

National Diabetes and Digestive and Kidney Diseases Advisory Council
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of
Health Department of Health and Human Services

I. CALL TO ORDER

Dr. Rodgers

Dr. Griffin Rodgers, Director, NIDDK, called to order a Special Meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 11:31 a.m. on November 23, 2021, via Zoom videoconference.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Iain Drummond

Dr. Penny Gordon-Larsen

Dr. Barbara Kahn

Dr. Mark Nelson

Dr. Richard Peek

Dr. David Penson

Ms. Ceciel Rooker

Dr. Kathleen Sakamoto

Dr. Michael Snyder

Dr. Ronald Sokol

Ms. Lorraine Stiehl

Dr. Gary Wu

Ex-officio members:

Dr. Ian Stewart

Also Present:

Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council

Dr. Karl F. Malik, Executive Secretary, NIDDK Advisory Council, Director, Division of Extramural Activities, NIDDK

Dr. Matthew E. Portnoy, Senior Advisor to Director on Innovation, Division of Extramural Activities, NIDDK

Dr. Gregory G. Germino, Deputy Director, NIDDK

Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK

Dr. Stephen P. James, Director, Division of Digestive Diseases and Nutrition, NIDDK

Dr. Robert A. Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

Dr. Christopher Mullins, Program Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

Dr. Cindy N. Roy, Program Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

Dr. Lisa Gansheroff, Deputy Director, Office of Scientific Program and Policy Analysis, NIDDK

Dr. Julie Wallace, Health Science Policy Analyst, Office of Scientific Program and Policy Analysis, NIDDK

Dr. Heather Rieff, Director, Office of Scientific Program and Policy Analysis, NIDDK

Dr. Sandeep Dayal, Health Science Policy Analyst, Office of Scientific Program and Policy Analysis, NIDDK

Dr. Robert Tilghman, Health Science Policy Analyst, Office of Scientific Program and Policy Analysis, NIDDK

Dr. Rebecca Cerio, Health Science Policy Analyst, Office of Scientific Program and

B. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers welcomed the Advisory Council members to this special meeting for consideration of the NIDDK Strategic Plan for Research as well as for a concept for a new pain research initiative.

Focusing first on the Strategic Plan, he expressed appreciation for the Members' input throughout the planning process, including past and present members who served as co-chairs for Subgroups of the Strategic Plan Working Group and those who also served on the working group or provided other input.

He then turned to Dr. Germino to give some background on the Strategic Plan process.

II. CONSIDERATION OF NIDDK STRATEGIC PLAN FOR RESEARCH

Dr. Germino

Dr. Germino reminded the group that the Strategic Plan is an overarching plan intended to complement NIDDK's disease-specific planning efforts. He reviewed the planning process, which included the input of people external to NIDDK, including:

- leading researchers and patient advocates from across the country who served on the Working Group,
- numerous organizations and individuals who responded to public Requests for Information (RFIs) in 2020 and 2021, and
- Council members.

The planning process started at the September 2019 Council meeting, at which NIDDK staff presented the draft framework for the Strategic Plan. In 2020, NIDDK convened the Working Group for multiple calls to gain ideas and insights. That year, NIDDK also released a public RFI, which garnered comments from organizations of scientists, healthcare professionals, and patient advocates, as well as from individuals living with diseases within the NIDDK mission. This was followed by another set of Working Group meetings to discuss these public comments.

Based on this input, NIDDK staff wrote a first draft of the Strategic Plan. That draft has gone through multiple rounds of review and revisions. The Working Group reviewed the initial draft. NIDDK then posted a revised draft on the web for public feedback. Staff again made revisions and sent a further-revised draft back to the Working Group for another review. Staff have provided updates to Council throughout the process, and Council members received the full document in advance of this meeting for final review and concurrence.

Next steps in the process include sending the Strategic Plan to the NIH Office of the

Director for a required review to ensure conformance with the NIH template for Institute Strategic Plans. Based on a preliminary review a couple of months ago, this should go well, and the final Strategic Plan will be released to the public in December 2021.

The unifying theme highlighted throughout this Strategic Plan for Research is *Multidisciplinary Researchers, Diverse Stakeholders, Pathways to Health for All*. The planning process reflected this theme, as NIDDK sought input from multidisciplinary researchers and diverse stakeholders to gain innovative ideas for pursuing pathways to health for all who have or are at risk for diseases within the NIDDK mission.

Before opening the vote on concurrence for the plan, Dr. Germino offered Council members the opportunity to make final remarks, starting with the co-chairs of the Working Group: Drs. Barbara Kahn, Penny Gordon-Larsen, and Gary Wu.

Dr. Gary Wu, co-chair of the Biological Pathways and Environmental Contributors Subgroup, commented that he has read the report numerous times and it hits the high points and more for his Subgroup, is nicely integrated with the other Subgroups, and is comprehensive and clearly stated. Dr. Kahn, co-chair of the Stewardship Subgroup, added that the vision was well laid out and is clearly expressed from a stewardship standpoint; the different parts are integrated very well; and it is timely in the emphasis of diversity and inclusion in many different realms. Dr. Gordon-Larsen, who co-chaired the Subgroup on translation aspects, noted that the report is cutting edge and the entire document is something to be proud of.

Dr. Germino asked the two other members of the Working Group to offer their comments. Ms. Ceciel Rooker said that this was the first time she had participated in this type of process with NIH or NIDDK. She was pleased with how well the patient voices were expressed and heard and incorporated through the whole document, and she is proud to have been a part of the process. Dr. Sakamoto added that it is a very comprehensive strategic plan and includes diversity in all aspects, and it was an educational and gratifying experience for her.

Dr. Germino then opened the discussion to all Council members.

Dr. Snyder asked what is the biggest difference between this report and what NIDDK was doing before?

Dr. Germino explained that this Plan gives an overlying structural framework for thinking about how all the different aspects of NIDDK and its research mission come together, from the pursuit of basic science discoveries to the actual impact on people's health. This Plan integrates community participation and the input of stakeholders. Now the community as a whole can develop implementation approaches to realize the vision outlined in the document. NIDDK is doing this actively in the health disparities and health equity space. We will be thinking about this for all of NIDDK's mission.

Dr. Drummond added that this Plan is inclusive, not just of patient populations, but also of the researchers and who commit themselves to the NIDDK mission. He added that there is an integration of all levels of research—from basic science to clinical care and social engagement—and it is also motivating for a wide spectrum of researchers.

Dr. Nelson commented that the document is very impressive.

Dr. Kahn added that the emphasis on training the next generation of researchers—which has always been part of NIH’s mission—comes through particularly clearly in this document.

Ms. Stiehl also commented on the Plan’s Scientific Goal to advance stakeholder engagement, including patients as true partners; she noted that this is very important and is a key component of the Strategic Plan.

There being no other comments, Dr. Germino thanked the many individuals, both within NIDDK and externally, who participated and offered valuable input for this Strategic Plan. He particularly thanked Dr. Lisa Gansheroff and her team at the NIDDK Office of Scientific Program and Policy Analysis for their leadership and hard work writing the report. He then turned the floor back to Dr. Rodgers for the vote.

Dr. Rodgers repeated thanks to everyone and asked for a motion for concurrence with the draft Strategic Plan. The Council approved by electronic vote. NIDDK will now submit the draft to the Office of the Director for final approval before release to the public on NIDDK’s website in December 2021.

III. CONCEPT PRESENTATION OF THE NIDDK PAIN RESEARCH INITIATIVE *Dr. Christopher Mullins*

Dr. Mullins presented this trans-NIDDK initiative on behalf of himself and his collaborators Drs. Dana Andersen and Teresa Jones, who developed this concept in anticipation of possible future funds to support pain research addressing both pain mechanisms and pain management for diseases and conditions within the NIDDK mission.

Pain is common and is often debilitating, resulting in diminished quality of life and broad morbidity affecting immune function, sleep, cognition, mobility, psychosocial health, and functional status. The 2012 National Health Survey found that approximately 40 million adults experience severe pain, 25 million experience pain daily, and an estimated 100 million adults suffer from chronic pain. Chronic pain is especially prevalent in women and older adults and disproportionately affects people from underrepresented groups. African Americans and Hispanics are less likely to receive adequate pain relief, despite comparable symptom severity.

Dr. Mullins explained that pain is particularly significant to disorders within NIDDK’s mission, including urinary stone disease, chronic pancreatitis, irritable bowel syndrome, gallbladder disorder, polycystic kidney disease, diabetic neuropathy, urologic chronic pelvic pain syndrome, and others. To address these needs, NIDDK proposes a new initiative entitled, “Advancing Research on Mechanisms and Management of Pain for Diseases and Conditions within NIDDK Mission Areas.” The goal would be to solicit broad basic, translational, and clinical research studies and development of new measures, tools, and methods to better understand pain

mechanisms and inform pain management for conditions within NIDDK's mission. Information gained is expected to significantly advance the characterization of pain as a defining symptom for disorders within the NIDDK's mission and inform new clinical strategies for improving pain management and outcomes in affected patients.

Dr. Rodgers then asked Council Members for questions or comments.

Council Questions and Discussion

Comment from Council: *Who usually funds pain research? Does it make sense to partner with those institutes or to keep this within NIDDK?*

Dr. Rodgers answered that pain research is usually funded by the National Institute of Neurological Disorders and Stroke (NINDS) and some of the other so-called "Brain Institutes" including the National Institute on Drug Abuse.

Some of these institutes received a boost in funding when Congress put in motion efforts to develop a better understanding of pain and alternatives to opioid pain medications to address the opioid epidemic. Dr. Rodgers said he understands the administration is interested in continuing this work, while also expanding research to include organ- and organ-system-specific pain-related disorders, which certainly falls within the mission of NIDDK.

Dr. Star added that this question is under discussion across NIH. This concept is written to be flexible. Dr. Nelson added that NINDS does not necessarily focus on the organs that fall under the NIDDK umbrella nor the extreme pain and disability that stems from the diseases within NIDDK's mission. This initiative would stimulate researchers who are already working on urinary, bladder and kidney conditions to think about the neural aspects of pain associated with these conditions. The general philosophy of the concept is to take what has been discovered about treating pain in other areas and apply them to NIDDK diseases. The concept is written broadly to give NIDDK a lot of flexibility.

Comment from Council: *How broadly will the mechanisms be defined? Are we talking only about biological mechanisms or is there room for investigation of structural factors that come into play, including racial and ethnic disparities in prescribing for NIDDK-related diseases?*

Dr. Star agreed that this is not clear as yet and explained that the concept has been written in response to Congressional interest in addressing this area of research. This issue of addressing health disparities could certainly be included in the final initiative, depending on the scope.

Comment from Council: *What about coordination with private foundations like the PKD Foundation or the U.S. Department of Veterans Administration, which also deals with pain?*

Dr. Star replied that this is under discussion as well.

Comment from Council: *Pain is an often-overlooked aspect of health that causes huge challenges for patients, including individuals with Type 1 diabetes. Current*

treatments are not sufficient. I applaud NIDDK's leadership here to address pain more effectively and improve quality of life for these patients.

Dr. Rodgers emphasized that many of the diseases and conditions within the NIDDK mission include visceral pain as a component and that this concept is to better understand and develop new therapies for pain within the context of NIDDK's mission.

He then asked the Council members to vote on the concept. The Council approved, by electronic poll, the concept.

XII. ADJOURNMENT

Dr. Rodgers

Dr. Rodgers thanked the Council members for accommodating this special meeting and took a moment to recognize several Council members who generously extended their Council terms to attend this special meeting and for whom this is the final meeting of their terms: Dr. Barbara Kahn, Dr. Richard Peek, Dr. Ron Sokol, and Ms. Lorraine Stiehl. He thanked them for their exemplary service over the past several years. He reminded the Council that the next regular meeting will be January 26 and 27, 2022, and will take place again in a virtual format. There being no other business, the special meeting of the NIDDK Advisory Council was adjourned at 12:01 p.m. on November 23, 2021.

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council