

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH  
NATIONAL CENTER FOR COMPLEMENTARY  
AND INTEGRATIVE HEALTH  
NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY  
AND INTEGRATIVE HEALTH  
Minutes of the Seventy-Seventh Meeting  
May 14, 2021**

**NACCIH Members Present Virtually**

Dr. Belinda Anderson, New York, NY  
Dr. Todd Braver, St. Louis, MO  
Dr. Robert Coghill, Cincinnati, OH  
Dr. Roni Evans, Minneapolis, MN  
Dr. Diana H. Fishbein, University Park, PA  
Dr. Margaret (Meg) Haney, New York, NY  
Dr. Richard E. Harris, Ann Arbor, MI  
Dr. Kendi Hensel, Fort Worth, TX  
Dr. Tammy Born Huizenga, Grand Rapids, MI  
Dr. Girardin Jean-Louis, New York, NY  
Dr. Benjamin Kligler, Washington, DC<sup>1</sup>  
Dr. John MacMillan, Santa Cruz, CA  
Dr. Wolf Mehling, San Francisco, CA  
Dr. Karen Sherman, Seattle, WA  
Dr. Lynne Shinto, Portland, OR  
Dr. Justin L. Sonnenburg, Stanford, CA  
Dr. Barbara Timmermann, Lawrence, KS  
Dr. Gloria Yeh, Boston, MA

**NACCIH Members Not Present**

Dr. Anthony Delitto, Pittsburgh, PA  
Dr. Eric Schoomaker, Bethesda, MD<sup>1</sup>

<sup>1</sup>Ex Officio Member

**I. Closed Session**

The first portion of the seventy-seventh meeting of the National Advisory Council for Complementary and Integrative Health (NACCIH) was closed to the public, in accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2). A total of 220 applications were assigned to NACCIH. Applications that were noncompetitive, not discussed, or

not recommended for further consideration by the scientific review groups were not considered by Council. Council agreed with staff recommendations on 110 scored applications, which requested \$44,409,200 in total costs.

## **II. Call to Order and Brief Review of Council Operating Procedures**

The open session convened at 11:40 a.m. ET. Dr. Partap Khalsa, NACCIH Executive Secretary, called the meeting to order. The minutes of the January 2021 Council meeting were approved unanimously. Dr. Khalsa explained that public comments can be submitted to him in writing within 15 days after this meeting and that they must be less than 700 words long. The comments will be added to the Council minutes.

## **III. NCCIH Director's Welcome and NCCIH Report**

Dr. Helene Langevin, director of NCCIH, welcomed everyone to the meeting. She announced that the National Institutes of Health (NIH) Office of Nutrition Research has moved to the Office of the Director and is now a trans-NIH effort. The NIH Common Fund will begin an initiative on nutrition for precision health, using data from the All of Us Research Program.

Dr. Langevin thanked Dr. Eric Schoomaker, who is ending his term as an ex-officio Council member, for his extensive help to NCCIH. She announced several new arrivals at NCCIH, including her new special assistant, Dr. Mark Pitcher, who will help her with day-to-day tasks, and a new program director, Dr. Erin Quinlan, who oversees a portfolio on neurobiological mechanisms of psychological approaches such as meditation and hypnosis.

NCCIH has continued to receive modest increases in its overall budget. Congress has not yet acted on the White House budget for the next fiscal year. NCCIH currently has two openings for junior-level health scientist administrators.

As discussed during the February 2020 Council meeting, NCCIH is updating its clinical research toolbox, and feedback and input from Council members is being taken into consideration. More information on the update will be provided at the September Council meeting. Five new research networks to advance emotional well-being research have been funded, three by NCCIH and two by the National Institute on Aging. Several other Institutes, Centers, and Offices (ICOs) are cofunding this initiative.

Dr. Langevin thanked the grantee community for their resilience and resourcefulness in adapting to the challenges of the COVID-19 pandemic, including their efforts to revise study designs and find new expertise as they discovered new approaches that would enable them to continue their research. NIH has launched an initiative to investigate post-acute sequelae of SARS-CoV-2 infection (PASC), also known as “long COVID.” Congress has provided \$1.15 billion in funding to NIH over 4 years for PASC research. Dr. Langevin will speak at a briefing for the Congressional Integrative Health and Wellness Caucus on PASC. The Rapid Acceleration of Diagnostics (RADx) initiative is continuing, with very extensive efforts to develop COVID-19 testing and provide access to it. Multiple NIH-funded COVID-19 vaccine studies and monoclonal antibody studies are in progress.

Highlights of recent NCCIH-funded research include:

- An analysis by Dr. Richard Nahin, NCCIH lead epidemiologist, of differences in pain prevalence among Hispanic subpopulations in the United States.
- A study coauthored by Dr. Nahin showing that young people with chronic musculoskeletal pain are still prescribed drugs more often than nondrug treatments.
- A study on the feasibility of integration of yoga into a behavioral weight-loss intervention. Two kinds of yoga were studied (restorative hatha yoga and vinyasa yoga); both were feasible, and weight loss was similar in both groups.
- A study showing that effects of resveratrol in acute respiratory distress syndrome are mediated by the microbiota of the lungs and gut.
- A study showing how 4D cine magnetic resonance imaging can be used to assess gut function in humans; this work may be relevant to the study of interoception.
- A study examining how different presentations of information, including graph-based visualization, influenced consumers' understanding of dietary supplement labeling.
- A study demonstrating clinically significant pain reduction in hospitalized patients receiving integrative medicine interventions.
- A study by intramural investigators that looked at the channels involved in innocuous pressure sensation.
- A commentary on implementation science by NCCIH authors, published in a special issue of the *Journal of Alternative and Complementary Medicine*.

NIH just announced the first funding opportunity for the fast-moving NIH Common Fund Bridge to Artificial Intelligence (Bridge2AI) initiative, which involves building datasets properly annotated and designed for use with AI. One topic that may be addressed by this initiative is salutogenesis, that is, restoration to health. Bridge2AI team building activities, including informational webinars, will be held in June.

NCCIH has funding opportunities for neural mechanisms of force-based manipulations, music and health, development of devices to monitor mind and body interventions, interoception research, and addressing the impact of racism on minority health and health disparities. Funding opportunities will be announced in response to the NIH HEAL (Helping to End Addiction Long-term<sup>SM</sup>) Initiative workshop on myofascial pain syndrome.

NCCIH led three sessions at the Integrative Medicine and Health Symposium in April and held a Hot Topic webinar on engaging diverse communities in complementary and integrative health research later that month. NCCIH's Division of Extramural Research (DER) has formed a diversity working group and launched a diversity webpage. Dr. Langevin has had many speaking engagements that provided opportunities to highlight the relevance of NCCIH's strategic plan.

An Integrative Medicine Research Lecture by Dr. Eric Garland of the University of Utah, "Healing the Opioid Crisis With Mindfulness-Oriented Recovery Enhancement (MORE): Clinical Efficacy and Neurological Mechanisms," was held in May. A second lecture, "Cooperative Pain Education and Self-Management (COPES): A Technology-Assisted

Intervention for Pain,” by Dr. Alicia Heapy of Yale School of Medicine, is scheduled for June 8. A series of expert panel discussions to provide input for a toolkit for research on music-based interventions for brain disorders of aging is in progress. Topics of upcoming workshops include sickle cell disease pain, whole person health, and precision probiotic therapy.

**Discussion:** Dr. Kligler told Council about a half-day virtual meeting on well-being outcome measures to be held on June 14. In response to a question from Dr. Jean-Louis, Dr. Langevin explained that research on underserved communities is an overarching priority at NIH. NIH seeks to ensure that every funded study includes outreach to communities, especially underserved communities. Dr. Emmeline Edwards, director of the DER, added that the hot topic webinar addressed this topic. Best practices and strategies to ensure engagement and maintain trust, as well as barriers to doing so, were discussed. Dr. Jean-Louis emphasized the importance of reaching people where they are.

Dr. Sherman suggested that research on robust and long-lived populations, as well as on people who do well in difficult situations, such as those who do well emotionally in a nursing home or assisted living setting despite poor physical health, would be worthwhile. Dr. Anderson noted that participants in integrative pain management seem to benefit most in the psychoemotional domain, which underscores the importance of NCCIH’s focus on emotional well-being. Dr. Langevin said that better methods to measure emotional well-being are needed; the meeting Dr. Kligler mentioned will address this topic. Dr. Edwards pointed out that one of the new emotional well-being networks focuses on measurement.

Dr. Harris suggested that shamanism could be an appropriate topic for NCCIH to study. Dr. Langevin agreed that shamanism is a good example of a complex intervention with traditional roots that could fit into multicomponent systems research.

#### **IV. 2021–2025 Strategic Plan Presentation**

Ms. Mary Beth Kester, director of the NCCIH Office of Policy, Planning, and Evaluation, announced that the final NCCIH strategic plan for fiscal years 2021 to 2025 has been posted to the NCCIH website. NCCIH staff have been working on the plan for more than a year, with input from Council, other NIH ICOs, and the public. Ms. Kester thanked NCCIH staff and Council for their work.

Dr. Langevin added her thanks to the NCCIH team. She explained that the process of developing the plan was very deliberate, beginning with the vision of the path to whole person health that she presented to Council a year ago. Current health care focuses on disease rather than health, and most health research focuses on analysis rather than synthesis; a better balance is needed. Learning more about health restoration and about supporting the networks that influence health in the whole person are important challenges. Effects of the physical and social environment on multiple health outcomes, including those related to the converging crises of opioids, pain, obesity, and now COVID-19, need to be better understood. There is a need for an evolution of thinking to encompass whole systems as well as isolated parts. Many other sciences are already evolving in this direction, but the health sciences have lagged behind.

The objectives and strategies in the new strategic plan focus on a spectrum of studies relevant to whole person health, including basic, translational, and clinical studies. These studies may focus on a single intervention that affects multiple systems, multiple interventions that affect a single system, or multiple interventions that affect multiple systems.

As discussed at previous Council meetings, the new strategic plan classifies complementary approaches by primary therapeutic input—nutritional, psychological, or physical—recognizing that there is overlap among these categories and overlap with other categories such as drugs and devices. Often, approaches are combined in multicomponent systems of care, which may have theoretical and diagnostic frameworks different from those of conventional medicine. In the strategic plan, the term “nutritional” has been substituted for “dietary” and “multicomponent” has been substituted for “multimodal” for clarity.

Key features of the new strategic plan include the following:

- The NCCIH framework for clinical research has been changed slightly to add a bubble for dissemination and implementation science, that is, research on how to facilitate uptake of effective interventions.
- The explanations of the terms “complementary,” “integrative,” and “health” have been updated to reflect the new therapeutic input terminology and the plan’s focus on health promotion and restoration, resilience, disease prevention, and symptom management.
- Objective 1, which addresses the fundamental building blocks of research, now incorporates methods development specifically aimed at testing the reliability and validity of complementary diagnostic systems, developing outcome measures for health restoration and resilience, and developing methods for implementation research.
- Objective 2 looks at several components of doing research on whole person health, including interactions among physiological systems.
- As in the previous plan, Objective 3 focuses on health promotion, disease prevention, and symptom management. Health restoration, resilience, and well-being are included.
- Objective 4, on enhancing the complementary and integrative health research workforce, includes special emphases on increasing diversity, on clinical sciences, and on collaborations between complementary health institutions and research-intensive institutions.
- Objective 5, on improving evidence-based information on complementary and integrative health, involves building on the current Know the Science effort.
- Women’s health and minority health are addressed as cross-cutting priorities. Women’s health should be recognized as whole person health; it is not limited to reproductive issues. NCCIH’s focus on minority health is well aligned with the trans-NIH priority of eliminating health disparities. Social and environmental determinants of health play key roles here.
- NCCIH’s approach to setting research priorities is also addressed as a cross-cutting topic. Amenability to rigorous inquiry is an important issue. If rigorous methods are not available to study particular topics, research on those topics should focus on methods development. Scientific promise, potential for changing health practice, and relationship to use and practice are also crucial for priority setting.



- The top scientific priorities described at the end of the plan include a mixture of new and continuing topics. The ten priorities are:
  - Research on whole person health
  - Interoception research
  - Health restoration, resilience, disease prevention, and health promotion across the lifespan
  - Implementation science for complementary and integrative health
  - Complementary and integrative management of pain
  - Complex interactions involving nutritional interventions
  - Mechanisms and biomarkers of mind and body approaches
  - Supporting impactful clinical trials of complementary and integrative health approaches
  - Enhancing the complementary and integrative health research workforce
  - Communications strategies and tools to enhance scientific literacy and understanding of clinical research

**Discussion:** In response to a question from Dr. Haney, Dr. Langevin clarified that dissemination and implementation science involves research on barriers to implementation of evidence-based interventions and on how to put these interventions into practice. Dr. Coghill said that NCCIH is in a good position to address the role of psychological therapies in pain management, a topic that tends to fall between the cracks at more specialized ICOs. Dr. Fishbein suggested looking at stressful factors at the environmental and community levels and how to ameliorate them. Dr. Mehling said that social interaction effects of multicomponent group interventions need to be measured, and Dr. Langevin suggested expanding this topic to include differences between virtual and in-person interactions.

In response to a question from Dr. Shinto, Dr. Edwards clarified that “impactful” clinical trials are those that address key public health issues, answer important questions, and are designed appropriately for the research question. There has been a misconception that NCCIH is exclusively interested in innovative trial designs. Dr. Wendy Weber, Chief of the Clinical Research Branch in the DER, added that NCCIH wants to move the research pipeline along from pilot and feasibility studies to fully powered trials and eventually dissemination and implementation research, when appropriate. She also explained that studies can be designed to understand social interactions and address the impact of being part of a group, virtually or in person, although not much work has been done in this space yet for complementary approaches. Dr. MacMillan commented that bioinformatics and computational methods will be important for studies of complex interventions.

In response to a question from Dr. Anderson, Dr. Lanay Mudd, a program director in the DER, explained that NCCIH is examining a range of opportunities to support the development of a pipeline of investigators. R25 grants are one possibility; NCCIH is looking at how other ICOs are using them.

In response to a question from Dr. Anderson about updating information on the NCCIH website as new scientific information emerges, Ms. Catherine Law, director of the Office of Communications and Public Liaison, explained that NCCIH makes an effort to keep up with new evidence as both science and methodology evolve, paying particular attention to large meta-analyses by groups such as the Cochrane Collaboration. NCCIH also keeps an eye on major emerging studies to see if they need to be reflected in the Center's website content.

Dr. Sherman made suggestions on three topics: distinguishing between pragmatic and effectiveness research, addressing the difficulties of getting interdisciplinary or novel projects funded, and considering holding workshops on newer methodology. Dr. Jean-Louis suggested making an effort to acquaint young researchers with integrative health early; often, scientists develop an interest in this field too late, after their careers have focused on other topics.

Dr. Sonnenberg cautioned about the importance of balancing the portfolio and recognizing that while mechanisms are important, rigorous science can be done even in their absence. Dr. Evans mentioned the need to train reviewers on current thinking and methodologies for addressing complex interventions and conditions. Dr. Kligler explained that medicine and the health care infrastructure are moving away from reductionistic explanatory models, recognizing that sometimes the complexity of systems is too great for them to ever be dissected into molecular pathways.

## **V. Whole Person Health Stakeholder Groups**

Dr. Langevin explained that NCCIH has created external and internal stakeholder working groups for research on whole person health. The external group includes 13 organizations whose mission resonates with the concept of whole person health. These are umbrella organizations, such as the Academic Consortium for Integrative Health, the Whole Health Institute, and the Consortium for Health and Military Performance, rather than groups representing specific professions. The internal group includes directors or deputy directors of components of NIH. At this early stage, the ICOs included are primarily noncategorical ones (those whose mission does not focus on a single disease or organ), such as the National Center for Advancing Translational Sciences and the National Institute for Nursing Research, with only one categorical Institute, the National Institute of Dental and Craniofacial Research, participating. Additional categorical Institutes will be invited to join the group later. Only a few meetings have been held so far, but the whole person health concept has resonated with many participants, and the overall response has been favorable.

**Discussion:** Dr. Sherman commented that bringing expertise on primary care, pediatrics, or geriatrics into the groups could be helpful. She also said that categorical Institutes that study diseases with whole person effects (e.g., the National Institute of Diabetes and Digestive and Kidney Diseases for diabetes) may be interested. Dr. Hensel suggested making sure someone familiar with osteopathic medicine is involved with the stakeholder groups.

## **VI. A Vision for the NIEHS and Possibilities for Collaboration With NCCIH**

Dr. Rick Woychik, Director of the National Institute of Environmental Health Sciences (NIEHS), said that collaboration is one of his leadership values for NIEHS, and he looks forward to working with NCCIH on whole person health. NIEHS's work is about prevention—about reducing exposures to deleterious agents in the environment to protect public health. This is a very large, very broad task. There are many types of exposures, and it was recently recognized that even low-dose exposures may act like drugs or hormones to disrupt the control of development and function, increasing the risk of common chronic diseases. Exposures very early in life may contribute to health problems that occur much later.

Exposures do not occur singly; everyone is exposed to many different chemicals, and combinations need to be examined. Environmental exposures may influence health risks through changes in the composition of the microbiome. A current challenge for environmental health research is measuring the exposome—that is, the totality of environmental exposures. Another is linking knowledge of exposure biology with that of human genetics; genetic differences may cause differential responses to toxic exposures. The environment is a critical factor in DNA expression; people are born with genes, but the environment affects epigenetic changes (changes in DNA expression independent of DNA sequence).

The International Common Disease Alliance (ICDA) is promoting the concept of global collaboration to study genetic predispositions to disease, bringing data from different cohorts together to enable identification of the networks of genes associated with common diseases. Integrating environmental exposure into the ICDA framework may provide insights into whole person health.

Health disparities are linked with exposure disparities. There is a renewed drive to address racial and ethnic disparities in environmental health research and to identify the social, political, and economic factors that lead to them. Community involvement and citizen science may play key roles in addressing exposure and health disparities. Climate change is another key priority in environmental health. Climate change is linked to weather events that affect health, with a disproportionate impact on minority communities.

**Discussion:** In response to a question from Dr. Langevin, Dr. Woychik explained that dietary influences and perhaps other factors in the environment may help to mitigate adverse effects of environmental exposures. Dr. Anderson asked about the combined impacts of different types of exposures, such as chemicals plus heavy environmental stress, and Dr. Woychik said that the exposome framework includes all types of exposures, including psychological stressors. There has been work on the molecular mechanisms of psychosocial stress, some of which may influence epigenetics. Collaborative strategies will be needed to address these complex problems.

Dr. Huizenga pointed out the complexity of patients who have had both toxic exposures and chronic health problems; she suggested that understanding these patients could help bridge the gap between research and clinical knowledge. Dr. Woychik said one of the first steps needed is better collection of environmental data. For example, environmental exposures could be included



in electronic health records. Dr. Woychik said that he is excited about working together with NCCIH. Sophisticated tools are now available that can be used to address complex problems.

## **VII. Concept Clearance: Optimized Therapies for Sickle Cell Disease Pain Management**

Dr. Della White, a program director in the DER, presented an NIH HEAL Initiative<sup>SM</sup> concept on optimizing therapies for sickle cell disease pain management. HEAL centers around two focus areas: enhancing pain management and improving treatment for opioid misuse and addiction. This concept is part of the pain management focus area.

Pain is the most common complication of sickle cell disease. People with this disease have multiple types of pain, and their pain management is very complex. Often, treatment doesn't address comorbidities that may exacerbate pain, and even after curative therapy, severe chronic pain persists for some individuals. Health disparities impact sickle cell disease pain care because the patient population primarily comprises racial and ethnic minorities. The biopsychosocial model of pain management can inform the treatment of individuals with sickle cell disease pain. It is important to be mindful that any approach used should protect access to opioid therapy, a primary method of treatment for sickle cell disease pain.

This concept proposes a twofold approach:

- Multisite clinical trials to test the efficacy and effectiveness of single or multicomponent nonopioid pharmacologic and nonpharmacologic approaches for sickle cell disease pain
- Multisite implementation science research trials to inform the uptake of evidence-based nonopioid approaches for sickle cell disease pain management in health care systems that serve these patients

**Discussion:** In response to a question from Dr. Haney, Dr. White explained that opioids are efficacious for sickle cell disease pain and are the first line of care, but patients would like to have nonopioid alternatives. Dr. Coghill commented that this proposal is important, especially for the study of combinations of treatments, which may include psychological therapies.

A motion to approve the concept was made, seconded, and approved with 15 votes for and 1 vote against.

## **VIII. Reminder of How To Submit Public Comments**

Dr. Khalsa reminded the audience that public comments could be sent to him by email or postal mail. Comments are limited to 700 words. If submitted within 15 days after this meeting, the comments will be included in the meeting minutes.

**“From:** Dr Hope Kellman <[drhopekellman@gmail.com](mailto:drhopekellman@gmail.com)>

**Sent:** Monday, May 10, 2021 8:09 PM

**To:** Khalsa, Partap (NIH/NCCIH) [E] <[khalsap@mail.nih.gov](mailto:khalsap@mail.nih.gov)>; Hope Kellman <[newhopemethod@gmail.com](mailto:newhopemethod@gmail.com)>

**Subject:** Advisory Council Public Comment

I would like to propose a gathering of the founders of the office. My question is it possible fall 2021 to do a zoom event of my dear friends and colleagues who help develop this office. And can we do this yearly

Thankyou

Dr Hope. Kellman”

#### **IX. Final Comments and Adjournment**

Dr. Langevin thanked Council members for their engagement, comments, and insights during the meeting and their support and input during the development of the new strategic plan. Dr. David Shurtleff, deputy director of NCCIH, added his thanks to Council members. Dr. Khalsa thanked the NCCIH and NIH staff who made the meeting possible.

The meeting was adjourned at 4 p.m.