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 Eightieth Meeting
May 13, 2022

Current NACCIH Members Present Virtually
Dr. Todd Braver, St. Louis, MO
Dr. Nadja Cech, Greensboro, NC
Dr. Robert Coghill, Cincinnati, OH
Dr. Anthony Delitto, Pittsburgh, PA
Dr. Roni Evans, Minneapolis, MN
Dr. Diana Fishbein, Chapel Hill, NC
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, Miami, FL
Dr. Benjamin Kligler, Washington, DC*
Ms. Lori Knutson, Bentonville, AR
Dr. Helen Lavretsky, Los Angeles, CA
Dr. Wolf Mehling, San Francisco, CA
Dr. Karen Sherman, Seattle, WA
Dr. Justin L. Sonnenburg, Stanford, CA

NACCIH Members Not Present
Dr. Chester "Trip" Buckenmaier, III, Rockville, MD*
Dr. Lynne Shinto, Portland, OR

*Ex Officio Member

I. Closed Session

The first portion of the eightieth 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 161 applications were assigned to the National Center for Complementary and Integrative Health (NCCIH). 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 82 scored applications, which requested $33,189,103 in total costs.

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

Dr. Partap Khalsa, NACCIH Executive Secretary, convened the open session at 11:40 a.m. ET. The minutes of the January 2022 Council meeting were approved unanimously. Dr. Khalsa noted that oral public comments cannot be given during this virtual meeting, but written comments can be submitted to him by email (Partap.Khalsa@nih.gov) or postal mail (address on the NCCIH website) within 15 days after the meeting. Comments must be under 700 words. The comments will be provided to Council members.

III. NCCIH Director's Welcome and NCCIH Report

Dr. Helene M. Langevin, director of NCCIH, welcomed three new program directors in the NCCIH Division of Extramural Research (DER): Drs. Sekai Chideya, Beda Jean-Francois, and Alex Tuttle. She announced that Dr. Miroslav "Misha" Bačkonja is now the acting clinical director of the Division of Intramural Research (DIR) and thanked Dr. Maryland Pao, who had served as NCCIH's acting clinical director since 2020.

NCCIH's budget increased 3.4 percent in fiscal year (FY) 2022. The FY 2022 President's budget had called for a substantial funding increase for NCCIH for pain research, but this did not come to fruition. The FY 2023 President's budget request includes a $26 million increase for pain research, but it may not be approved.

Three U24 awards have been made for research networks on the neural mechanisms of force-based manipulation; NCCIH and the National Institute of Neurological Disorders and Stroke are funding these networks. The first embedded clinical trial in the All of Us program, the Nutrition for Precision Health study, has been funded; more such ancillary studies are expected.

Dr. Langevin highlighted multiple publications by current and former members of the DIR, including Drs. Richard Nahin, Lauren Atlas, and Laura Case. She also discussed the following studies:

- An analysis of data from the Ginkgo Evaluation of Memory Study that indicated that neighborhood greenspace exposure has a protective effect against dementia risk in older adults (pubmed.ncbi.nlm.nih.gov/35033073; funded by the National Institute on Aging and U.S. Environmental Protection Agency)
- A small study showing that gut microbiome diversity and abundance correlate with gray matter volume in older adults with depression (pubmed.ncbi.nlm.nih.gov/35206594; partially funded by NCCIH)
- A clinical pharmacokinetic assessment of kratom in healthy adults, which provides background for future studies on its possible use in managing opioid withdrawal and on its safety (pubmed.ncbi.nlm.nih.gov/35335999; partially funded by NCCIH)
- A clinical trial of the Mindfulness-Oriented Recovery Enhancement (MORE) intervention for co-occurring opioid misuse and chronic pain, which had positive results (pubmed.ncbi.nlm.nih.gov/35226053; funded by the National Institute on Drug Abuse)

NCCIH has issued a request for information on identification of a set of determinants for whole person health. Current funding opportunity announcements (FOAs) include the NIH Pragmatic Trials Collaboratory (formerly the NIH Health Care Systems Research Collaboratory) FOA for pragmatic and implementation trials of embedded interventions; a Notice of Special Interest on mental, emotional, and behavioral health preventive interventions in school settings; and several NCCIH administrative supplements (NOT-AT-22-010, NOT-AT-21-013, and NOT-AT-21-014).

Recent events include an NCCIH hot topic webinar on structural racism and discrimination and whole person health and the first of three talks in the spring 2022 Integrative Medicine Research Lecture Series (IMLS). A recent workshop on precision probiotic therapies, led by NCCIH and the Office of Dietary Supplements (ODS), attracted widespread interest, with 9 other NIH Institutes, Centers, and Offices participating; 2,000 viewers on the first day; and 1,500 viewers on the second day. Two additional IMLS lectures and several presentations by NCCIH staff at the 2022 International Congress on Integrative Medicine and Health are scheduled soon. Dr. Langevin asked Council members for their thoughts on holding the next Council meeting in a hybrid format, where Council members could choose to attend in person or remotely. She also mentioned that she participated in a Congressional briefing with two members of Congress who are cochairs of the integrative health conference, where she discussed whole person health and the importance of chronic stress.

Discussion: Dr. Cech noted the theme of interconnectivity throughout Dr. Langevin's presentation and said it is exciting to see the results of NCCIH's efforts to connect with other Institutes and Centers and projects across NIH. Dr. Langevin explained that reaching out to other groups allows NCCIH to augment its limited funding. Dr. Kligler asked about other groups' receptivity to the whole person health concept. Dr. Langevin said there is much interest, as shown by the willingness of other groups to collaborate in NCCIH's whole person research workshop. The NIH Institutes devoted to environmental health, nursing, minority health, and aging already think in an integrative way, and others are becoming interested.

Dr. Sonnenburg said that the recent probiotics workshop was inspiring and thanked NCCIH staff involved in holding this event. Dr. Emmeline Edwards, director of the NCCIH DER, mentioned that the two upcoming IMLS lectures will feature investigators from the emotional well-being research networks. Dr. Sherman and Dr. Lavretsky urged NCCIH to make information about coping with stress available to the public as soon as possible. Dr. Langevin explained that the communications team is already working on this. Dr. Harris suggested that an FOA on internet or app approaches for established practices such as meditation or acupressure could be helpful. Dr. Sonnenburg cautioned about the need to consider safety in rapid trials. Dr. Knutson said that stress information needs to be packaged for the general public and employers. Dr. Langevin asked for members' feedback on the ease or difficulty of obtaining information from the NCCIH website. Dr. Haney advocated for a bigger Twitter presence. Dr. Khalsa noted that the afternoon mini-symposium would focus on clinical trials for stress.

IV. Oral Health for All: The Benefits of Integration

Dr. Rena N. D'Souza, director of the National Institute of Dental and Craniofacial Research (NIDCR), explained that NIDCR's goals and priorities are very much in line with those of NCCIH and that NIDCR embraces an integrative approach, with an emphasis on partnerships and teamwork.

Oral health is important in itself and also because the oral cavity is the portal of entry for risk factors for systemic diseases. Manifestations of systemic diseases can also affect the mouth. The NIDCR-led report *Oral Health in America,* released in December 2021, examined the progress in oral health over the last two decades and articulated a vision for the future. The report stressed that good oral health is vitally important to everyone's health and well-being, but oral health care is not equitably available across America. Oral diseases, including untreated caries, periodontitis, oral and pharyngeal cancers, and tooth loss, represent a huge disease burden. Poor oral health is particularly common among Native American tribes, many of whose members have access only to polluted well water, and among African Americans

and Hispanics who lack access to dental care. The World Health Organization and others have stressed that oral health care should be part of universal health coverage.

NIDCR is the steward for the profession of dentistry, with a mission very intertwined with the practice of dentistry. The missions of the Institute and the profession strengthen each other. Challenges facing NIDCR and the dental profession include the misconception that oral health is not a critical determinant of overall health, the lack of a strong research focus in dental professional organizations and education, and a procedure-based rather than prevention-based approach to oral care. Members of minority groups are underrepresented in the dental workforce and among NIDCR grantees. NIDCR is working toward changing the culture and landscape to increase participation of individuals from underrepresented groups at every level of the dental, oral, and craniofacial research training pipeline. NIDCR's new strategic plan emphasizes translation; core values that include equity, diversity, and inclusion; and a focus on metrics and delivery of results.

NIDCR has launched a dental public health residency and fellowship and a dental clinical research fellowship and is involved in a variety of research programs. Dr. D'Souza emphasized that both NCCIH and NIDCR need to be at the table for NIH-wide collaborations and initiatives, including the Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative® and initiatives related to temporomandibular joint (TMJ) disorders. Partnering opportunities for NCCIH and NIDCR could include phenotyping dental pain, collaborative first-in-human dental trials, investigating the safety and efficacy of complementary approaches targeted to oral health promotion and restoration, engaging complementary approaches for oral disease prevention and symptom management in diverse populations and settings, and probing interoceptive processes in the context of oral disease.

Discussion: Dr. Langevin said she has been impressed with Dr. D'Souza's spirit of collaboration during the short time since she took on the leadership of NIDCR. Dr. Harris suggested that the tongue and its importance in traditional Chinese medicine diagnostic concepts might be an area of overlap for NCCIH and NIDCR. Dr. D'Souza explained that many disease conditions affect the tongue, and it can provide a good indication of overall health. Dr. Cech said that some population groups use alternative therapies based on botanicals for pain management or oral hygiene. Dr. D'Souza said that in the United States, alternative practices for oral health tend to occur outside the context of dentistry except for those used for TMJ disorders. Dr. Langevin explained NCCIH's interest in complementary diagnostic systems and suggested that it could be an area of collaboration. Dr. D'Souza said that digital imaging could help with work in this area. Dr. Langevin thanked Dr. D'Souza for speaking to Council and said she would follow up on potential collaborations.

V. Mini-Symposium—Clinical Trials To Address Stress in Different Contexts: What Makes Trials Impactful?

Dr. Edwards explained that supporting impactful clinical trials is one of the top scientific priorities identified in NCCIH's strategic plan. Also, as Council heard earlier, NCCIH is interested in developing new programs related to stress reduction. This mini-symposium will discuss impactful clinical trials in the context of stress research. Dr. Wendy Weber, chief of the Clinical Research Branch in the DER, will introduce the topic, and three investigators who are conducting research projects on stress in different contexts will use their own work to illustrate various aspects of what makes a trial impactful, including the science being targeted, the approach, the population studied, and the process being followed.

Introduction to NCCIH Trial Funding

Dr. Weber introduced the three investigators who will present their research. Dr. Michael Christopher of Pacific University will describe his experience with adaptation and feasibility testing of an intervention in a work setting, Dr. Zev Schuman-Olivier of the Cambridge Health Alliance and Harvard Medical School will discuss population-based screening in a health care setting, and Dr. Judith Moskowitz of Northwestern University will talk about work that involves addressing implementation barriers in community settings.

Dr. Weber explained that even before the COVID-19 pandemic, NCCIH was interested in the impact of stress on health. The 2017 Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies was a conversation between Dr. Vivek Murthy, the U.S. Surgeon General, and Dr. Francis Collins, then director of NIH, on the public health consequences of stress in America. Stress has greatly worsened with the pandemic. In July 2020, 68 percent of U.S. adults viewed COVID-19 as a severe or extreme crisis; 62 percent reported increased stress, anxiety, and/or depression; and of those who felt stressed, anxious, or depressed due to COVID-19, 55 percent reported that COVID-19–related stressors interfered moderately, severely, or overwhelmingly in their lives. Two years later, there has not been much improvement. Data released in March 2022 by the American Psychological Association indicated that 80 percent or more of U.S. adults consider rising prices, supply chain issues, global uncertainty, potential retaliation from Russia, and the invasion of Ukraine to be significant stressors. More than 60 percent say that their lives have been forever changed by the pandemic and that with each new variant, they lose hope that the pandemic will ever end. The impact of economic stressors varies for different racial and ethnic groups; in particular, housing is more of a stressor for Black and Latino adults than White adults.

The Centers for Disease Control and Prevention has addressed stress during the pandemic with targeted sets of tips on self-care for different segments of the population. NCCIH's role is to determine how to fund the research to provide evidence on whether taking the recommended actions will reduce stress. NCCIH's research framework calls for studies not just on mechanisms (how an intervention works) but also on how to refine and optimize interventions, test whether they work, and get them out into clinical practice in health care settings or community-based or employer-based settings. NCCIH has funding mechanisms for different stages of research on mind and body interventions and natural product interventions. These funding opportunities have been streamlined to enable researchers to move past feasibility work and proceed to efficacy/effectiveness clinical trials as soon as possible, while still providing opportunities to obtain needed preliminary data. Details about specific funding opportunities can be found on the NCCIH website.

Dr. Weber mentioned work by Dr. Linda Collins of New York University, who has introduced the acronym EASE, which is achieved by balancing Effectiveness of interventions against their Affordability, Scalability, and Efficiency so they can be used in health care or community-based settings. Scalability is crucial if an intervention is to be tailored for different settings or populations.

In considering whether an intervention is ready for efficacy clinical trials, NCCIH considers whether natural products have reproducible effects on biological signatures and whether mind and body interventions are feasible and can be delivered with fidelity across sites. Once interventions are found to have efficacy/effectiveness, pragmatic clinical trials determine whether they remain effective when integrated into health care systems, and other research studies determine how to disseminate or implement the interventions into clinical or community-based settings. Trials all along the continuum of research can be impactful. NCCIH considers success to include supporting a range of clinical trials along the framework, the movement of interventions along the framework when they are found to be feasible and

effective, and the completion of trials that provide strong evidence for clinical guideline development and health care policy decisions.

Results From Single and Multisite Feasibility Trials of Mindfulness-Based Resilience Training With Law Enforcement Officers

Dr. Christopher began with an anecdote about a police officer who enrolled in a mindfulness-based stress reduction (MBSR) program and found it life-changing. The officer thought that a program of this type would benefit everyone in his profession, and Dr. Christopher believed it might also benefit communities through better policing. Dr. Christopher's laboratory and a group of officers then collaborated to jointly conduct an MBSR program for police officers. Focus groups conducted after this program indicated that the intervention needed adaptations to make it more suitable for law enforcement officers, including an increased focus on resilience enhancement and modifications to decrease officers' feelings of vulnerability during certain exercises.

The adapted program, called mindfulness-based resilience training, was then evaluated in an NCCIH-funded single-site feasibility and acceptability trial that also obtained preliminary data on the impact of the intervention on law enforcement officers' physiological stress reactivity, aggression and implicit race bias activation, and psychological health and risk. The trial met its feasibility and acceptability goals except that the participants found the home practice requirement of 45 minutes a day unreasonable. Compliance with study assessments was high, and interviews with the participants indicated that they saw benefits from the program, particularly in terms of decreasing their reactivity to stressful situations. From this trial, the study team learned that police leadership needed to be engaged early, that better buy-in at the beginning of the program was needed to decrease early dropouts, that the implicit bias measure used in the trial lacked ecological validity, that few participants continued any formal meditation practice at 3 months' follow-up, and that efforts needed to be made to recruit a more diverse sample.

The next step was a multisite feasibility trial, also funded by NCCIH, to assess the fidelity of all randomized controlled trial (RCT) procedures across three sites in preparation for a full-scale efficacy trial. The intervention was further adapted in response to experiences in the previous study, with increased emphases on reactivity, trauma, and interoceptive awareness; an initial immersion session to increase buy-in; and booster sessions to encourage continued mindfulness practice. An active control condition was included in this second study. The investigators intended to use an entirely in-person protocol, and the protocol was completed successfully for one group at the first site just before the COVID-19 pandemic began. Work was then delayed by COVID-19 and by concerns about the appropriateness of the study, considering social justice concerns and protests at the time. The study then switched to an entirely virtual protocol, with different assessments and biomarkers than originally planned. The interventions have now been completed, and 6-month follow-up data have been collected. Most feasibility and acceptability benchmarks, including diversity recruitment targets, were achieved. The researchers are assessing multisite fidelity through reviews of session recordings, and they have developed a coding scheme for qualitative findings from participant interviews. The next steps include completion of data analysis and submission of an application for funding for a multisite efficacy trial.

CHAMindWell and The Resilience Study

Dr. Schuman-Olivier described a large project that started at the beginning of the COVID-19 pandemic, when it was recognized that the pandemic had caused a tsunami of mental health needs, as well as increases in a variety of psychosocial stressors that impact mental health. The Cambridge Health Alliance (CHA) and the Harvard psychiatry team quickly put together a free online mental wellness program,

called CHAMindWell, to connect patients and employees with services and an online community. Participants completed computer adaptive testing for mental health and social determinants of health at baseline and on several later occasions throughout the year, were grouped into three tiers (for severe, mild/moderate, or no/minimal symptoms), and received personalized recommendations and access to resources based on the tiers, with those in the two higher tiers referred to clinical care.

In a pilot conducted in the early stages of lockdown, participation in CHAMindWell and a mindfulness program led to decreases in anxiety and depressive symptoms. Data from CHAMindWell were integrated into a Research Electronic Data Capture (REDcap) external module. Focus groups were conducted with patients and community members in summer and fall 2020. Dr. Schuman-Olivier and his colleagues then submitted an NIH grant application for a comparative effectiveness RCT, called The Resilience Study, within CHAMindWell, and NIH funded it. There were substantial COVID-19–related delays in getting institutional review board (IRB) approval of the RCT. Implementation was stopped between January and March 2021 to deal with internal impacts and staff changes, as well as with delayed IRB review. When enrollment in the RCT began, the response was beyond the capacity of the system, and it was necessary to close or limit enrollment on several occasions.

The Resilience Study is a comparative effectiveness trial that compares CHAMindWell with two online versions of evidence-based treatments for depression, with the specific aims of examining the effects of the programs on levels of depressive symptoms, substance use, and televisit utilization. A substudy that involves collection of saliva samples was hampered by the classification of saliva as a Category B infectious substance because of COVID-19, which led to delays due to the need for changes in sample collection and transport methods, plus additional required safety reviews.

Preliminary national data suggest that the pandemic triggered dramatic increases in symptoms of depression and anxiety beginning in 2020, with symptoms remaining twice as prevalent in 2021 as in 2019. Thus, the goal of CHAMindWell is to reduce symptoms, but it would not be realistic to expect symptoms to return to prepandemic levels. CHAMindWell enrollment data (for the program as a whole, not the RCT) show that proportions of participants from various race/ethnicity groups reflected those in the CHA service area. Initial data indicate that CHAMindWell participation led to reductions in symptoms of anxiety, post-traumatic stress disorder, depression, and mania over time. Many people in the higher tiers of symptoms moved down to lower tiers during follow-up. The majority of participants referred for therapy participated in group-based programs, which was a desirable finding from the standpoint of feasibility because access to individual therapy was limited by high demand. The RCT is in progress and has almost reached its enrollment goal.

FOREST: Fostering Optimal Regulation of Emotion To Prevent Secondary Trauma (R21AT011863)

Dr. Moskowitz has conducted research on a multicomponent intervention that teaches people to have more positive emotions on a daily basis to cope with stress. Multiple trials in several population groups have provided evidence that the intervention is effective. In the FOREST study, which she summarized here, implementation of this intervention is being evaluated in a real-world setting with front-line staff at READI Chicago (READI stands for Rapid Employment and Development Initiative), a program that is designed to reduce gun violence by providing community-based outreach, psychosocial support, and job skills training to adults living in Chicago neighborhoods with high rates of unemployment, poverty, and firearm injury and mortality. Front-line staff at READI Chicago experience high levels of stress and have high risks of burnout and secondary trauma, as well as high turnover rates.

A small pilot test of the intervention, designed as a train-the-trainers program, was conducted virtually with READI Chicago staff in fall 2020, and positive feedback was obtained from participants. As the pilot test was ending, NIH released an FOA (PAR-21-191, R21/R33) for firearm injury and mortality prevention research. Dr. Moskowitz and her colleagues submitted an application and received a grant to adapt, implement, and manualize the intervention and build capacity for READI Chicago to sustainably enhance resilience, prevent burnout, and reduce turnover among front-line staff. The research is currently in the R21 (exploration/preparation) phase, which includes adapting and finalizing the content of the intervention; informing strategies for implementation at three READI Chicago sites based on system, organization, and staff factors; and designing a prospective longitudinal pilot study to examine implementation and effectiveness outcomes. Five focus groups with staff members in different roles have been conducted, and several facilitators for and barriers to implementation have been identified. In-depth interviews will be conducted to follow up on the focus group findings. If the R21 benchmarks are met, Dr. Moskowitz's team will proceed to the R33 phase, which includes conducting the longitudinal pilot study, assessing sustainability of the intervention at the organization level, and preparing to disseminate the intervention to other gun violence prevention programs.

Discussion: Dr. Langevin asked whether less could be more when it comes to expectations for practice of a technique. Might setting a smaller, more achievable goal be better in terms of empowering individuals? Dr. Christopher said that Dr. Langevin's idea is consistent with what he found in his study. If the practice goal was set too high, people would not even try to achieve it. Dr. Schuman-Olivier added that there is a dosing effect with mindfulness interventions: the more you practice, the greater the effects. However, if the requirement for practice is too great, participants become overwhelmed and do not practice at all. People may need coaching about self-compassion before they can do mindfulness practice. Dr. Harris said that when graduate students were taught mindfulness-based meditation as a course, reductions in anxiety and depression were seen even with a small practice requirement. Dr. Sherman said that after people become accustomed to mindfulness, the next challenge is applying it to daily life, and this step may be harder to figure out. Dr. Schuman-Olivier said that over an 8-week learning period, applying mindfulness to daily life becomes automatic for many people. Dr. Christopher said that informal mindfulness practice may build on formal practice.

Dr. Evans asked how the impact of COVID-19 on research will affect data analysis. Both increased stress and modifications of interventions during the pandemic could make analysis more complex. Dr. Moskowitz said that in her research, it has been helpful that both intervention and control groups have gone through the same experiences. Dr. Weber said that investigators who are conducting pragmatic trials are looking at how to manage statistical analysis in these situations, and publications will be forthcoming. The trials that were most disrupted were those with stepped wedge designs or parallel group designs; biostatisticians are looking at the issues and will make recommendations. Dr. Lavretsky said that patient preferences are rarely included in study designs, yet if patients do not like an intervention, they will not do it. Dr. Schuman-Olivier said that programs labeled as "stress" or "resilience" interventions get different reactions from participants than those labeled as "mindfulness." He also noted that the importance of informal versus formal practice varies in different populations.

Dr. Weber thanked the speakers and said that their presentations had illustrated how different types of studies and stages of research can be important for different reasons. Studies that focus on feasibility, tailoring, efficacy, or implementation can all be impactful.

VI. Concept Clearances

1. **Validation Studies of Analytical Methods for Dietary Supplement Constituents**

Dr. Adam Kuszek of ODS presented a concept for reissuance of administrative supplements for validation studies of analytical methods for dietary supplements and natural products. The FOA would be a component of the ODS Analytical Methods and Reference Materials Program. Formal validation studies are critical in assessing an analytical method's accuracy, precision, applicability, sensitivity, and repeatability.

This initiative began in 2011 and is funded entirely by ODS. NCCIH has been a strong partner, with 12 of the 17 awards to date and about $1 million in funding going to NCCIH grantees. The majority of the methods that have been studied were for natural product metabolites in biological samples.

ODS is requesting clearance for a proposed reissue with a continued focus on identifying and quantifying chemical constituents and metabolites in reagents, clinical interventions, and biological samples. The proposed reissue will more clearly include metabolomic methods in the scope of applicable methods for validation and will emphasize considering methods for source identification, establishing quality control, and monitoring experimental preparation reproducibility.

Discussion: Dr. Cech said she had benefited from this program and asked whether ODS was looking for a focus on any specific botanicals. Dr. Kuszek said there was no focus on a particular botanical right now, and ODS intended to allow investigators to choose the focus areas. Both prominent and less prominent botanicals have been studied.

Council approved the concept unanimously.

2. **Research Networks To Promote Innovative Mechanistic and Translational Studies of Sickle Cell Pain**

Dr. Inna Belfer, a program director in the NCCIH DER, presented a concept for the creation of multidisciplinary networks to develop a framework and resources for translational and reverse translational research on sickle cell disease (SCD) pain.

SCD is an understudied lifelong disease that impacts an underserved population in the United States. Pain—including severe acute pain episodes, chronic persistent pain, and neuropathic pain—is its most common clinical complication, and pain may continue even after curative therapy. NCCIH and the National Heart, Lung, and Blood Institute co-led a July 2021 workshop on the current status of research on SCD pain and future research needs. Workshop speakers emphasized that while SCD as a disease is well understood, the mechanisms of SCD pain are not. Pain in SCD is complex and heterogenous; it may affect multiple organs and change over time.

Current barriers in SCD pain research include limited opportunities to integrate research across multiple disciplines; limited opportunities to connect SCD pain researchers and experts from other pain fields; limited platforms for dissimilation of knowledge among SCD pain researchers and between researchers, clinicians, and patients; and limited diversity and inclusion of underrepresented researchers. The proposed networks would bring together investigators from different disciplines to provide multidisciplinary cross training, conduct meetings and conferences, develop platforms for information dissemination, and support small-scale pilot projects in these priority areas: potential therapeutic targets, reverse translation, biomarkers, multimodal interventions, and whole person health. The structure of the networks would be similar to that of NCCIH-supported networks on emotional well-being and force-based manipulation.

Discussion: Dr. Coghill said that SCD is woefully under researched, and therefore the idea of collaboration across disciplines is exciting. Dr. Harris pointed out that because of the rarity of SCD, multisite recruitment is essential for clinical studies. Dr. Belfer said that patient engagement will be a big aspect of the networks. Dr. Coghill said that obtaining equity is challenging. Dr. Sherman said that these networks could serve as models for building networks for other complex conditions and interdisciplinary topics. Dr. Edwards said that NCCIH has been experimenting with this model; if approved, this will be the third set of networks. NCCIH sees this as an economical way to jumpstart a field. Dr. Mehling asked about existing clinical networks for SCD. Dr. Belfer explained that several networks exist, but they are focused on other aspects of the disease.

Council approved the concept with 13 votes in favor and 1 abstention.

3. Building Cross-Cutting Research Network(s) To Promote Multidisciplinary Mechanistic Studies of Music and Health

Dr. Wen Chen, chief of the Basic and Mechanistic Research Branch in the DER, explained that NIH held a workshop in January 2017, "Music and the Brain: Research Across the Lifespan." The report from this workshop made recommendations for enhancing research in four broad areas: basic and mechanistic research, translational and clinical research, methods and outcomes, and capacity building and infrastructure. The first two recommendations have been addressed through grants awarded in 2019 and 2020, and the third was addressed through a series of workshops in 2021 that have led to the creation of a toolkit for research on music-based interventions. The concept presented here addresses the final recommendation, on capacity building and infrastructure.

The proposed new initiative would support a group of research networks, each focusing on a specific health condition highly relevant to music-based interventions, such as pain, Alzheimer's disease, Parkinson's disease, stroke, or aging. The networks will develop frameworks to guide future clinical research, use consistent terminology and taxonomy, and support interdisciplinary collaborations and pilot studies to test novel mechanistic hypotheses and develop mechanistic measures, outcomes, and biomarkers. These objectives will be accomplished through meetings, workshops, and conferences, as well as collaborative discussions and exchanges through visiting scientist arrangements and training opportunities. The networks will also fund pilot research projects to provide preliminary data needed for music and health investigators to compete for larger NIH grants. The networks would sustain their scientific impact through publications, dissemination, and outreach. High-priority topics for the networks include defining and differentiating music-based interventions and identifying their active components, exploring mechanisms and biomarkers relevant to music-based interventions for a specific health condition, and developing novel technologies, tools, and models.

Discussion: In response to questions from Dr. Lavretsky on whether the networks would only generate opportunities for funding and about criteria for investigators joining the networks, Dr. Chen said that the networks would bring people from different disciplines together to generate preliminary data to help them be competitive. Typically, there would be a broad call for pilot projects that would go beyond the institutions receiving support. Dr. Edwards said that networks of this type always have a set of high-priority topics. Successful investigators must demonstrate that they can address some of these topics and conceptualize projects that move the field forward. Dr. Mehling asked whether dance-based interventions for Parkinson's disease could be included. Dr. Chen said yes, unless no music is involved. A metronome or drumming would qualify as music because these interventions have rhythm.

Council approved the concept unanimously.

VII. Final Remarks and Public Comment

Dr. Khalsa reviewed the process for submitting public comments. Dr. Edwards thanked everyone and said that the special hybrid format for this meeting (in which some NCCIH staff attended in person but Council members, other staff, and the public participated virtually) had worked well. Dr. David Shurtleff, deputy director of NCCIH, thanked Council for their enthusiasm, feedback, and advice. Dr. Langevin said that Council meetings provide a cross-sectional snapshot of the process of identifying a knowledge gap, formulating a concept, issuing an FOA, reviewing applications, and issuing awards. She complimented the many divisions and offices at NCCIH that keep this process going. Dr. Langevin urged Council members to attend the September meeting in person if the option becomes available. Dr. Khalsa shared his personal thanks to the meeting staff and said that NCCIH will communicate with Council members during the summer about the possible hybrid meeting.

VIII. Adjournment

The meeting adjourned at 4:30 p.m. ET.

We hereby certify that, to the best of our knowledge, the foregoing minutes are accurate and complete.