

216th NDDK Advisory Council Meeting
Division of Diabetes and Endocrinology and Metabolic Diseases (DDEMD)
Sub-committee Meeting – Open Session
May 13, 2021

Attendees

DDEMD Sub-committee Members: Ms. Tracey Brown, Dr. David D'Alessio, Dr. Robert Eckel, Dr. Barbara Kahn, Dr. Michael Snyder, Ms. Lorraine Stiehl, Dr. Dale Abel

DDEMD Staff Members: Dr. Kristin Abraham, Dr. Beena Akolkar, Dr. Guillermo Arreaza-Rubin, Dr. Miranda Broadney, Dr. Henry Burch, Dr. Arthur Castle, Dr. William Cefalu, Dr. Brad Cooke, Dr. Thomas Eggerman, Mr. Neal Green, Dr. Carol Haft, Dr. Teresa Jones, Dr. Maren Laughlin, Dr. Jean Lawrence, Dr. Christine Lee, Dr. Ellen Leschek, Dr. Yan Li, Dr. Barbara Linder, Dr. Saul Malozowski, Mr. Louis Martey, Mr. Michael Mensah, Ms. Crystall Okolo, Mrs. Heidi Otradovec, Dr. Sheryl Sato, Dr. Salvatore Sechi, Dr. Corinne Silva, Dr. Lisa Spain, Dr. Philip Smith, Dr. Karen Teff, Dr. Pamela Thornton, Dr. Xujing Wang, Dr. Norann Zaghoul

NIDDK/NIH Staff: Mr. Terry Barnes, Dr. Najma Begum, Dr. John Connaughton, Ms. Leslie Curtis, Mr. Tim Kerns, Dr. Peter Kozel, Dr. Jennie Larkin, Mr. Jaron Lockett, Mr. Richard Peek, Mr. David Robinson, Dr. Thomas Tatham, Dr. Kenneth Wilkins

Welcome and Approval of Jan 2021 Sub-committee Minutes (Dr. Cefalu)

Dr. Cefalu welcomed everyone to the DEM Sub-committee Open Session virtual meeting and provided an overview of the agenda. He then introduced and welcomed former Council member, Dr. Robert Eckel and visiting scientific expert, Dr. Dale Abel. Minutes from the January 2021 Sub-committee meeting were approved. Dr. Cefalu then informed Council members that the Special Diabetes Program (SDP) funds were recently appropriated at \$150M per year in FY21, FY22, and FY23. Dr. Cefalu expressed his excitement and emphasized how receiving three years of no year funds helps tremendously with initiative planning. He also noted that an expert panel will meet on March 9, 2022 to discuss new SDP initiative concepts. Dr. Cefalu then introduced Dr. Leschek who presented the accomplishments of the Epidemiology of Diabetes Interventions and Complications in the last five years.

The Epidemiology of Diabetes Interventions and Complications (EDIC) (Dr. Leschek)

Dr. Leschek reviewed EDIC's current grant cycle accomplishments with respect to each of the five specific aims, emphasizing recently published data. Aim 1 involves prevalence of cognitive, affective, and physical impairment. Aim 2 addresses risk factors for severe and advanced microvascular complications. Aim 3 focuses on risk factors for cardiovascular disease and mortality. Aim 4 involves co-progression and trajectory of outcomes, and Aim 5 focuses on long term economic and quality of life issues in the long-standing cohort of individuals with T1D. Ancillary studies focus on neuroimaging, hypoglycemia and its correlation to arrhythmia and skeletal health of adults with T1D. Dr. Leschek reviewed current cohort demographics, including the high prevalence of overweight and obesity.

Dr. Cefalu indicated that the EDIC update was provided to offer background for upcoming

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NIDDK discussions about the future of this study. Dr. Snyder voiced enthusiasm and support for the study. Dr. Abel indicated that EDIC has provided insight into the natural history of T1D, even as the approach to therapy has evolved over the course of the study. He said that EDIC is a landmark study. Dr. Eckel concurred that EDIC is incredibly important and indicated that it should be continued.. Dr. Kahn was also enthusiastic and said there are mechanistic insights that can come from EDIC as well as information about use of new diabetic devices. Dr. Kahn also indicated that it is important to emphasize studies on T1D complications. Dr. D'Alessio added that the natural history aspect of EDIC has generated most of the data.

Training and Career Development Programs (Dr. Haft)

Dr. Haft provided an overview of the DEM training and career development portfolios. NIDDK uses a variety of grant mechanisms to support biomedical researchers at different stages in their research careers from a student's individual training, a post-doctoral fellow's training and career development, to individual faculty support. Over the last decade, DEM supported 30 to 40 trainees each year, with a particular emphasis on supporting post-doctoral fellows. It was noted that over the last 3 years the number of F32 applications (post-doctoral fellowships) submitted to DEM has declined, and this downward trend appears to be in line with the NIH-wide F32 application submission trend. Staff would like to understand better the reason(s) for this decline so that they can perhaps find ways to mitigate the decrease.

Dr. Haft then presented slides on DEM's efforts to diversify its workforce by releasing two special National Research Service Award fellowship FOAs designed to provide training to graduate students and fellows in both bioinformatics and diabetes research methods.

Next Dr. Haft presented an overview of the DEM Institutional Training Grants portfolio that supports more than 200 trainees working on important unanswered research questions in adult and pediatric endocrinology and basic biology in diabetes and obesity pathogenesis. In 2020 DEM supported 173 post docs –a sizable fraction of whom are doing research as part of their endocrinology fellowship training and 54 pre-docs, including URM individuals and four specialty T32s focused on bioengineering and diabetes/obesity, and two emphasizing bioinformatics and metabolic disease training. Dr. Haft then highlighted two new programs that DEM developed that focus on a critical time period, especially for physician-scientists: the transition from fellowship training on a T32 to a junior faculty position doing research. The two new programs to support emerging physician-scientists are 1) an opportunity for a DEM funded PI to apply for supplemental funds to support key protected time for an emerging MD to gather key preliminary data and publish prior to applying for a K award and 2) co-funding of clinical P&Fs through DRCs for those individuals who need more time to obtain preliminary data and develop their own research project.

Dr. Haft then provided an overview of the current career development portfolio which includes individual grant mechanisms (K01, K08, K23, K25, K00/R00). Dr. Haft further explained the pathway to independence award (K99/R00) and its distinction from the other K awards. Since

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its inception in 2007, DEM has received several dozen K99/R00 applications per year but only had funds to support a small number of projects. A cohort analysis showed the K99/R00 awardees were 89% more successful in getting follow-on R01 support than their counterparts who applied but did not receive K99 support.

Dr. Haft also presented several NIH-wide new and future programs to support trainees and junior investigators, such as childcare support for fellowship holders, life event supplements to F and K awardees, and extension of eligibility for K-award applicants. Dr. Haft ended the presentation by posing the following questions for Council's feedback: 1) Is there specialty training that our workforce of the future should be getting now? 2) Should we be concerned about the recent decrease in post-doctoral F32 applications? 3) Should we consider funding additional K99/R00 applications?

Dr. Abel mentioned he was surprised by the reduction in the number of K08 applications submitted over the last decade and asked if the success rate in that pool was reduced as well. Dr. Spain responded that there were fewer applications; they were reviewed carefully; and given special consideration for funding so the number of MD candidates doing basic science research doesn't get even lower. Dr. Eckel recommended that after clinical training, physician-scientists should be encouraged to spend time in laboratories to learn and explore so that they will have the chance to start thinking how aspects of basic science relate to translational research. Staff agreed. Dr. Cefalu noted the National K12 initiative concept presented by Dr. Spain the day before would be helpful to meet the need noted by Dr. Eckel. Dr. Abel thought that the administrative supplements to funded R01s to support emerging physician-scientists is a good idea and mentioned the StARR program supported by NHLBI and NCI where individuals receive funding of up to two years of residency time, to increase the pool of MDs who are exposed to research. Dr. Snyder provided the following feedback: a) very much in favor of supporting K99/R00 applications; b) Are there fewer NIDDK R01 funded labs than in the past?—that may be why we are getting fewer F32 applications submitted; c) Encouraged staff to advertise at meetings that DEM is looking for top fellows to fund; d) Partner with other institutes. Dr. Kahn commented on the Endocrinology Fellowship T32 at her institution where there are 3 slots per year, but 2 of them are for clinical research projects only. She commented that it is important for MDs to be able to spend time in a lab not making career commitment, but just to gain lab experience and think about their career path.

DEM Centers COVID-19 Follow-Up (Dr. Silva)

Dr. Silva gave a brief update on the session from January Council where the DRCs and CDTRs were asked to consider ways in which they could leverage the Centers and address COVID-19 and Diabetes. Since January, the leadership of the DRCs and CDTRs has been leveraging infrastructure, facilities, and programs to study the interplay between COVID-19 and diabetes and other co-morbidities. Recommendations were presented in three phases: Phase 1 involved an immediate action that has already been implemented that is a combined Center-sponsored National COVID-19 enrichment program aimed at coordinating network-wide activities. A panel

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discussion on COVID-19, Diabetes and Health Disparities took place virtually on April 14, 2021. A Phase 2 action is being implemented as the Centers will establish a trans-CDTR and trans - DRC programs on a mini grant for core use and an expanded Pilot and Feasibility program to address COVID-19-diabetes related projects. Dr. Silva briefly discussed the two trans-Center programs. Both programs will be overseen and evaluated by governance committees that will also determine if these programs will move forward. For the expanded Pilot and Feasibility program that will focus on COVID-19 and diabetes, a collaboration between two or more Centers will be required, and evaluation will also be done to determine if the program will continue. Dr. Snyder thought the mini grants may be too small and not worth the effort, but the P&Fs would be substantial. Dr. Cefalu expressed his excitement for the Centers leveraging resources and collaboration.

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 providing details at a future meeting on the progress made on the programs discussed today. Dr. Cefalu noted that new ideas and suggestions are always welcome. Please send them to him or Dr. Haft.