

220th NDDK Advisory Council Meeting
Division of Diabetes and Endocrinology and Metabolic Diseases (DDEMD)
Sub-committee Meeting – Open Session
September 7, 2022

Attendees

DDEMD Sub-committee Members: Dr. David D'Alessio, Dr. Debra Haire-Joshu, Ms. Davida Kruger, Dr. Philipp Scherer, Dr. Elizabeth Seaquist, Dr. Michael Snyder, Mr. Hector Soto (subject matter expert)

DDEMD Staff Members: Dr. Kristin Abraham, Dr. Beena Akolkar, Dr. Guillermo Arreaza-Rubin, Dr. Shavon Artis Dickerson, Dr. Miranda Broadney, Dr. Henry Burch, Dr. Art Castle, Dr. William Cefalu, Dr. Maureen Monaghan Center, Dr. Brad Cooke, Dr. Thomas Eggerman, Mr. Neal Green, Dr. Carol Haft, Dr. Albert Hwa, Dr. Maren Laughlin, Dr. Jean Lawrence, Dr. Yan Li, Dr. Hanyu (Maggie) Liang, Dr. Barbara Linder, Dr. Saul Malozowski, Mr. Louis Martey, Dr. Saira Mehmood, Ms. Mansi Mehta, Mrs. Heidi Otradovec, Dr. Salvatore Sechi, Dr. Corinne Silva, Dr. Lisa Spain, Mr. Kyle Sullivan, Dr. Karen Teff, 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. Rebecca Cerio, Dr. John Connaughton, Mr. Randy Copeland, Dr. Ann Jerkins, Dr. Jaron Lockett, Dr. Karl Malik, Dr. Charlene Repique, Dr. Paul Rushing, Dr. Elena Sandovich, Dr. Tori Stone, Ms. Alyssa Voss

I. Welcome and Approval of May 2022 Sub-committee Minutes (Dr. Cefalu)

Dr. Cefalu welcomed everyone to the DEM Sub-committee Open Session virtual meeting. He explained that as discussed previously with Council members, DEM has worked to make the Sub-committee meeting more interactive and allow more time for discussion by advisory members on the topics presented. Dr. Cefalu then introduced the topics to be discussed: digital health technologies in the treatment of T2D and DEM career development and training. This was followed by a call to approve the minutes from May 22nd. The minutes were approved.

II. Council Member/Staff Transitions (Dr. Cefalu)

Dr. Cefalu welcomed Mr. Hector Soto, a subject member expert. Mr. Soto then made a few remarks. He was born and raised in New York City and has lived in the Bronx for the last 50 years. He teaches public policy and law at the Hostos Community college (part of the CUNY system). Mr. Soto has been a practicing attorney since 1976 with most of his work around issues of police-community relations in the broadest possible sense, and in the most specific sense police misconduct, police accountability, police reform. He has also been the chair of the Committee on Equity, Diversity, and Inclusion. Dr. Cefalu then went on to note that this was Dr. Karen Teff's last council meeting, as she will be retiring at the end of this month.

Lastly, Dr. Cefalu mentioned four upcoming DEM workshops; 1) the Mid-Atlantic Diabetes Obesity Symposium on September 23rd; 2) the Annual Directors meeting for CDTRs on September 27th and 28th; 3) the 14th Annual Isotope Tracers Course in Metabolic Research on November 7th-11th and 4) the Targeted Mass Spectrometric Assays symposium on December 1st.

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III. Digital Health Technology (DHT) for the Treatment of Type 2 Diabetes (Henry Burch)

Dr. Burch started with a brief introduction and then spoke on the application of digital health technologies in the treatment of type 2 diabetes, the need to change the way we're currently managing our patients with diabetes (particularly type 2 diabetes), the goals of DHT use, some of the existing tools, and some of the barriers to the application of DHT to type 2 diabetes management. He then touched on the current DEM portfolio in this area, and then briefly discussed a possible workshop for this topic.

Dr. Burch noted that there's been a convergence of technological advances over the past two decades. Broadband internet is becoming faster and more widely available, smartphones are more capable than ever, there's been an explosion of digital health applications and wearable devices. The cloud can now store a large dataset in a secure manner, health records are now electronic and there's been a huge shift to telehealth during the COVID-19 pandemic. Taking data from all these sources and analyzing it using artificial intelligence leads to digital health technology, and from that to digital health therapeutics where there is a huge investment from the corporate sector.

Dr. Burch explained that the way we are currently delivering care for our patients with type 2 diabetes is very cumbersome. There are many steps a patient has to go through just for a 15-20 minute appointment with a provider. It is an ineffective means of delivering diabetes care, and unfortunately over the past decade the percentage of patients with an HbA1c less than 8 declined rather than improved. Clearly, this is an area where we need to change our approach. Digital health technology provides an opportunity to improve access to care for patients to make the clinic visit more efficient. It is also a way to give patients a sense of empowerment, to decrease clinical inertia and improve patients' satisfaction.

Dr. Burch then briefed the Sub-committee on several digital health tools including telemedicine, mobile devices, wearable devices/ remote monitoring capability, artificial intelligence, electronic healthcare records and associated patient portals. He then discussed some of the more holistic digital solutions for diabetes management being developed by industry. These holistic systems provide many levels and layers of support. They have community support, interactive learning that's attuned to a particular patient's needs, activity tracking through smart watches, food tracking progress, tracking daily reminders, all in one package. There are at least a dozen of these systems available.

Another topic discussed by Dr. Burch was the barriers to the effective use of digital health technology to the management of type 2 diabetes such as poor uptake by healthcare organizations, poor interoperability between most forms of digital health technology and electronic healthcare records, limited effectiveness data, and a huge digital divide that persists in our country.

He then went over the current DEM portfolio in DHT and type 1/2 diabetes noting that many of the recently funded DHT R01s focused on wearable devices (either CGM or activity monitors),

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while a few others focused on tailored text messaging, telemedicine, patient portals, and mobile applications.

Dr. Burch ended his presentation restating the discussion questions previously posed to the council on this topic.

- 1) What are the major research gaps in DHT as applied to type 2 diabetes?
- 2) Which gaps are uniquely addressable by NIDDK? How would you prioritize in terms of clinical impact, sustainability, and mitigation of barriers?
- 3) How can we best address the many existing DHT applications and systems to further focus DK-funding efforts?
- 4) How should the large corporate footprint impact our efforts?
- 5) What additional stakeholders /expertise should be included in a DHT-T2D workshop?

Dr. Cefalu then moderated the discussion.

Dr. Snyder was enthusiastic about this topic and thought it was the way of the future. He pointed out that one area in need of attention is “behavioral modification” and strategies related to modifying behaviors. He also thought the focus should not just be on type 2 diabetes but should start earlier than that by focusing on young people at risk for diabetes and prediabetes so that you can at least delay the onset of diabetes for a few years. He thought that personal coaches are fine for now but does not know how successful they will be in the future. The big issue and gap he saw was with data sharing, there is not enough of that going on in the field.

Ms. Kruger was also very enthusiastic about this topic as most of the patients she sees daily are virtual. She pointed out a couple things to iron out such as CGM. All CGM should be considered, not just flash. Abbott’s new CGM is no longer flash and is not available from Medicare because it does not have a reader. Medicare would need to change its guidelines for Abbott’s CGM to be available, but that might not happen. These programs are also very costly, so another thing to consider is whether institutions want to buy into these costly programs. She also echoed Dr. Snyder’s sentiments about concerns with data sharing in the field. She mentioned the use of all this technology needs to be utilized at the primary care level and that workshops should focus on primary care. There are fellows that can't finish their fellowship without experience with sensors, pumps, and apps, but the primary care world is intimidated by all this technology and at this time, not adequately trained to address this program in this field. Finally, she mentioned that many patients do not have access to phones still, or they don’t know how to utilize them. Ms. Kruger thought primary care needs to take the lead on this and that we should support them in fully understanding it. We also have to recognize limitations of people with diabetes in terms of their understanding and willingness. and access to these devices.

Dr. Haire-Joshu also considered DHT an important topic but also cautioned that a potential problem is that digital health technology if not addressed adequately could contribute to an increase in health inequities. She works with a community that does not ever get primary care, or minimally gets primary care because they cannot leave their jobs. This opens a way to reach

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those communities, but we still don't know what the content is that works well or how it works well. Implementation science in this area is very important so we can increase the rigor and make sure we do so equitably. We should understand who this works for in a very thoughtful and systematic way. We can apply what we have learned through COVID to develop interventions targeted to populations we were not able to target before. She echoed Dr. Snyder's sentiments on earlier interventions in the younger generation and targeting prediabetes instead. She mentioned we should start with prevention and use these technologies to support behavior change. We would be able to study what works with different cultures, with different populations, with different communities, in a way we've never been able to do that before. This can be done rigorously if we start early which can really advance the field. Lastly, she touched on clinical applications and how important it is to share information back and forth within communities.

Dr. Seaquist was also excited about this topic and mentioned that she sees 50% of her patients via telehealth. The major concern she worries about is patient compliance. She sees these technologies being really successful with patients who are excited to try new technologies. These studies have been done with people who agree to be part of this research because they're excited and they want to adapt to it. However, that is not all patients, and the challenge is to get patients who are not so readily open to new technologies to try the programs.

Dr. Cefalu expressed that Dr. Seaquist's point was well made and that he thought it was analogous to what we're doing with automated insulin delivery approaches. He mentioned that it is important not only to develop the technology, but to make sure there is uptake of the technology and reduced barriers for all patients, and not just those who are willing to use it and have access to the technology.

Dr. D'Alessio echoed Dr. Seaquist's sentiments on telehealth. He believes it is here to stay and a really good way to do endocrinology and very effective way to collect data. He was very concerned about the amount of resulting data and thought there's a big need to be able to distill it into actionable bits. He was also concerned these technologies would not result in behavioral modifications. He was not sure how motivational the information from these devices would be for patients and patient compliance. It could be viewed as burdensome. The data on other forms of behavioral modification and their impact on health have been mixed at best. He concluded that this has a lot of potential but needs to be executed in a very systematic and clear way.

Mr. Soto thought the presentation was very informative. He mentioned that there are doctors who have incorporated the new technologies in their practices and doctors who haven't. He suggested that doctors have patients who appreciate those specific approaches so there are clear preferences within the population. He agreed that focusing on prevention and targeting the younger population could be helpful but there is a huge issue of equity especially with individuals of low-income, and Latino and African American populations. There are all kinds of health facilities in the South Bronx, yet every year the South Bronx comes in at the top of many indicators of poor health.

Dr. Snyder encouraged brainstorming to try to find helpful strategies that lead to successful

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implementation of these technologies by different groups, and suggested thinking about strategies by which providers can give discounts or financial rewards to lead to behavioral change. This can actually benefit the patients so that they can take advantage of these programs. He believes in the ability of technology like CGM leading to behavioral change, as patients can see how their everyday diet is affecting their health in real time.

Dr. Cefalu thanked the committee members for their comments. He asked that council members think specifically about the questions posed, talk to their colleagues about this topic and submit answers back to DEM so that they can be collated and discussed internally for our initiative considerations and at the next council meeting.

IV. DEM Training and Career Development Portfolio (Drs. Castle and Spain)

Dr. Castle presented an overview of DEM's training portfolio. He described the features of each individual fellowship type that support individuals at different career stages (F30, F31 and F32) and the institutional training grants (T32) where the institution chooses which trainees to support with their T32 funding. The number of individuals supported by individual fellowships has remained stable over the last 4 years. However, the number of F32 submissions has been significantly lower in each of the last 5 years than seen in the previous five-year period (2013-2017). This decrease in submission of applications by postdoctoral fellows was not unique to DEM. Looking at NIH-wide data one sees a similar multi-year decrease across many ICs and last year NIH F32 submissions were down by ~20%.

Institutional training awards were then discussed (T32s). At present, there are only five DEM training grants that train exclusively MD postdocs and many pediatric endocrinology and endocrinology training programs are struggling to fill slots. Most programs that historically trained only MD postdocs have switched to include more PhDs and trainees pursuing more basic science projects. In general, MD fellows have much lower rates of staying in research so there are concerns about being able to retain a vibrant pool of physician scientists. To increase the opportunities and to generate interest to become a physician scientist, DEM has a program where students from medical schools apply to do short-term research training during the summer at one of the diabetes research centers across the country. This is an on-going effort designed to increase interest of physician scientists in diabetes research.

Dr. Spain then discussed DEM's career development portfolio (K01, K08, K23, K25 and K99/R00 awards) which supports mentored research projects of individuals transiting from senior postdoctoral positions to junior faculty. Over the last six years, the number of K awards has remained relatively stable. However, the number of K08 submissions and awards has been limited. Overall, NIDDK K08 awards are declining. Dr. Spain next spoke about the K12 program, administrative supplements to R01 to support emerging physician scientists and co-funding for clinical P&Fs through DEM centers. She also discussed the T1D Gateway Awards for junior investigators, DKnet sponsored P&Fs, and training opportunities for students, postdocs and new PIs to bring bioinformatics tools and skills to DEM research, and the Mosaic K99/R00 program to support junior researchers under-represented in biomedical research.

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Dr. Haft then moderated the discussion section by going over the questions posed to the council. The discussion was as follows:

Dr. Scherer answered the first question by stating that he agrees there are fewer postdocs in the pipeline. He stated that at UT Southwestern, there is a crisis committee in place along with consultants to figure out why. This is a situation that is going on across the board at many institutions. He stated that part of the reason is that more PhD's are leaving academics after they get their degree to go into industry rather than remaining in academia as postdoctoral fellows. He suggested that since the number of F32 applications have decreased, would it be appropriate to consider selectively increasing the funding percentile for the remaining applications, or would that increase be at the cost of quality? Dr. Scherer reported that at UTSW, T32 recipients are mandated to apply for an F32 or equivalent within their first year of appointment. As such, he questioned if there was any insight into the lower retention rate of T32 appointees versus F32 awardees.

Dr. Cefalu asked Dr. Scherer if most of their T32 slots are filled by PhD's rather than MDs. Dr. Scherer answered "yes" and that it was a lifeline for their training grant because most of the MDs who were on the training grants went into private practice. They were able to improve the rate of retention in academia significantly by moving towards more PhDs on the grants instead. He expressed concern that the postdoctoral scientist is a "disappearing species" whether they are a PhD, an MD/PhD, or an MD and that is the issue we should be considering.

Dr. Seaquist echoed all the points Dr. Scherer made. She also pointed out at her institution there is a major decrease in citizens or permanent residents applying for these grants. She is seeing an increase in amazing international individuals who would want to be physician scientists but do not qualify for the training grants, and the program cannot afford that. That is something that should be addressed. Another issue is funding individuals who are in the physician scientist training program. Residents coming into internal medicine, who are interested in a research career, short track their residency where they do two years of residency and three years of research training. The problem here is that when they come in as a resident, they have to be assured of funding for those three years-which is technically five years into the future- beyond the budget period of the T32. They would be perfect T32 appointees if there were a way we could include them. Some divisions/programs won't consider them because they're concerned that they will need to support them with division funds.

Dr. D'Alessio also agreed with the comments of the previous council members. At Duke he is seeing the same issues. He questioned if there is data on how many awardees who participate in the medical student research programs end up in internal medicine or pediatrics or endocrine fellowships. He worries that individuals may be using this opportunity to buff up their CVs to go into other more competitive residencies, such as orthopedics, radiology, etc. Dr. Castle expressed that he did not have the data, however the numbers are coming in and looked encouraging for the number of appointees pursuing research. Additional data will be forthcoming.

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Dr. Snyder requested clarification on whether roughly 5% of MDs go on to continue research or was it 5% of all T32 appointees. Dr. Castle replied that it is 5% of the MD's and considerably higher for PhD's, and much higher for those receiving fellowships. He went on to explain that people who submit and obtain individual fellowships are much more likely to get subsequent awards than people who are on T32s. Dr. Snyder also commented that postdocs are now commonly entering industry much more so than in the past. Dr. Castle felt that one reason for the interest in industry jobs is pay. NRSA starting pay is now \$55,000, but you can get at least 50% more in industry. Another reason for the huge drop off is the COVID factor. Most people submit applications about 1-2 years into their postdoc so this year and next year we're probably seeing a big effect of COVID across NIH and specifically in DEM.

Dr. Snyder also noted that the level of stress felt by PI's and then noted by trainees has also likely contributed to the drop off people wanting to do postdoctoral training in academia. He believes that postdocs do not want to take on that level of stress in their careers. There may also be an issue with women obtaining postdoc faculty positions because they're concerned about family issues as well. Dr. Haft added that NIDDK was quite aware of the stress that PIs and potential PIs feel when R01 pay lines are at 8 or 10%, and how if pay lines remain low for an extended period, this can chip away at researchers' desire to stay in the enterprise even if they are really excited about their science. This was one important reason that NIDDK has worked hard to establish and maintain our R01 pay line at 25% for early-stage investigators and 16% for established PIs over the last few years.

Dr. Haft then asked council members if their institutions had any special perks/incentives to attract and maintain post-docs and junior faculty, and if they are now using research technicians or staff scientists to do what post-docs used to do.

Dr. Cefalu then reiterated that DEM has a variety of unique and innovative programs focused on training, career development and retention in science, but is interested to hear about each council member's institutions' best practices to inform what we should consider as a division. Dr. Snyder mentioned that NHGRI is out in front of their constituents. They are always advertising their programs, even at meetings and conferences. NIDDK should mention their pay line because at 25%, it is pretty good, and he is not sure that everyone is aware. He suggested advertising these programs at meetings such as ADA and other relevant meetings. Dr. Scherer agreed with Dr. Snyder on advertising these opportunities more, particularly specialty programs, which is what sets DEM apart. Dr. Snyder pointed out that although these programs are on the NIDDK website, it is not always convenient for applicants to search through the website. A more proactive approach by DEM would work better.

Dr. Haft asked that as was requested with the DHT questions, council members after the council meeting work with their colleagues at their institutions to provide answers to the questions posed concerning DEM training and career development. Dr. Cefalu thanked the council members for the great discussions and proceeded to end the open session.