

223rd NIDDK Advisory Council Meeting
Division of Diabetes and Endocrinology and Metabolic Diseases (DDEMD) Sub-committee
Meeting – Open Session
September 13, 2023

Attendees

DDEMD Sub-committee Members: Dr. David D'Alessio, Dr. Jose Florez, Dr. Debra Haire-Joshu, Ms. Davida Kruger, Ms. Neicey Johnson Dr. Philipp Scherer, Dr. Elizabeth Seaquist

DDEMD Staff Members: Dr. Kristin Abraham, Dr. Beena Akolkar, Dr. Guillermo Arreaza-Rubin, Dr. Raj Basu, Dr. Miranda Broadney, Dr. Art Castle, Dr. William Cefalu, Dr. Maureen Monaghan Center, Dr. Thomas Eggerman, Dr. Rafael Gorospe, Mr. Neal Green, Dr. Jay Gupta, Dr. Carol Haft, Ms. Amelia Hayward, Dr. Albert Hwa, Dr. Teresa Jones, Dr. Maren Laughlin, Dr. Jean Lawrence, Dr. Yan Li, Dr. Hanyu (Maggie) Liang, Dr. Barbara Linder, Mr. Louis Martey, Mr. Michael Mensah, Mrs. Heidi Otradovec, Mr. Daniel Rothwell, Dr. Salvatore Sechi, Dr. Corinne Silva, Dr. Pamela Thornton, Dr. Xujing Wang, Dr. Theresa Woo, Dr. Ashley Xia, Dr. Norann Zaghoul

NIDDK/NIH Staff: Mr. Terry Barnes, Dr. Najma Begum, Dr. John Connaughton, Dr. Greg Germino, Dr. Jaron Lockett, Mrs. Mary K Rosenberg, Dr. Kenneth Ryan, Ms. Nisrin Suterwala, Dr. Thomas Tatham, Dr. Kenneth Wilkins

Welcome and Approval of May 2023 Sub-committee Minutes (Dr. Cefalu)

Dr. Cefalu welcomed everyone to the DEM Sub-committee Open Session meeting and provided an overview of the agenda. Minutes were moved for approval and approved by committee members. He then introduced and welcomed new DEM program director, Dr. Jay Gupta, and acknowledged subject matter expert Dr. Jose Florez for his service, as well as, introduced Ms. Neicey Johnson as a new ad hoc member.

Heterogeneity of T2D Working Group of Council (Dr. Cefalu)

Dr. Cefalu provided updates on the Heterogeneity of T2D Working Group of Council (WGoC). He provided a general overview of the working group and how the work will align with NIDDK's strategic plan goal of understanding disease heterogeneity. The goal of the program is to provide a detailed overview of the current state of knowledge on the heterogeneity of diabetes and inform NIDDK scientific staff of evolving concepts in this field from a global perspective. Dr. Cefalu reviewed an initial activity of the WGoC where global partners convened on June 23rd prior to the ADA Scientific Sessions in San Diego, CA. The meeting was extremely well received, and a follow-up meeting is planned for Oct 5th in Hamburg, Germany with the objectives to review participant comments from the June 2023 meeting, discuss the vision for the global partnership/consortium moving forward, and to propose next steps and action items.

The program aims to produce a final report outlining the needs of the field as well as the opportunities available that can be used to stimulate research efforts to develop more discrete definitions of subtypes of Type 2 diabetes. Dr. Cefalu also outlined that the WGoC has identified

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and begun the formation of subgroups with the “charge” of each subgroup to address more defined and specific areas on the overall heterogeneity of diabetes topic. The proposed subgroups are clinical, pre-clinical, innovation, lifestyle, and engagement.

Dr. Cefalu emphasized that at the conclusion of this WGoC, a blueprint will be produced that will guide plans for research opportunities to address heterogeneity of diabetes for the next 10-15 years. Dr. Seaquist praised DEM for their efforts and use of structure to address this critical topic and looks forward to the final report.

Glycemic Observation and Metabolic Outcomes in T2D (Dr. Linder)

Dr. Cefalu introduced Dr. Linder who presented on the Glycemic Observation and Metabolic Outcome in Mothers (GO MOMs) in T2D. She provided a general overview of the program and reviewed Gestational Diabetes (GDM), Hyperglycemia and Adverse Pregnancy Outcomes (HAPO), HAPO Follow-Up Study (HAPO FUS), GDM: Treatment, Treatment Timing, and Vicious Cycling, and the GO MOMs study. GO MOMs is a comprehensive, longitudinal characterization of maternal glucose during pregnancy with the two long term goals of improved screening for GDM (including alternative diagnostic markers) and informing the timing/design of future clinical trials to decrease long-term sequelae of dysglycemia during pregnancy in both women and children.

Dr. Florez mentioned how remarkable the progress has been for this study despite the challenges faced from COVID and noted some of the issues that COVID may have presented to funding. Dr. Linder responded by saying that applications received no cost extensions in the middle of the award which resulted in the total number of funded years being 6 years instead of 5 years due to COVID.

DEM PI Workforce Diversification (Staff)

Dr. Cefalu introduced DEM staff members Dr. Gorospe and Dr. Laughlin who presented projects focused on enriching DEM PI Workforce Diversity. NIDDK’s strategic plan envisions a diverse multidisciplinary workforce to reduce health disparities and create a healthier path forward for all. Dr. Cefalu described the NIDDK-supported Training & Career Development Pathway pipeline and stated that at today’s meeting, we will discuss specific initiatives from our division. Those initiatives are the PRIDE RFA, DiabDocs, and MMPC-Live Vibrant programs. Dr. Gorospe first discussed the PRIDE RFA which seeks to provide research experience and mentoring to underrepresented individuals interested in pursuing biomedical research careers and to enable successful entry into and completion of a biomedical doctoral degree program.

Dr. Florez noted that Hispanics and Latinos should be noted in the charts and studies that Dr. Gorospe showed in the presentation. He stated that Hispanics and Latino demographics are not well documented and should be as they are another underrepresented demographic.

Dr. Cefalu discussed the DiabDocs program which seeks to improve the critical mass of clinician scientists in Type 1 research and to increase researcher diversity by expanding the geographical

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reach of the program. In that way, we can identify more eligible scholar candidates who then apply, create a cohort of up-and-coming MD research leaders and to have a more visible pipeline to research careers for physician-scientists. The program is also designed to improve the consistency and effectiveness of mentoring across research centers nationally through shared resources and an annual retreat.

Dr. Seaquist questioned if the number of type 1 scholars will be expanded as well alongside the type 2 scholars. Dr. Cefalu responded by saying that the program has funding for type 1 diabetes for now through the SDP and that additional funding from NIDDK now allows funding for scholars focusing on Type 2 diabetes.

Dr. Laughlin discussed the MMPCLive Vibrant Program which aims to enhance diversity in the research workforce. The goal of this program is to improve the ability of basic researchers from underrepresented communities to compete for research funding by providing phenotyping services and pilot funding, to do the highly sophisticated in vivo experiments demanded by top tier journals and NIH study sections.

Dr. Scherer had a question about the implementation of the national MMPCLive Vibrant Pilot funding program. Dr. Laughlin responded by saying that unlike a typical local diabetes center, the MMPC has a coordination center which can solicit applications and make awards/sub-awards. The Vibrant program is currently in the planning phase.

Islet Transplantation Biological License Agreement (Dr. Eggerman)

Dr. Cefalu introduced Dr. Eggerman who provided an overview related to the recent licensure of human islets as a treatment for type 1 diabetes. Dr. Eggerman discussed the process of islet isolation from donor pancreata and infusion for clinical transplantation, history of clinical islet transplantation, and the efforts of the NIDDK and NIAID funded Clinical Islet Transplantation (CIT) Consortium which conducted phase III trials contributing to licensure. He also presented the significant clinical outcomes from one of the pivotal CIT trials as well as the potential islet transplantation risks and issues that limit the target population. The significance of the newly licensed human islet therapy was discussed, especially as it related to the challenging aspects of cellular therapies in general. The reasons why it took 20 years for licensing human islets as a biologic product was also presented. In addition, Dr. Eggerman pointed out how human islet transplantation licensure has facilitated the efforts of stem cell derived cellular therapies to treat type 1 diabetes.

Dr. Scherer acknowledged that this is a major step forward in the field and asked how competitive it is currently to obtain islets for research, and whether there are any shortages in the market. Dr. Eggerman discussed the Integrated Islet Distribution Program (IIDP) program which has had difficulty obtaining pancreata for isolating islets; Dr. Eggerman expressed that it is not clear to him why there is difficulty in obtaining islets but acknowledged that progress is being made to make islets more available for research purposes.

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Dr. Seaquist praised Dr. Eggerman for the achievement of the islet program that led to licensure and questioned what the future of donor centers would look like in relation to this process. Dr. Eggerman responded by saying right now there is only one location that is allowed to do this process. There are opportunities for licensing at other academic centers with a history of islet transplantation. In terms of being competitive, several methods can be taken to lower cost and increase availability/distribution. Dr. Germino asked questions about costs related to the islet transplantation. Dr. Eggerman responded by saying the costs for islet transplantation has varied over time and that the program has been supported by the CMS which covered the cost for all Medicare patients years ago for the Clinical Islet Transplantation Consortium (CIT), current costs are unknown. Dr. Laughlin suggested if the costs could be commercialized by a company. Dr. Eggerman responded by saying that the licensure is actually to a company called CellTrans that was formed by the CIT investigator Dr. Jose Oberholzer and that islet transplantation is not a profitable business model and is not well desired as an opportunity for private sector partners.

Dr. Cefalu had an open-ended question for the group of council regarding what other ideas should be considered in reference to workforce diversity for the division. Dr. Seaquist would like to see the use of the recipients of these programs/awards as ambassadors for science reaching out to younger populations to bolster general interest in science. Dr. Florez suggested to bolster the existing NIH summer research medical student program with an improved emphasis on URMs and suggested that supplements can be used as a tool. Dr. Silva commented on the program referenced by Dr. Florez by saying the program has encountered a decrease in the medical student programs and dwindling participation due to a lack of time before students first and second years of medical school in the summer. Dr. Florez suggested that for premedical students at the undergraduate level, a program could be introduced that exposes students to NIDDK/DEM research/science while also improving their chances of getting into medical school. Dr. Cefalu also then went on to ask how NIDDK can retain endocrinologists in the field. Dr. Florez also stated that endocrinology must be incentivized to garner participation and gave examples of how his institution was able to address the issue of endocrinology resident retention. Dr. Seaquist acknowledged the possibility of NIDDK providing more support to international students to help bolster programs and increase diversity. Dr. Germino mentioned the Aspirnaut program from Vanderbilt that targets individuals from rural, diverse, and underrepresented backgrounds for research opportunities that has been incredibly successful in supporting K-12 and graduate applicants and has produced graduates in the biomedical sciences; the program could serve as a model for NIDDK to follow. Dr. Florez reiterated Dr. Seaquist's point about supporting international students. Dr. Germino mentioned that generally NIH/NIDDK cannot always support individuals that are not US citizens and that training funds are meant to be used on domestic applicants. Dr. Seaquist suggested that this should possibly be changed with a mechanism that could include a path to citizenship because we are losing a significant number of physician scientists in this subject area the international pool of applicants can help to address.

DEM Workshops (Dr. Cefalu)

Dr. Cefalu introduced and presented on future workshops for DK in the near future:

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- Human Islet Research Network (HIRN) 2023 Investigator Meeting
 - September 19-21, 2023
 - Omni Shoreham Hotel in Washington, DC and Virtual
- 2023 NIDDK CDTR Directors' Annual Meeting
 - September 21-22, 2023
 - Two Rockledge Center, Bethesda, MD
- 2023 Annual Mid-Atlantic Diabetes and Obesity Research Symposium
 - September 22, 2023
 - Natcher Conference Center, NIH Campus, Bethesda, MD and virtual
- Microphysiological Systems (MPS) for Studying T2D, Obesity, and Their Complications
 - September 28-29, 2023
 - Natcher Conference Center, NIH Campus, Bethesda, MD and virtual
- 2023 NMRI West Region Workshop
 - October 24-25, 2023
 - University of Nevada, Las Vegas Nevada
- Diabetes Mellitus Interagency Coordinating Committee (DMICC) Meeting: Application of Digital Health Technology to Type 2 Diabetes Management: Current Status, Research Gaps, and Opportunities
 - November 14, 2023
 - Virtual
- Understanding the Biological Mechanisms Underlying the Health Consequences of Racism, Marginalization, and Discrimination
 - April 2024
- NIDDK Dissemination and Implementation (D&I) Health Equity Workshop
 - May 20-21, 2024
 - NIH Campus, Bethesda, MD and virtual

Concluding Remarks (Dr. Cefalu)

Dr. Cefalu thanked the Sub-committee members and DEM staff for their presentations and comments. He noted that DEM looks forward to hearing new ideas for improving workforce diversity, as well as, bolstering strength in existing programs and noted that new ideas and suggestions are always welcome.