mentored Research Pathway for Otolaryngology Residents and Medical Students (R25): The Council voted to support three applications.
9. RFA-DC-22-002 NIDCD's National Human Ear Resource Network (U24): The Council voted to support.

OPEN SESSION – September 8, 2022

Opening Remarks ..... Dr. Tucci

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting which was available to the public from the NIH Videocast website. (https://videocast.nih.gov/watch=45775)

Council Introduction

Dr. Tucci invited each council member to introduce themselves to begin the meeting.

Consideration of Minutes of the Meeting of May 19 and 20, 2022

Dr. Tucci called the members' attention to the minutes of the May 19 and 20, 2022 meeting of the NDCDAC. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2024 have been established. A list of these meetings was distributed to the Council members and posted on the NIDCD website prior to this meeting. The next meeting of the Council is scheduled for Thursday February 2, and Friday, February 3, 2023.

[*Executive Secretary Note: The February 2023 council meeting will be virtual and held on Thursday, February 2, 2023, and Friday February 3,2023. Check the NIDCD Council website for meeting specifics.]*

NIDCD Director's Report ..... **Dr. Tucci**

NIDCD Updates:

Dr. Tucci began her Director's Report by introducing Dr. Cendrine Robinson as NIDCD's first Chief Diversity Officer. Expanding diversity, equity, and inclusion within the NIDCD and the intramural and extramural workforce has been a high priority for Dr. Tucci since becoming director in 2019.

Dr. Robinson joins NIDCD from the Department of Veterans Affairs (VA) where she served as a scientific program officer and Diversity, Equity, and Inclusion (DEI) chair, since 2020. In this position, she developed and executed initiatives to expand the pipeline of researchers from historically excluded groups and to promote health equity; developed policy recommendations and forged strategic partnerships; created and managed a stakeholder advisory board; developed funding announcements for the VA Office of Research and Development diversity research supplements; and directed the implementation of summer research programs in 21 VA medical centers.

Prior to joining the VA, Dr. Robinson worked at the National Cancer Institute (NCI) Tobacco Control Research Branch/Cancer Prevention Fellowship Program as a cancer prevention fellow and as project manager for the Smokefree.gov initiative.

Earlier in her career, Dr. Robinson was a psychology resident and research fellow at the Edward Hines Jr., Veteran Affairs Hospital, in Hines, Illinois, and a graduate research fellow at the Uniformed Services University of the Health Sciences (USUHS) in Bethesda.

Dr. Robinson received her bachelor's degree in brain and cognitive sciences from the University of Rochester, a master's, and doctoral degree in medical and clinical psychology from USUHS, and a Master of Public Health degree in quantitative methods from Harvard School of Public Health. She is a member of the American Psychological Association Health Disparities Committee and a mentoring program chair for the Society for Research on Nicotine and Tobacco.

Dr. Tucci expressed that she looks forward to working together with Dr. Robinson to build and maintain a culture of inclusiveness throughout NIDCD.

The search to recruit a new Clinical Director for NIDCD is underway to replace Dr. Carter Van Waes, who retired as the NIDCD Clinical Director this past June. Dr. Clint Allen is serving as the NIDCD's Acting Clinical Director while recruitment is ongoing. Dr. Allen also serves as a principal investigator in the Section on Translational Tumor Immunology. His lab studies various therapeutic approaches to reverse local immunosuppression within the tumor microenvironment to enhance responses to immune-activating anti-cancer treatments. Dr. Allen holds a faculty appointment in the department of otolaryngology-head and neck surgery at Johns Hopkins School of Medicine and has an active otolaryngology clinical practice in Bethesda, Maryland. He is also a member of the inpatient otolaryngology consultation team at the NIH Clinical Center. Dr. Allen joined the NIDCD as an investigator in the Otolaryngology Surgeon-Scientist Program in late 2013.

Dr. Tucci announced that NIDCD will host a hybrid retirement symposium celebrating the career of Carmen Brewer, chief research audiologist of the NIDCD and chief of the NIDCD Audiology Unit. This half day-long symposium will highlight the impact Dr. Brewer has had on the NIDCD clinical program and the critical contributions she has made to audiology research. Dr. Brewer has been at NIDCD for 20 years and under her leadership, the Audiology Unit's research productivity has expanded, and a comprehensive mentoring program was developed. Dr. Brewer will be retiring in October and recruitment is underway for her replacement. Dr. Tucci expressed that she will miss Carmen, her leadership, and her clinical expertise.

In Memoriam:

Dr. Tucci announced great sadness for the passing of colleagues who played roles in shaping NIDCD.

Former NIDCD director Dr. James Byron Snow, Jr. passed away on May 28. Dr. Snow made significant contributions to research and clinical practice in otolaryngology and was considered a pioneer in the field. He served as the NIDCD's first official director, succeeding acting director Jay Moskowitz. Dr. Snow organized the new institute and recruited a distinguished cadre of scientists. He encouraged the application of molecular biology to the study of disorders of human communication and served as the liaison between NASA and the National Institutes of Health. In 1990, he established the NIDCD's Division of Intramural Research, and in 1991 he created the NIDCD Board of Scientific Counselors to advise the director of the Division of Intramural Research.

Following his retirement from NIDCD in 1997, he served as president of the international Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum. Dr. Snow served as convener/correspondent of the Tinnitus Research Consortium. Subsequently, the James B. Snow Jr., M.D., Tinnitus Research Award was established in his honor by the Collegium Oto-Rhino-Laryngologicum Amicitiae Sacrum and he is considered a pioneer in the field. Dr. Snow was a world-class otolaryngologist who encouraged collaboration among scientists in the field. As the first official NIDCD director, he created significant opportunities for scientists and trainees alike to perform impactful research in the NIDCD's mission areas. Dr. Snow paved the way for the immense research contributions of internationally known NIDCD intramural scientists and grantees. He will be missed by all those who had the privilege to work with him.

Dr. Neil Segil passed away on July 2. He served on the NDCD Advisory Council from 2017-2019 and served on the NIDCD Board of Scientific Counselors from 2009-2014. Dr. Segil was professor at the Department of Stem Cell Biology and Regenerative Medicine at the University of Southern California. He established an international reputation for his pioneering research on the development and regeneration of hearing through studies of the inner ear. His influential research was founded on insightful and innovative experiments, as well as an ease in extending his laboratory's research through collaborative partnerships. Dr. Segil remained energized by, and active in, his laboratory's research, and that of his colleagues, to the time of his passing.

Former Congressman John Edward Porter passed away on June 3. He served on the U.S. House of Representatives from 1980 until his retirement from Congress in 2001. He was a member of the House Appropriations Committee and chair of its Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. The Committee's jurisdiction covered all the health programs of the NIH, as well as those of other health-related federal agencies. Over the period of 1998 to 2003, Congress doubled the NIH

budget. Mr. Porter was widely recognized as the lead architect of this remarkable legislative achievement. In 2014, NIH dedicated The John Edward Porter Neuroscience Research Center, a new type of research facility that would unite intramural neuroscience research across the NIH. The center is the home for 85 groups from 10 NIH institutes and centers, including most of NIDCD's intramural laboratories.

NIH Updates:

Dr. Tucci then turned to NIH updates. She reminded the research community that NIH is implementing a new Data Management and Sharing Policy that will impact nearly all NIH grant applicants. Dr. Mike Lauer presented on this at the May NIDCD Council meeting. This policy reinforces NIH's longstanding commitment to making the research it funds available to the public and sets the baseline expectation that sharing data is a fundamental component of the research process and it goes into effect on January 25, 2023. The NIH Office of Science Policy and the Office of Extramural Research is hosting an informative webinar series focused on the new policy. Registration is open for this 2-part series, "A Conversation with NIH: Implementing the New Data Management and Sharing Policy." In this series, NIH policy experts will break down what the policy means and discuss key factors to consider when sharing data. Registration is required separately for each webinar by visiting the NIH Guide for Grants and Contracts notice NOT-OD-22-184.

The August webinar discussed the policy expectations, the applicability of the policy, how to prepare a Data Management and Sharing Plan, and considerations for sharing data responsibly. The September webinar will expand upon the information presented in the first webinar and dive deeper into topics including privacy protections for data from human participants and justifiable limitations on sharing data. These webinars will be recorded and made available for on-demand viewing after the event.

The American Medical Association is the largest and only national association that convenes 190+ state and specialty medical societies and other critical stakeholders. Its mission is to promote the art and science of medicine and the betterment of public health. At this summer's American Medical Association's House of Delegates meeting, the members adopted Resolution 113, Prevention of Hearing Loss-Associated-Cognitive-Impairment through Earlier Recognition and Remediation. The AMA's resolution highlights these three areas of action:

- Promote awareness to physicians and to the public of hearing impairment as a potential contributor to the development of cognitive impairment or dementia in later life
- Promote and encourage the conduct and acceleration of research into specific patterns and degrees of hearing loss to determine those most linked to cognitive impairment or dementia
- Work with interested national medical specialty societies and state medical associations to encourage and promote research into hearing loss as a contributor to cognitive impairment, and to increase patient access to hearing loss identification and remediation services

Dr. Richard Hodes, the Director of the National Institute on Aging, came to speak at the NIDCD advisory council meeting earlier this year to discuss the mutual interest between NIA and NIDCD on research about the connection between untreated hearing loss and dementias, such as Alzheimer's disease and the AMA's resolution falls directly in NIDCD and NIA's research mission. Both NIDCD and NIA are interested in working with the AMA as they implement this resolution.

Over-the-counter (OTC) hearing aids:

By 2050, the World Health Organization estimates that more than 700 million people—or one in every 10 people around the globe—will have disabling hearing loss. In the U.S. alone, hearing loss affects an estimated 37 million people. Hearing loss can be frustrating, isolating, and even dangerous. It is also associated with dementia, depression, anxiety, reduced mobility, and falls.

Although hearing technologies, such as hearing aids, have improved, not everyone has equal access to these

advancements. In fact, though hearing aids and other assistive devices can significantly improve quality of life, only one in four U.S. adults who could benefit from these devices has ever used one. Dr. Tucci indicated that people commonly report encountering economic barriers, such as the high cost of hearing aids and limited access to hearing health care. For some, the reasons are more personal such as they may not believe that hearing aids are effective, or they may worry about a perceived negative association with aging.

On August 16, the Food and Drug Administration issued its final rule for over-the-counter hearing aids, intended for adults with perceived mild-to-moderate hearing loss. NIDCD applauds this momentous step toward improving hearing health care. The new regulation is the culmination of decades of research efforts by NIDCD and other scientists exploring key issues faced by people with hearing loss.

In 2009, NIDCD's Working Group on Accessible and Affordable Hearing Health Care for Adults with Mild to Moderate Hearing Loss created a blueprint for research priorities. The working group's blueprint led to NIDCD funding of more than 60 research projects spanning the landscape of accessible and affordable hearing health care issues. One study showed that people with hearing loss can independently adjust the settings on their hearing devices in response to changing acoustic environments and, when given the ability to control their own hearing aid settings, they were generally more satisfied with the sound of the devices than with the audiologist fit. In 2017, the first randomized, double-blind, placebo-controlled clinical trial comparing an over-the-counter delivery model of hearing aids with traditional fitting by an audiologist also found that hearing aid users in both groups reported similar benefits. A 2019 follow-up study confirmed these results, supporting the viability of a direct-to-consumer service delivery model. A small-business research grant funded by NIDCD led to the first FDA-approved self-fitting hearing aid.

In 2016, NIDCD co-sponsored a consensus report from the National Academies of Sciences, Engineering, and Medicine (NASEM), *Hearing Health Care for Adults, Priorities for Improving Access and Affordability*, recommending that the FDA create and regulate a new category of OTC hearing aids to improve access to hearing aids for adults with perceived mild-to-moderate hearing loss. Dr. Tucci served on the panel to develop the NASEM report.

At nearly the same time, the President's Council of Advisors on Science and Technology (PCAST) under President Obama developed an independent report, *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*. The report also recommended that the FDA should approve a class of hearing aids for bilateral, gradual onset, mild-to-moderate, age-related hearing loss and to be sold OTC.

Following the publication of the NASEM and PCAST reports, Sen. Elizabeth Warren's staff contacted NIDCD to learn about the research NIDCD funds that support the development of OTC hearing aids. Soon afterwards, Sen. Warren and Sen. Chuck Grassley introduced S. 670, the Over-the-Counter Hearing Aid Act of 2017. The companion bill, H.R. 1652, was introduced to the House by Representatives Joseph Kennedy and Marsha Blackburn. There was large bipartisan support for OTC hearing aid legislation from both chambers. However, in the 115th Congress, an OTC hearing aid bill was not going to see movement standing on its own. Congress attached the bill as a provision to the must-pass FDA reauthorization act, H.R. 2430. President Trump signed the bill into law on August 18, 2017.

The OTC hearing aid category established in this final rule applies to certain air-conduction hearing aids intended for people 18 years of age and older who have perceived mild to moderate hearing impairment. Hearing aids that do not meet the requirements for the OTC category (for example, because they are intended for severe hearing impairment or users younger than age 18) are prescription devices.

In response to public comments and to assure the safety and effectiveness of OTC hearing aids, the final rule incorporates several changes from the proposed rule, including lowering the maximum sound output to reduce the risk to hearing from over-amplification of sound, revising the insertion depth limit in the ear canal, requiring that all OTC hearing aids have a user-adjustable volume control, and simplifying the phrasing throughout the required device labeling to ensure it is easily understood. The final rule also includes performance specifications and device design requirements specific to OTC hearing aids.

Furthermore, the final rule correspondingly amends existing rules that apply to prescription hearing aids for consistency with the new OTC category, it repeals the conditions for sale for hearing aids, and it includes provisions that address some of the effects of the FDA OTC hearing aid regulations on state regulation of hearing aids.

Concurrently with issuing the final rule, the FDA also issued the final guidance, Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products or PSAPs, to clarify the differences between hearing aids, which are medical devices, and PSAPs, consumer products that help people with normal hearing amplify sounds. The effective date for the final rule is October 17, 2022.

INCLUDE Update .....Dr. Kelly King
Dr Melissa Parisi
Dr. Brian Skotko

The INCLUDE (INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE) Project is a program that was launched in June 2018 in support of a Congressional directive in the fiscal year (FY) 2018 Omnibus Appropriations and in which the NIDCD has a major part in. Dr. Tucci introduced NIDCD program officer Dr. Kelly King, who represents the institute efforts with INCLUDE.

Dr. King shared that INCLUDE is an initiative that spans the NIH the institutes, centers and offices and reaches the collective mission to enhance health, lengthen life and reduce illness and disability. The formation of the INCLUDE Project was in immediate response to a congressional directive and funds were set aside in the federal budget specifically to create this new research initiative on the critical health and quality of life needs for individuals with Down syndrome. Dr. King introduced Dr. Melissa Parisi, chief of the intellectual and developmental disabilities branch at the Eunice Kennedy Shriver Institute of Child Health and Human Development (NICHD). Dr. Parisi provides leadership to the intellectual disabilities research centers program at NICHD, the Down syndrome patient registry, which is known as DS Connect, and the INCLUDE Project. Dr. King thanked Dr. Parisi for joining today and for her leadership with INCLUDE.

Dr. Parisi began by explaining that Down syndrome is a result of the most common chromosomal disorder, the most common genetic cause of intellectual disability and occurs in 1/770 newborns. For about 95% of those with Down syndrome they have three full copies of chromosome 21 and about 5% have a translocation, a partial trisomy for mosaic for 21. The focus of the INCLUDE initiative is the co-occurring conditions with Down syndrome. Almost all the individuals have mild to moderate intellectual disability and sleep apnea is extremely common. Hearing loss is also very common in Down syndrome, with estimates that between 50 and 75% of children experience hearing loss. While only about 5% of individuals with hearing loss is due to sensory neural causes, a lot of hearing loss is associated with otitis media with effusion and due to the alterations of the in the anatomy with the ear structure. This is a real problem for children and adults with Down syndrome. Autoimmune problems are common in Down syndrome and heart defects impact about 50% of individuals. There is also an increased risk of early Alzheimer’s disease.

In the 1970s, the most common cause of death for individuals with Down syndrome was congenital heart defects but advancements in surgical care in the 1970s and onwards has greatly lowered this as a cause of death. Dementia in individuals with Down syndrome has been increasing and is now the most common cause of death in the year 2020. The life expectancy has increased from nine-years-old in 1959 to now about 60 years of age and the numbers of individuals that are in the higher age ranges, has continued to increase since 1950s. This is all good news. But that means that there are people with Down syndrome who are living with these conditions, and we want to improve their quality of life and that's the genesis for the INCLUDE Project. There are three components to the INCLUDE initiative, the first is focusing on high-risk, high reward basic science studies trying to understand the biology of Down syndrome. The second component is building a large cohort of individuals with Down syndrome across the lifespan for comprehensive biomarker evaluation. Finally, the third component is to include people with Down syndrome in existing and future clinical trials. She indicated that the total amount of funding for Down syndrome research has increased because of the INCLUDE initiative across NIH from the early 2010s where20 to $30 million per year was awarded for Down syndrome research to

FY21 when NIH had $109 million dedicated for Down syndrome research and 65 came from INCLUDE awards. NIH is on track to add $75 million for INCLUDE funding for FY22. She showed a breakdown of those awards and how they are distributed across the NIH in FY21 with $65 million is distributed in 53 new awards, a couple of it are at NIDCD assigned for $1.24 million. She highlighted the reissue of some of the initial Request for Funding Announcements (RFAs) that were first published in 2019, and a couple of those really speak to some of the priorities and the components of the project. For the basic science area, there is a focus on transformative R01s looking at basic science types of research. There has been data analysis and secondary data analysis projects through the R03 mechanism and there are a couple of RFAs that are focused on clinical trials both now and for the future. There have also been several additional funding opportunities to encourage trainees in this space. We have a particular notice specifically for fellowship trainees and F awards and career development awards or K awards and those for institutions that have not had a substantial NIH investment known as the area and REAP awards or the R15s. Additionally, there are some specific training awards that are linked to the CTSA program, the clinical translational science awards that are led by NCATS. She encouraged everyone to visit the INCLUDE funding website for a list of additional notices.

Dr. Parisi highlighted some of the results from the past four years. There has been approximately 200 new projects, and $183 million, to support multiple areas of Down syndrome research including rat models of Down syndrome; approaches to silence the extra chromosome 21 in cell lines; the impact of covid-19 on the immune system of individuals with Down syndrome; clinical studies looking at eye glass prescriptions and how to optimize those; development efforts for cognitive measures that are part of the NIH toolbox that are specific for children with Down syndrome; studies looking at language acquisition and articulation in children with Down syndrome; studies on sleep apnea and interventions; and studies to predict which individuals are likely to develop Alzheimer's disease in the near future.

With regard to Alzheimer's disease in Down syndrome, Dr. Parisi explained that by virtue of the fact that the amyloid precursor protein is found in chromosome 21, every person born with Down syndrome has three copies of this gene and it puts them increase developing Alzheimer's and beta amyloid is a trigger and a first stage in developing dementia. Unfortunately, many adults start to show symptoms of AD in their 50s and 60s. The biomarker consortium of Down syndrome is a longitudinal study in its seventh year that is studying over 400 adults with Down syndrome from 25 years of age and on and looking at a variety of different cognitive, genetic, and blood-based brain scan imaging biomarkers to help understand the evolution of dementia in this population. As a consequence of these studies, INCLUDE is also supporting studies looking at lifestyle risk and resiliency factors, diet, and exercise, to see if those modify the risk of dementia in the population. She highlighted a new clinical trial to test a preventative medication for dementia for adults with Down syndrome and a study that is in its early stages looking at GM-CSF potential treatment to improve cognition in adults with Down syndrome. This initial ABC-DS project has really spurred a lot of additional studies looking at dementia in the Down syndrome population.

Dr. Parisi stressed that one of the important components of INCLUDE is the cohort development. The INCLUDE data coordinating center (DCC) was funded two years ago to start understanding these large cohorts and put together the data in a way that would make it accessible to a large group of individuals. The DCC has three separate units, a data portal, which was just launched recently, and the data management core which is working behind the scenes to aggregate data from a variety of different studies and put that in a format that it can be present today a wider audience and the administrative and outreach core working with the public and with investigators to help make the data accessible to them. The INCLUDE data hub was just launched on world Down syndrome day and has over 6,000 clinical individuals participating through a variety of different studies that are collated under the data hub. There are 2,500 genome sequences and over 400 targeted metabolomics as part of the studies. The data are accessible to the public or investigators and is incorporating additional INCLUDE and other funded studies as part of the data acquisition.
Dr. Parisi discussed the DS-Connect which is a Down syndrome registry and an important resource that will help increase the cohort and lead to improvements and recruitment for clinical trials. DS Connect is a secure and on-line registry that was created by NICHD in 2013 to help facilitate research participation in Down syndrome clinical studies. The registry includes a Spanish language option and there are over 5,500 currently registered participants in this registry. Families upload some basic demographic and health information about

their family members with Down syndrome and they are given a specific invitation to participate in research projects that they have expressed an interest in. Their private health information is never shared with investigators but rather NIH serves as the trusted liaison between the participants and the investigators who are interested in recruiting for their studies. In the past seven years over 90 studies have requested recruitment support and 90% of those have been approved by the research recruitment committee which is composed of parents, family members, researchers, and others with an interest in Down syndrome research. Over 12 INCLUDE projects have received recruitment supporting including five of clinical trials.

Finally, Dr. Parisi closed by sharing a little bit about some of the community engagement and outreach efforts. Many people know that research in the past utilizing or based on studies of individuals with intellectual disabilities, have often been fraught with ethical concerns and there has been a hesitation on the part of the Down syndrome and the community of individuals with intellectual disabilities to participate in research. NIH recognizes that and has been engaging in advocacy group, community outreach and a variety of different mechanisms to increase the availability of these resources and an electronic toolkit is now available with information cards, flyers, and social media. The goal is to recruit 10,000 participants for DS-Connect by the 10-year anniversary of that initiative. She indicated that they are working hard to enhance diversity and that there is an upcoming diversity workshop. In preparation for this workshop, two listening sessions were held with families and with researchers to understand more about some of the issues for families to participate in research and ways in which diversity can be improved. She discussed other diversity activities including a data science for diverse scholars in Down syndrome summer course, hosting a clinical trials webinar series with presentations on assent and consent, and funding opportunities that are designed to encourage diversity, promoting mobile health activities that would make some outreach more broadly available to the Down syndrome community where they live whether it is in rural or more metropolitan areas

Dr. King highlighted some of the ways NIDCD science mission areas have benefited from partnering with INCLUDE. In 2018 NIDCD awarded three administrative supplements to investigators working in NIDCD mission areas to take on going work that was not focused on Down syndrome and expand it into populations with Down syndrome. She indicated that at least one of these supplements was leveraged into a follow-up R01 from Dr. Lori Leibold looking at speech perception and auditory ability in infants, children, and adults with Down syndrome. A grant from Dr. Stephen Camarata at Vanderbilt University examined articulation accuracy and speech intelligibility. As indicated by Dr. Parisi acknowledge, communication and the ability to be understood when you are expressing yourself, are significant issues for individuals with Down syndrome and their families. Dr. Ruth Litovsky known from her work in cochlear implants and binaural hearing recently expanded her science towards working with individuals with Down syndrome and is looking at auditory function, cognition, language, and brain structure. Dr. Heather Porter at Boys Town National Research Hospital did her doctoral work many years ago looking at hearing in children with Down syndrome and is now leveraging her rich experience as a clinician scientist by continuing in this area with aims around advancing clinical practice and establishing foundational theory for auditory function in individuals with Down syndrome.

Finally, Dr. King introduced Dr. Brian Skotko to present his ongoing clinical trial with Dr. Chris Hartnick on the effects of hypoglossal nerve stimulation on cognition and language in Down syndrome. Dr. Skotko is a board-certified medical geneticist and endowed chair at Massachusetts General Hospital (MGH) and is the director of hospital's Down syndrome program. He co-authored the national award-winning books, Common Threads, Celebrating Life with Down Syndrome and Fasten Your Seatbelt, A Crash Course on Down Syndrome for Brothers and Sisters. He is a graduate of Duke University, Harvard Medical School and Harvard Kennedy School and currently associate professor at Harvard Medical School. Dr. Skotko is a leader in clinical and translational research about Down syndrome and has been featured in the Wall Street Journal, New York Times, Washington Post, L.A. Times, NPRs On Point, and ABCs "Good Morning America". He has a sister with Down syndrome and serves on the honorary Board of Directors for the Massachusetts Down Syndrome Congress.

Dr. Skotko began by recognizing his 'partners in crime' Dr. Chris Hartnick and his sister Kristen. Dr. Skotko noted that he has had the opportunity to be involved in many activities within the Down syndrome community but one that he is most proud of is his adult sister with Down syndrome, Kristen. As director of the Down

syndrome clinic at MGH his team follows approximately 600 patients with Down syndrome every year of all ages. They provide Down syndrome specialty care and often interact with ears, nose and throat specialists (ENT) like Dr. Hartnick which led to this collaboration and this project.

Dr. Skotko talked about obstructive sleep apnea (OSA) and his work on a treatment that could also improvement on articulation and expressive language option for people with Down syndrome. In general, obstructive sleep apnea is when there is a decrease or a cessation of air flow into your lungs when you are sleeping. Air flow normally comes through our mouth and our nose. For many people, including people with Down syndrome that have hypotonia or low muscle tone including in the tongue, the tongue will relax and fall back and obstruct the airway. There are some structures that can get in the way like tonsils or adenoids and some of the classic signs and symptoms are snoring, choking, or gasping during sleep. Many people with Down syndrome have silent obstructive sleep apnea which is often the most difficult to detect because it gives us no clues whatsoever, while you are sleeping, and we need to look for other clues like changes in behavior or changes in cognition. Untreated obstructive sleep apnea, for the neurotypical population comes with a lot of comorbidities, when you add Down syndrome, it only compounds this. It can lead to short and long-term cognitive deficits. The brain fog and feeling like you are not getting a good, oxygenated sleep night after night could exacerbate or lead to some behavioral disturbances. When you cannot concentrate, when you are having behavioral issues, you are not able to attend school and obstructive sleep apnea is one of the biggest challenges in terms of academic performance, often leading to school failure. On the medical side, it leads to hypertension, high blood pressure, it can lead to poor glucose metabolism, and we start to develop heart issues and vascular issues and could start to lead to failure to thrive at its worse, pulmonary hypertension and in the most extreme cases exacerbate to death.

Dr. Skotko explained that surgical and medical treatment can prevent or even reverse these outcomes so early detection in treatment is key. The reason why OSA is so common in people with Down syndrome is because of the different craniofacial anatomy. These anatomical differences include a midface and mandibular hypoplasia, smaller nasal passages, the size of the tongue in relation to a smaller midface anatomy leads to relative macroglossia or bigger tongue. Additionally, the tongue can protrude, and the adenoids are enlarged and even if removed can grow back large again. Relatively large, medially-positioned palatine tonsils and increased secretions are also seen and obesity goes along with more than 50% of people with Down syndrome contributing to pressing Down on that neck when they are in the supine sleeping position. In the general population 1-4% of the pediatric age neurotypical will develop OSA and 10% to 25% in the neurotypical adult population. When it comes to people with Down syndrome of all ages, 55 to 97% develop OSA. It is prevalent, persistent, and recurrent. Dr. Skotko indicated that as a practicing physician, it is one of the conditions that he is most often talking about and most often struggling with families to find an appropriate treatment. Apnea-hypopnea index (AHI) is an indicator of how severe the obstructive sleep apnea is. The number refers to how many events per hour that someone is not getting enough oxygen. An AHI of 2, indicates that two times every hour when someone is sleeping that they are not getting enough oxygen. In the pediatric population, obstructive sleep apnea is classified where less than one time per hour indicates no apnea, one to five times per hour is mild; five to 10 times per hour moderate; and greater than 10 times per hour is severe.

The first step for a Down syndrome patient with OSA is surgical removal of the tonsils and the adenoids and typically about eight weeks after surgery, a sleep study is repeated to see if this impacted the apnea. When an individual has exhausted all surgical options and they are still OSA continuous positive airway pressure (CPAP) is recommended for treatment. This requires an individual to wear a mask at night that can cover the nose, or the mouth or both. People with Down syndrome often have some sensitivities, particularly in their facial areas and getting them to wear it is a challenge and often involves working with occupational therapists who are experts in desensitization techniques. However, many people with Down syndrome are not able to tolerate this and this is particularly true for those individuals with Down syndrome that might have other co-occurring conditions like autism or other sensory disorders.

The hypoglossal nerve stimulator is new option for treatment. The hypoglossal nerve is the motor nerve in the tongue that helps regulate the motor functions of the tongue. A minimally invasive surgery is performed to insert a small battery pack under the skin with a lead that connects to the lungs and a lead that clips on and

connects to the back of the hypoglossal nerve. When it is time to go to bed, a remote control is used to activate the battery to turn on. When the lungs give the signal that it is time to breathe, it gives a signal to the tongue and the hypoglossal nerve says move it and you are lifting the tongue slightly protruding it out which allows the air to get through. This is an FDA-approved device for all adults 18 and older with a publication in the New England Journal of Medicine in 2014. Dr. Hartnick and Dr. Skotko have completed the safety and efficacy trial in children and adolescents with Down syndrome. They have collected data on what the hypoglossal nerve stimulator looks like in pediatric patients with Down syndrome and this has been published in a JAMA Otolaryngology-Head and Neck Surgery article.

Dr. Skotko described the phase I single group multicenter safety and efficacy trial including eligibility criteria and study protocol. He explained that the goal was to see whether the severity of the obstructive sleep apnea could be decreased by implanting a hypoglossal nerve stimulator and he detailed primary and secondary outcome measures. He stated that they were able to show that the implant was safe and that some of the non-serious adverse events included discomfort and a rash at the sites and cheek swelling all of which resolved and were temporary in nature. He discussed the serious adverse events of seen in the study including five that required readmission and one of which was unrelated to surgery. Of the four that were related to surgery, two of them were for individuals that had picked at their scab and required a readmission and treatment with antibiotics that led to a full recovery. The other two were briefly readmitted because of discomfort and pain. The results from the study show the implant was effective in the first phase I trial. AHI was reduced by more than half over 12 months. The study resulted in 65.9% of individuals cut their obstructive sleep apnea in half with 73% of patients at the end of the 12-month period achieving an AHI less than 10 events per hour. He indicated that the device was well tolerated, and the average nightly use was 8.9 hours which contrasts with CPAP.

Dr. Skotko discussed how they are working on improving on these measures and what should the ideal target level of AHI be. We know He discussed other anecdotal results such as patients feeling more refreshed, teachers saying individuals are sharper at school, and parents reporting commenting on improved articulation or expressive language of their children with Down syndrome. He noted that sixteen of the caregivers reported objective assessments of positive neuro cognitive changes and 14 of these 16 caregivers also talked about speech. They tried to do was a nested pilot study for the last six patients that were implanted with the addition of pre and post neuro cognitive testing to look at expressive language testing. In the small pilot population baseline to follow-up scores improved on each domain and this also matched what was perceived by the caregivers who were taking care of our patients with Down syndrome. Dr. Skotko described how they partnered with Dr. Len Abbeduto at UC Davis who is a leading expert on measuring expressive language in individuals with Down syndrome. They implemented the expressive language test that Dr. Abbeduto created which showed that there was an improvement on this test and supported some of the anecdotal evidence from the clinic and parents. The preliminary data were used as the basis for an NIDCD and INCLUDE funded U01 focused on implanting the hypoglossal nerve stimulator are looking at the effects on cognition and language. Our study procedure is the same as it was before but in addition to implanting the hypoglossal nerve stimulator, they are now also performing baseline neuro testing and baseline expressive language sampling. Dr. Skotko thanked all individuals involved and commented that he would like to come back and share the results when the study is completed.

Discussion

Dr. Nirupa Chaudhari asked about the study power especially related to efficacy of the protocol across ages to see if earlier intervention would be. Dr. Skotko responded that the eligibility is 10 years of age to up until 21 and 11 months and to date has recruited 16 individuals who fall into that age category. He said that the hope at the end of the study, is to have a spread of ages, that will allow him to look at age and be able to put it into a multi-regression model to see if age has an impact.

Ms. Vicki Deal-Williams inquired about the demographics and diversity given Dr. Parisi's talk. Dr. Skotko emphasized that Down syndrome occurs naturally in individuals of all different races and ethnic backgrounds and commented that of the first 16 participants, two have self-identified as being black and are actively working on identifying ways to reach the underrepresented and minority populations. That started with the strategic

selection of sites being demographically diverse. He commented that they are engaging family members and that a lot of their outreach is speaking at local Down syndrome organizations. In terms of language, Dr. Skotko indicated that for safety reasons the grant was limited to English-speakers only because at the time all the safety manuals for the implant device from the company were only in English. They have now converted into Spanish-speaking working with a team with the NIH to translate everything into Spanish so that for individuals with Down syndrome, who speak English or bilingual but have primarily Spanish-speaking parents, will soon be able to be involved in the research and open eligibility particularly from the UT Southwestern site.

Dr. Tucci thanked Drs. King, Parisi and Skotko for the informative presentations on this important program. She asked Dr. Skotko if they measured how the stimulation affected tongue movement or if this could be why not all individuals responded the same way. Dr. Skotko responded that the hypoglossal nerve stimulator has different voltages, so the ENT doctor can titrate it to have maximum movement of the tongue at the most minimal symptoms. When turned on, a person will feel their tongue moving, which might be uncomfortable. For each individual with Down syndrome the goal was trying to titrate it to maximal movement while making sure that it was within the comfort of the person with Down syndrome. He commented that they noticed that as the person with Down syndrome progressed over time and got used to the feeling, sometimes the ENT was able to increase the voltage.

Dr. Lisa Goffman followed-up on Dr. Tucci's question. As a speech and language person she commented that she is curious about the potential for facilitating the expressive language sample measures. She postulated that there could be two reasons. One relates to Dr. Tucci's comment regarding tongue motion and motor control and a second reason could be related though positive influences, sleep on learning and consolidation. She asked Dr. Skotko to elaborate on his hypothesis about this relationship, especially related to this interesting population with their special profile. Dr. Skotko indicated that his hypotheses are in line with hers. One is known generalized hypotonia in individuals with Down syndrome and it is possible that the motor workout from the stimulator increases the muscular tone of the tongue. The other hypothesis is that a better oxygenated sleep results in feeling

Budget Report .....Mr. Eric Williams

The budget report was given by NIDCD chief budget officer, Mr. Eric Williams. He indicated that President Biden signed the current spending bill giving NIH/NIDCD a budget after four continuing resolutions this year. The final enacted budget is $514.9 million which represent a 3.4% increase in funding. Dr. Tucci mentioned that noncompeting awards are fully funded.

The breakdown of the budget shows what NIDCD spent in FY 2021 compared with the operating plan of spending for FY 2022. Most of the funding in the Research Projects is for non-competing awards followed by competing awards. He also covered the small business set aside funds (SBIR/STTR) which must be spent on small business applications, the research centers line, individual and institutional training grants, R & D Contracts, the intramural Research, and research management and support lines.

Data showing the success rates for funding across the NIH compared with the NIDCD were presented. The graphs indicate that NIDCD success rates are above the NIH success rates for both Research Project Grants and the Fellowship program.

Report of the Division of Scientific Programs..... Dr. Judith Cooper

Dr. Judith Cooper, as Division of Scientific Programs director, presented an update introducing three new staff members including Ms. Tanji Johnson as program analyst, Dr. Holly Storkel as program officer for the language program, and Dr. Jean Verheyden as medical officer for the clinical trials program.

Report of the Director Division of Extramural Activities ..... Dr. Wagenaar-Miller

Dr. Becky Wagenaar-Miller, as Division of Extramural Activities (DEA) director, summarized several new NIH policies. She began by welcoming Ms. Tanya Holmes as a new staff assistant in DEA. Dr. Wagenaar-Miller reminded attendees that NIH has published an updated policy on data management and sharing which extends the long-standing data sharing expectations and raises the level, extent and depth of data sharing. She encouraged applicants to check out the NIH data sharing website for useful information such as links to webinars, help in planning and budgeting for data management and sharing, and an optional DMS plan format page.

NIH is extending the period of delayed enforcement for registration and results reporting of Basic Experimental Studies with Human Participants (BESH) through September 24, 2024 as outlined in NOT-OD-22-205. BESH studies meet both the NIH definition of a clinical trial and the definition of basic research. She indicated that this delayed enforcement is only applicable to BESH studies submitted to funding opportunities designated as "basic experimental studies with humans." NIH recognizes that registering and reporting results in ClinicalTrials.gov poses a challenge for some types of BESH projects. NIH is working with the BESH community to continue to explore solutions to facilitate the dissemination of information in ways that are useful to other researchers and members of the public, while also maintaining the NIH commitment to stewardship and increasing transparency. NIH continues to expect registration and results reporting for these BESH, but with the additional flexibility to register and report results on alternative publicly available platforms.

Dr. Wagenaar-Miller encouraged individuals to register for and attend the revamped Virtual NIH Grants Conference and PreCon Events. This replaces the NIH regional seminar. The new format has a two-day conference that takes place Nov 1-2, 2022, as well as numerous Pre-Con events occurring from August – January. This is a free event hosted by NIH that is useful for all levels of researchers and administrators. During the two-day conference stop by the Exhibit Hall to visit the NIDCD booth. Individuals can make appointments with NIDCD staff including scientific review officers, program officers and grants management specialists.

NIDCD continues to encourage interested individuals to submit a peer reviewer interest form to self-nominate for NIDCD peer review meetings. Dr. Wagenaar-Miller concluded by thanking all the staff of DEA for their hard work in managing the review of grant applications, in the management of the council and committees, and in awarding the grants and monitoring for compliance. They are an outstanding group of talented and committed individuals who often work behind the scenes to ensure that NIDCD funds the best research and research training in disease prevention and health promotion for communication impairments and disorders.

Remarks from Retiring Members **Mr. Richard Einhorn**
Dr. Robert Hillman
Dr. Cynthia Morton

Dr. Tucci thanked the retiring members for their thoughtful advice and service on the NDCD Advisory Council. She invited them to say a few closing words. Dr. Tucci noted that Dr. Hillman was not able to attend the meeting today. Mr. Einhorn stated that he has learned a lot from serving on the panel and that as a public member he came into his term with limited knowledge of how NIH works. He has seen the professionalism and passion that staff have for hearing health. He concluded by commenting that NIDCD is an example of how government can work for the benefit of all. Dr. Cynthia Morton thanked everyone for professionalism, patience, and persistence and commented that she will miss working with everyone.

Closed Session – September 9, 2022

Call to Order and Opening Remarks ..... Dr. Debara L. Tucci

The meeting was called to order by Dr. Tucci, Director, NIDCD, who expressed appreciation to the entire

Council for their service and advice.

Council Procedures.....Dr. Becky Wagenaar-Miller

Dr. Wagenaar-Miller briefly reminded Council of the procedures of this special closed session and that the meeting would move into Open Session at approximately 11:00 a.m.

Board of Scientific Counselors Report .....Dr. Lisa Cunningham

Dr. Tucci welcomed Dr. Lisa Cunningham, Director of NIDCD's Division of Intramural Research. As stipulated by law, each institute must provide annually to its National Advisory Council an overview of the Intramural Research Program. The overview includes reports of the Board of Scientific Counselors (BSC), and the responses of the Scientific Director. This presentation is informational only and Council members are not asked to recommend approval or disapproval of the reports or to modify them in any way. However, the Council may make recommendations to the Director, NIDCD regarding such research on the basis of the materials provided.

Dr. Cunningham presented Reports of the BSC regarding the review of one intramural laboratory. She then presented her response to the reports and responded to questions from Council. Next, Dr. Cunningham was recused and Dr. Tucci presented the BSC Report on Dr. Cunningham's lab.

[Executive Secretary Note: During the BSC presentation, attendance was restricted to the Council members, the Executive Secretary and a few senior NIDCD administrators.]

Open Session – September 9, 2022

Director's Greeting ..... Dr. Tucci

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting which was available to the public from the NIH Videocast website. (https://videocast.nih.gov/watch=45777)

Division of Intramural Research (DIR) Report .....Dr. Cunningham

Dr. Cunningham began by updating council on the new intramural investigators. Dr. Angela Ballesteros Morcillo is a new tenure-track investigator and Dr. Clint Allen has achieved tenure. Dr. Carter Van Waes has retired after many years as the NIDCD clinical director. Dr. Ballesteros Morcillo is the first NIDCD Stadtman Investigator. She received an MS in biochemistry and molecular biology and teaching. She earned her Ph.D. in molecular biology and completed her first post-doctoral fellowship at the Food and Drug Administration (FDA). She then came to NIH and completed her second post-doctoral fellowship with Drs. Andrew Griffith and Bechara Kachar and her third fellowship was with Dr. Kenton Swartz at NINDS.

Dr. Van Waes retired after 27 years as the NIDCD clinical director. On May 13th, NIDCD hosted a symposium that highlighted his work. His impact on the NIDCD clinical program, and his impact in the field of head and neck cancer. Dr. Allen is currently serving as the acting NIDCD clinical director and there is a search under way for new clinical director for NIDCD.

Dr. Cunningham announced that Dr. Carmen Brewer will also be retiring. She will retire in October after 20 years as the chief of the NIDCD audiology unit. A symposium honoring Dr. Brewer and highlighting her contributions to the field of audiology will be held on September 30, 2022. Dr. Cunningham noted that a search for Dr. Brewer's successor is also currently underway.

Dr. Cunningham then provided an update on the membership of the NIDCD Board of Scientific Counselors (BSC). Dr. Ellen Lumpkin has taken on the role of the BSC chair and Dr. Marlan Hansen has joined as a new member.

Dr. Cunningham summarized the recommendations from a recent Blue Ribbon Panel that reviewed the intramural program as a whole in 2021. The key recommendations were presented, including supporting joint hires to optimize space and strengthen trans-NIH ties. Additionally, the NIDCD Audiology Unit should pursue its own research and DIR should consider making the unit a principal investigator-based unit. A third recommendation was that the intramural program take advantage of opportunities to work with extramural investigators (e.g., U01s). It was further recommended that the intramural program should work to create databases that should be shared with extramural investigators to benefit the entire research community. It was recommended that NIDCD prioritize participating in NIH-wide programs (Stadtman, Distinguished Scholars Program, Lasker) and Dr. Cunningham reiterated that Dr. Ballesteros Morcillo was recently hired as a Stadtman Investigator. She indicated that specific recommendations for the clinical program will be revisited once the new clinical director is in place.

In response to the Blue Ribbon Panel, DIR held strategic planning meetings in the fall of 2021 focused on setting priorities, a desire to foster an innovative culture, opportunities for trans-NIH collaboration, and building efficient pathways to translate basic research into the clinic. The strategic planning meeting resulted in several implementation priorities for DIR such as forming a program to foster innovative and high-risk, high-reward projects, forming strategic interactions and collaborations, resource building to benefit the entire community, mechanisms of translating basic science research into clinical therapies. Additionally, one of the priorities was a focus on data science with machine learning and computational analysis capabilities. In response to the strategic planning meeting, working groups were formed to make specific recommendations for implementation.

In response to the recommendations of those working groups and the Blue Ribbon Panel recommendations, the Office of the Scientific Director has developed an Innovation Award program to incentivize high-risk, high-impact projects within DIR and across NIH. She explained that DIR is in talks to develop a neuroscience-focused poster session in the Porter Neuroscience research center, which is the building that most of the DIR laboratories are in, with the goal of fostering increased interactions between DIR labs and labs in other institutes across NIH. She also stated that DIR has obtained funding for and started work on an NIH-wide clinical database of hearing and balance function. The goal is to have the clinical database available sometime in 2023.

Dr. Cunningham then provided an update on the DIR diversity efforts. She highlighted the efforts that were taken related to the NIH postbaccalaureate program. A committee was formed to identify a diverse pool of highly qualified applicants to that program for consideration by NIDCD intramural labs. From this pool, three fellows were selected. Additional efforts included providing a standard relocation allowance for all NIDCD trainees appointed in 2022. This was done to make sure that the cost of relocating to Bethesda does not inhibit any trainees from coming and joining an intramural lab. In addition, the NIDCD intramural Office of the Scientific Director supported and funded all the summer interns in 2022. The summer internship program is a great opportunity to provide a good first research experience in NIDCD mission areas to young people who are very Interested in scientific research and perhaps have not yet selected a specific field. Dr. Cunningham also stated that an NIDCD recruitment strategist was trained by the NIH chief officer for scientific workforce diversity in how to best assist the search committees in making sure that there is a diverse pool of applicants for all faculty positions, and she highlighted a few of the methods used.

Dr. Cunningham then highlighted the EARssentials course taught by NIDCD faculty along with extramural faculty. This is a free course focused on concepts and techniques of contemporary hearing research. In 2022 the EARssentials course was held in a hybrid format where faculty presented a mini-lecture in the morning with archived lectures available online for more in-depth learning. There were over 100 registered participants with individuals from institutions in eleven countries and fifteen states and Puerto Rico. Interested participants are mostly trainees or people who are outside the field and interested in learning more about inner ear research. This year there was also training in mouse genetics, an introduction to the gene expression in auditory research (gEAR) resource and a zebrafish laboratory.

Dr. Cunningham concluded by providing more information about the summer internship program which was held in a hybrid format. NIDCD hosted three summer interns in person and one virtually. The virtual intern was hosted as part of the NIH Graduate Data Science Summer Program. The interns were supported with regular meetings with the NIDCD training director and NIH provided resources for deaf and hard of hearing trainees.

Discussion

Dr. Ruth Anne Eatock commented that it was great to see all the multi-lateral connections being made with other programs and asked if NIDCD has planned or increased its presence at big society meetings such as Society for Neuroscience (SfN) or Biophysical Society and others in related fields for recruitment or to partner with those societies to introduce more people to this field of research. Dr. Cunningham thanked Dr. Eatock for her suggestion and responded that NIDCD has focused its efforts on outreach and building relationships with specific groups including Association of Medical Professionals with Hearing Loss (AMPHL), Howard University, and the National Black Association for Speech-Language and Hearing. She agreed that it would be beneficial to expand this outreach.

Dr. Cynthia Morton indicated she wanted to hear more about the clinical database of hearing and balance function and weather it also includes genetic data. Dr. Cunningham indicated the data will include data that has been collected over many years in the audiology unit and includes data on several rare diseases. Some of the individuals who had their hearing tested at the audiology unit will have genetic data associated with it through the NIH clinical center but at this point genetic data is not collected for every patient at the clinical center and Dr. Cunningham stated that this would fall more into phase two of the database.

Dr. Carol Espy-Wilson asked how the diversity in the pool of applicants this year compared with previous years. Dr. Cunningham responded that she thought this year was the most diverse group that NIDCD has had.

Dr. Chaudhari added to Dr. Eatock's comments regarding outreach at other meetings. She encouraged NIDCD to partner with BSC or Council members to propose symposia for the annual SfN meeting to showcase the innovative and broad-reaching programs of the intramural program.

Walking the Path to Hair Cell Regeneration with Developmental Biology as a Guide ..... Dr. Matthew Kelley

Dr. Tucci welcomed and introduced Dr. Matt Kelley from the NIDCD intramural program. Dr. Kelley stated that his lab is interested in developmental biology and linking those efforts to regenerate hair cells to impact hearing loss and communication disorders. Dr. Kelley explained that approximately 30% of individuals have hearing loss at age 65 and 47% at age 75. While there are several factors that can cause or contribute to age-related hearing loss, typically permanent hearing loss is the result of loss of sensory hair cells. Dr. Kelley summarized data from several labs that looked at hair cell regeneration and restoration of auditory function in several animal systems. Experiments with chickens demonstrated that chickens regrow hair cells and restore auditory function to almost normal even after repeated injury. Mammals are unique from other animals in their inability to regenerate hair cells and restore auditory function. It has been shown that mice are capable of a small amount of regeneration of hair cells, but this has been shown to take a long time and does not lead to any real meaningful recovery of function. He discussed one strategy that he is studying to promote hair regeneration in mammals that mimics what is seen in avian regeneration where existing cells within the organ of Corti transdifferentiate from a supporting cell to a hair cell phenotype. He mentioned that an approach taken by other labs looks at introducing new hair cells into the organ of Corti.

Understanding developmental biology is key to inducing cells to change their fates. Identifying transcription factors, proteins that turn on other genes, that regulate hair cell formation is needed. Work from Dr. Kelley's lab and others has shown that to successfully regenerate a functioning auditory organ, not only is a generic hair cell needed, but the hair cell must be driven to a particular phenotype - outer hair cells and inner hair cells in particular. There is some work to suggest in addition to needing to provide positive genes to make cells

become hair cells, it may be necessary to eliminate inhibitory cues that prevent supporting cells from becoming hair cells. There is a need to understand more about the epigenetic modifications within the genome of those cells that will prevent cells from making this conversion from a supporting cell to a hair cell.

Dr. Kelley stated that the gene most intensely focused in terms of regeneration over the last 20 years is a gene called Atoh1 which is a basic Helix-Loop-Helix (bHLH) transcription factor that binds to DNA and other transcription factors. *Atoh1* is the homolog of the *Drosophila* gene *Atonal* which flies use for the formation of hearing organs and photoreceptors. In the developing cochlea, Atoh1 is expressed for a brief period in the nuclei of hair cells. Its timing is consistent with it playing a role in the early decisions of cells becoming hair cells. Research by Dr. Kelley's lab and others over the past 20 years has shown that *Atoh1* is essential for hair cell formation. Initial studies by several labs showed that Atoh1 was sufficient to induce regeneration of hair cells, but further evaluation showed that this effect was not on regeneration of hair cells but rather on survival of cells. Dr. Kelley explained that this was likely due to epigenetics, or the changes in the state of the chromosome that alters how easy or hard it is for a transcription factor to gain access to the genes within that chromosome to turn them on or off. There are two main types of epigenetic changes. One is methylation of cystines and the second is DNA winding around histones. The research to this point supports that regenerative effort that use gene therapy is going to have to start with *Atoh1,* but it is not going to be a magic bullet that by itself will induce regeneration. Atoh1 will have to be incorporated with other types of treatments to successfully induce hair cell regeneration.

Dr. Kelley said he is trying to build out more of the developmental process at a molecular level to understand the transcription factors turned on as the cell is becoming an auditory hair cell. He explained that he has been using single cell RNA sequences to build that pathway. The approach is to collect RNA and characterize the messenger RNA from single hair cells from different time periods and look at their transcriptome to build a trajectory for those cells through their developmental process. He noted that his lab developed a triple transgenic mouse where all the hair cells are red and most of the supporting cells are green. This was used to develop an effective disassociation technique to isolate the epithelium from the cochlea down to single cells. These cells were analyzed using a commercial platform to obtain the transcriptome for single cells on about 2,000 genes. Dr. Kelley indicated that future plans include identification of full length reads and splice variants. Machine learning was used to identify cells with similar transcriptomes and identify the different cell types. From this four phases of gene expression were identified within the developmental trajectory examined. From this transcription factors important at each phase were identified. The results showed some transcription factors that are already in hair cell formation, but a number of other genes were found that have not been previously linked to hair cell formation.

Dr. Kelly focused the remainder of his presentation on one of these novel findings, Casz1, which is a zinc finger family transcription factor. The drosophila homolog plays a role in regulating the temporal cascade that alters neuroblast fate and helps neuroblasts move from one possible cell fate to another. In invertebrates it has been shown to regulate cell fate specification, commitment and differentiation. *Casz1* has been implicated as a causal gene in chromosome 1p36 deletion syndrome which can include sensorineural hearing loss. Dr. Kelley presented data from his lab on characterizing Casz1 expression in developing hair cells and the modulation of Casz1 target genes as well. Further he described work that his lab did to target the deletion of *Casz1* in the inner ear only in mice. He showed results in which hair cells are still present in the targeted mice, but developmental defects are observed such as abnormal formation of pillar cells and decrease in the size of the hair cells. The adult ear of these mutant mice shows continued defects. Additionally, hearing assessments in the mutant mice show that defects in auditory brain stem response and a complete loss of otoacoustic emissions.

Discussion

Dr. Andy Groves commented that in the retina there is evidence that Casz1 promotes photoreceptor fates by repressing glial cell fates. It recruits some of these negative epigenetic modulators. He asked if Dr. Kelley could see an analogy where it might be involved in hair cell supporting cell decisions and if there was any evidence in the mutants of supporting cell genes starting to come on. Dr. Kelley indicated that it was a great point and that they could easily do it without waiting for RNA-seq analysis.

Dr. Eatock asked if increasing expression of Atoh1 had any impact on the differential expression of the two major hair cell types in the vestibular epithelia. Dr. Kelley responded that the regeneration done with Atoh1 suggests that Atoh1 is much better at making hair cells in the adult epithelia in the vestibular system than in the cochlea and they tend to be type II. He speculated that it is likely that additional specification factors are needed to make type I phenotype. Dr. Eatock followed up that type I cells do not express Atoh1 and type II cells in the adult do which might impact the number of type I cells in those animals. She then asked about the impact of the Casz1 mutant on the epithelium of the otolith as Emx2 is expressed in the otolith in the utricle. Dr. Kelley responded that they had not done the dissections yet but that the animals do not appear to have a significant vestibular deficit.

Dr. Morton commented that everyone appreciates that age-related hearing loss is probably a more complex thing to understand because of the normal aging and environmental impact from drugs and noise for example. She asked if the GWAS studies done to date show any evidence of a strial problem, sort of a metabolic problem, and then part also loss of hair cells. She further asked related to the Novartis study how possible that some people need something that strial problem but would also need the Atoh1 boost as well. Dr. Kelley responded that the inclusion criteria did not take any consideration of those issues but was solely focused on patients with hearing loss. He also commented that it was a Phase I trial, so its focus was on safety and no patients in the trial developed worsening hearing loss as part of the trial. This demonstrated that the inner ear seems to be a safe place to conduct a gene therapy trial.

Dr. Chaudhari focused her question on what is known in humans of the transcriptional developmental progression. She asked about the possibility of additional cascades of transcriptional targeting such that there is an additional stop point. Dr. Kelley responded that the time points were chosen due to technical limitations and that advances need to be made in isolating and collecting older hair cells to be able to profile them and look at the more complete trajectory. He also postulated that for the older age hair cells there will be a lot more transcriptional data on a lot fewer cells and that marrying this data with the data collected at earlier time points will be a challenge.

All of Us Research Program: Opportunities for Ancillary Studies with NIDCD .....Dr. Geoff Ginsburg

Dr. Tucci welcomed Dr. Geoffrey Ginsburg, the chief medical and scientific officer of the *All of Us* Research Program at the National Institutes of Health to provide an overview of the *All of Us* program and to discuss the possibilities of ancillary studies with NIDCD and All of Us. Dr. Ginsburg provided an overview of the program, discussed the types of data that have been collected, and highlighted ancillary study opportunities. The *All of Us* Research Program is the precision medicine initiative started by President Obama and launched in 2016 with a vision to accelerate health research, medical breakthroughs and to enable in the clinic the individualized prevention, treatment, and care for everyone. The program set about to establish strategic partnerships with participating communities and having them engage and willing to share their data and creating one of the largest biomedical research databases on the planet. The goal of the program is to recruit a million or more individuals across the United States representative of the population. To date 500,000 participants have been consented and 372,000 participants data have gone through the curation process and been released into the program's common data repository. Of these, eighty percent are from underrepresented communities and forty-five percent are from racial and ethnic minorities. He indicated that a key feature of the program is the ability to follow participants for decades. The program will add pediatric populations next year. The program has multi-dimensional data including surveys, electronic health records (EHR), genomics, biospecimen collections, and wearable technology with data from Fitbit and apple health kit. Dr. Ginsburg noted that the genomics data released in March included 600 million unique variants that had not been seen in prior publicly available datasets and that this is a testament to the inclusion of underrepresented minorities. He indicated that the program has a specific directive to make the work as accessible to as many researchers as possible with a goal this year of 2,300 researchers as active participants in the program's workbench. He reported that this goal was exceeded and highlighted partnerships with historically black colleges and universities as well as

Hispanic serving institutions. Dr. Ginsburg noted that the publication on data from the *All of Us* Research Program are just now happening and that there will be a geometric rise in publications soon.

Dr. Ginsburg then discussed the *All of Us* Data Workbench which can be accessed through ResearchAllofUS.org. Training on the workbench can be done through online tutorials or through workshops with an instructor with a goal of making use of the workbench as easy as possible. He discussed the multi-tiered system of access with different levels of data depending on the tier. The public level contains mainly aggregate data, the registered tier has more granularity, and the control tier has the highest privacy as it is where the genomic data exists. Training is required to access the higher tiers. He also outlined the scientific framework for the *All of Us* program from the foundation of the data to an impact on health through predicting risk, developing prevention strategics, improvements in diagnosis and screening and treatments and outcomes.

The next portion of Dr. Ginsburg presentation highlighted the NIDCD relevant conditions that are represented in the participants. To date approximately 35,000 participants in the *All of Us* database have been identified with hearing loss. Additionally, seven projects on the workbench mention hearing loss in their title. While this is a small number, Dr. Ginsburg expressed hope that this number grows with the help of the council and audience. He then turned to opportunities for ancillary studies which are announced through publication of Notices of Special Interest (NOSI) or Funding Opportunity Announcements (FOA) in FY22 and FY23. Dr. Ginsburg defined an ancillary study as a partnership that expands the dataset to answer new scientific questions. It can be done by adding new participants that normally would not be recruited to the program or by adding new data which could come from previously collected biospecimens, data tied to the EHR. These studies could be on a small subset of participants such as a thousand or across the entire cohort depending on the types of questions being asked. He gave examples of the ancillary studies such as ones that involve biospecimens, new questionnaires, participant recontact, or even randomized controlled clinical trials. Currently there are three ancillary studies as part of the program, and it is hoped to have twenty studies in the pipeline by 2026. Dr. Ginsburg concluded by highlighting what he saw as some opportunities for program studies that align to the NIDCD strategic plan.

Discussion

Dr. Anil Lalwani moderated the discussion. He commented that hearing and balance studies are often hampered by being an afterthought and not part of the larger data collection. He asked if there were opportunities for a study with wearables to be able to measure sound levels and correlating that exposure to noise-induced hearing loss. Dr. Ginsburg responded that everything mentioned is a possibility. He encouraged individuals to look at what data might be hidden in the EHR that could address some of the questions raised. He commented that if the wearable devices provide a valid technology to capture quality data that it would be relatively easy to do. Dr. Ginsburg also encouraged the thinking of pilot studies on the small scale to ensure that the quality of the data is understood before it gets scaled up.

Dr. Lalwani asked if the All of Us program was expanding the model to other larger databases such as NHANES where the genetic part is missing but the database has a richness and specificity of data. Dr. Ginsburg emphasized the strong connection to the CDC and efforts or underway to try to work with NHANES. He also welcomed other groups that want to adopt the *All of Us* model.

Dr. Morton commented that the Veterans Administration (VA) has very rich audiology records and asked if the Million Veteran Program (MVP) was incorporated into *All of Us* or if it still existed separately. Dr. Ginsburg explained that while the programs are separate there is overlap. The *All of Us* program is actively recruiting participants form some VAs. He expressed a desire to have the MVP and All of Us programs to work more synergistically in the future.

Dr. Tucci focused her question on the logistics. She wanted to know if an ancillary study that involved getting data which is not available through the EHR, such as audiometric data, would be done through academic medical centers or through direct solicitation to the participants. Dr. Ginsburg responded that both are possible, and the investigators or clinics might already overlap with *All of Us* recruitment sites. Additionally, it could be

possible that audiogram stations could be added to the recruitment sites and participants would have an audiogram done as a standard part of their recruitment. Dr. Tucci mentioned that the technology is getting to the point where patients could do a hearing test on their phone for certain kinds of hearing loss. Dr. Ginsburg cautioned that consideration be given to the need for medical grade versus non-medical grade devices to ensure analytic and clinical validity.

Dr. Lalwani also asked if the *All of Us* database could be used to see if individuals with hearing loss have a mutation in the gene that Dr. Kelley presented on, *Casz1*. Dr. Ginsburg responded that the genomic data is available for institutions with the control tier agreement in place. He commented that the database could be used to look at extreme phenotypes and the underpinnings to provide a feedback loop from labs like Dr. Kelley's.

Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.

Rebecca A. Miller -S

Digitally signed by Rebecca A. Miller -S
Date: 2023.03.02 11:55:29 -05'00'

Rebecca Wagenaar-Miller, Ph.D.
Executive Secretary
National Deafness and Other Communication Disorders Advisory Council

Debara L. Tucci -S

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Debara L. Tucci, M.D., M.S., M.B.A.
Chair
National Deafness and Other Communication Disorders Advisory Council
Director
National Institute on Deafness and Other Communication Disorders

Appendices

Roster
National Deafness and Other Communication Disorders Advisory Council

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Executive Secretary

WAGENAAR-MILLER, Becky, Ph.D. Director, Division of Extramural Activities
National Institute on Deafness and Other Communication Disorders
Bethesda, MD 20892

NIDCD Council Budget Report

Eric Williams, Budget Officer
NIDCD Advisory Council Meeting
September 8, 2022

National Institute on Deafness and Other Communication Disorders (NIDCD)

FY 2021 vs FY 2022 Operating Plan

(Dollars in thousands)

	FY 2021 Final Allocation		FY 2022 Operating Plan*	
Budget Mechanism	*Number*	*Amount*	*Number*	*Amount*
Research Projects				
Noncompeting	582	$256,482	**590**	**$270,884**
Admin. Supplements	60	$6,524	**48**	**$2,800**
Competing	180	$80,605	**176**	**$78,379**
Subtotal	762	$343,612	766	$352,063
SBIR/STTR	21	$15,492	22	$15,860
Subtotal, RPG's	783	$359,103	788	$367,923
Research Centers	7	$18,220	6	$15,243
Other Research	85	$12,048	**90**	**$12,913**
Total Research Grants	875	$389,371	884	$396,079
Individual Training	156	$7,359	155	$7,402
Institutional Training	157	$8,892	163	$9,541
R & D Contracts	43	$21,907	**42**	**$24,920**
Intramural Research		$44,747		$52,000
Research Mgmt. & Support		$24,297		**$24,940**
TOTAL		$496,574		$514,882
Lapse		$4		

*Projected

National Institute on Deafness and Other Communication Disorders (NIDCD)

FY 2023 Budget Outlook

(Dollars in thousands)

- FY 2019 Enacted: $474,404
- FY 2020 Enacted: $490,692
- FY 2021 Enacted: $498,073
- FY 2022 Enacted: $514,885

FY 2023

- House Mark-up: $531,136
- Senate Mark-up: $530,847
- President's Budget*: $508,704

* FY 2023 President's Budget was developed under a Continuing Resolution where FY 2022 was based on the FY 2021 Enacted level.

Appendix 3

NIH Staff Present
Closed Session Day 1

Chris Adams
Kathy Bainbridge
Tian Biao (CSR)
John Bishop (CSR)
Maribeth Champoux (CSR)
Laura Cole
Judith Cooper
Janet Cyr
Hoai Doan
Nancy Freeman
Maria Garcia
Rochelle Hentges (CSR)
Howard Hoffman
Nichelle Johnson
Tanji Johnson
Lisa Kennedy
Andrea Kelly
Kelly King
Alexei Kondratyev (CSR)
Eliane Lazar-Wesley
Mimi Lee
Trinh Ly
Castilla McNamara
Chuan-Ming Li
Roger Miller
Christopher Myers
Edward Myrbeck
Eric Nunn
Hua Ou
Amy Poremba
Kausik (Bobby) Ray
Alberto Rivera-Rentas
Cathy Rowe
Merav Sabri
Elka Scordalakes-Ferrante
Brian Scott (CSR)
Anu Sharman
Lana Shekim
Katherine Shim
Nanette Stephenson
Melissa Stick
Holly Storkel
Susan Sullivan
Debara Tucci
Jean Verheyden
Becky Wagenaar-Miller
Bracie Watson
Ginger Webb
Tim Wheeles
Eric Williams
Baldwin Wong
Shiguang Yang

Other NIH Staff
Felice Harper
Joy Jackson Farrar
CART Captioner

NIH Staff Present
Open Session

Chris Adams
Kathy Bainbridge
Laura Cole
Judith Cooper
Janet Cyr
Hoai Doan
Nancy Freeman
Maria Garcia
Howard Hoffman
Nichelle Johnson
Tanji Johnson
Joanne Karimbakas
Lisa Kennedy
Andrea Kelly
Kelly King
Eliane Lazar-Wesley
Mimi Lee
Chuan-Ming Li
Trinh Ly
Castilla McNamara
Christopher Myers
Edward Myrbeck
Eric Nunn
Hua Ou
Melissa Parisi
Amy Poremba
Kausik (Bobby) Ray
Alberto Rivera-Rentas
Cathy Rowe
Merav Sabri
Elka Scordalakes-Ferrante
Lana Shekim
Katherine Shim
Shirley Simson
Nanette Stephenson
Melissa Stick
Holly Storkel
Susan Sullivan
Debara Tucci
Jean Verheyden
Becky Wagenaar-Miller
Bracie Watson
Ginger Webb
Tim Wheeles
Eric Williams
Baldwin Wong
Shiguang Yang

Other NIH Staff
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Joy Jackson Farrar
CART Captioner
ASL Interpreter (Emma)

NIH Staff Present
Closed Session Day 2

Judith Cooper
Lisa Cunningham
Tanji Johnson
Elyssa Monzack
Debara Tucci
Becky Wagenaar-Miller
Ginger Webb
Tim Wheeles

Other NIH Staff
Felice Harper
Joy Jackson Farrar