

**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-Ninth Meeting
January 21, 2022**

Current NACCIH Members Present Virtually

Dr. Todd Braver, St. Louis, MO
Dr. Chester (Trip) Buckenmaier, III, Bethesda, MD
Dr. Nadja Cech, Greensboro, NC
Dr. Robert Coghill, Cincinnati, OH
Dr. Anthony Delitto, Pittsburgh, PA
Dr. Roni Evans, Minneapolis, MN
Dr. Diana 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
Ms. Lori Knutson, Bentonville, AR
Dr. Helen Lavretsky, Los Angeles, 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*

Recently Retired Members Present for the Service Ceremony

Dr. Belinda Anderson, New York, NY
Dr. Gloria Yeh, Boston, MA

*Retired as of end of this meeting

I. Closed Session

The first portion of the seventy-ninth 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 158 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 74 scored applications, which requested \$27,852,709 in total costs.

II. Open Session Call to Order; Review of Council Operating Procedures

Dr. Partap Khalsa, NACCIH Executive Secretary, convened the open session at 11:40 a.m. ET. As required by the Council charter, he presented the annual review of Council operating procedures for secondary review of grant applications, NCCIH reports to Council, Council review of concepts for research initiatives, appeals and appeal criteria, and Council involvement in policy and research priorities. Council unanimously approved the operating procedures and the minutes of the last Council meeting.

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 within 15 days of this meeting (by February 5, 2022). Comments must be under 700 words and will be shared directly with Council members.

III. NCCIH Director's Welcome and NCCIH Report

Dr. Helene M. Langevin, director of NCCIH, welcomed the three new Council members: Dr. Nadja Cech, Ms. Lori Knutson; and Dr. Helen Lavretsky.

Dr. Langevin presented a tribute to Dr. Francis Collins, who recently retired as director of the National Institutes of Health (NIH). Dr. Lawrence Tabak is now acting director. Dr. Ardem Patapoutian and Dr. David Julius, NIH grantees, jointly won the 2021 Nobel Prize in Physiology or Medicine for their work on identifying receptors that allow cells to sense temperature and touch.

Dr. Shelley Headley, NCCIH chief grants management officer, has retired. Dr. Langevin welcomed Ms. Debbie Chen, her successor. There are two new program directors in the Division of Extramural Research, Dr. Elizabeth Ginexi and Dr. Emrin Horgusluoglu. Three NCCIH program directors have moved to other NIH positions: Drs. Merav Sabri, Dave Clark, and Della White. Dr. Robin Boineau has transitioned from acting director to director of the Office of Clinical and Regulatory Affairs.

The NIH Health Care Systems Research Collaboratory will soon mark its 10th anniversary and has been rebranded as the NIH Pragmatic Trials Collaboratory, a shorter name that better captures its full scope and purpose. The Collaboratory's funding source is moving from the NIH Common Fund to 10 NIH Institutes and Centers (ICs) and the Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®. The Collaboratory is co-led by NCCIH and the National Institute on Aging. Its new areas of focus are strategies to implement evidence-based interventions into health care delivery and trials to address health disparities in health care delivery.

Dr. Langevin presented the NCCIH budget mechanism table. NIH is operating under a Continuing Resolution (CR) through February 18, 2022. The president's budget for NIH includes a substantial proposed increase in funding for NCCIH, from approximately \$154 million in fiscal year (FY) 2021 to \$185.3 million, including an increase of \$26 million earmarked for research on pain and pain management. The President's budget is still going through Congress and has not yet been approved. NCCIH recently participated in a congressional briefing with Representative Jackie Walorski (R-IN), co-chair of the House Integrative Health Caucus, who is interested in NCCIH's strategic plan. NCCIH will follow up with the Caucus. The Democratic Women's Caucus had a briefing with leaders of NIH and the ICs.

Dr. Langevin thanked the grantee community, who have met and overcome many hurdles related to the COVID-19 pandemic while putting safety first and adapting to resource limitations and changes. She highlighted some areas of achievement. NIH awarded nearly \$470 million (supported by the American Rescue Plan) to build a national study population of diverse research volunteers and support large-scale studies on the long-term effects of COVID-19. The NIH REsearching COVID to Enhance Recovery (RECOVER) Initiative made the parent award to New York University (NYU) Langone Health, which will serve as the RECOVER Clinical Science Core and make subawards to more than 100

researchers at more than 30 institutions. This program will support new studies of COVID-19 survivors and leverage existing large, long-running cohort studies, thus forming a meta-cohort, and will expand the research focus.

Highlights of recently published NCCIH-funded research include:

- A laboratory study on components of holy basil (tulsi) and clove, especially eugenol, for effects on the SARS-CoV-2 infection process and a model of COVID-19 symptoms in mice
- A study on the effects of exposure to green light-emitting diodes in a mouse model of pain
- A systematic review and meta-analysis of literature on the associations between back pain and mortality rates
- A study based on the NIH Pragmatic Trials Collaboratory on lessons learned and best practices for conducting pragmatic clinical trials that use electronic health records

Dr. Langevin drew members' attention to two new NIH HEAL Initiative RFAs:

- RFA-AT-22-003, HEAL Initiative: Developing Quantitative Imaging and Other Relevant Biomarkers of Myofascial Tissues for Clinical Pain Management. A [related technical assistance webinar](#) was held in December 2021, followed by a researcher networking session in January 2022.
- RFA-AR-22-009, HEAL Initiative: Restoring Joint Health and Function to Reduce Pain Consortium (RE-JOIN). A technical assistance webinar is scheduled for February 2022.

The virtual "[Methodological Approaches for Whole Person Research Workshop](#)" was held in September 2021, with a goal of identifying research methods from other fields that can be applied to whole person research, as well as gaps, opportunities, and needs related to new research. Dr. Sean Young, University of California Institute for Prediction Technology, gave a virtual Integrative Medicine Research Lecture in November 2021, "[Reading Between the Tweets: Social Technologies for Predicting and Changing Health Behavior](#)." The virtual 2021 Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies was "[Mindfulness as a Support for Healing Conversations and Actions Toward Social Justice and Equity](#)," given virtually by Professor Rhonda V. Magee, University of San Francisco School of Law.

Upcoming events include a workshop on "Precision Probiotic Therapies—Challenges and Opportunities" in April 2022. The annual NIH Pain Consortium Symposium will be held on June 1–2, 2022 and will focus on "Pain Management Through the Lens of Whole Person Health." The 2022 International Congress on Integrative Medicine and Health, in May 2022, will feature two pre-Congress workshops and nine symposia organized by NCCIH. In addition, Dr. Langevin will have a keynote conversation with Dr. Suzanne Simard, University of British Columbia, a pioneering researcher in forest management (a topic relevant to whole person health).

Discussion: Dr. Haney asked when the 2022 budget could be approved, and Dr. Langevin explained that the timing for approval is unknown. Dr. Mehling asked if the current cuts to R34s for year 2 could be reversed if the budget increase comes through. Dr. Langevin said this is among the topics that will be assessed when NCCIH receives its budget. Dr. Khalsa added more detail about procedures under CR and a subsequent budget. In response to a question from Dr. Lavretsky about funding decisions in the NYU Langone project, Dr. Langevin responded that she understands those decisions are made in tandem between NIH and the institution. Dr. Lavretsky asked for more clarification regarding engagement in discussion of other projects for funding. Dr. Langevin responded that NCCIH has no authority over this. The multi-IC consortium project has been proceeding very carefully, under tremendous time constraints. Dr. Sonnenburg praised the report and asked whether the extra funds, if received, would come in earmarked for specific programs. Dr. Langevin said that if the funding is received, it would be for pain research but not specific projects. All projects would have to be completed during FY 2022.

IV. Examples from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) Pain Portfolio

Dr. Lindsey A. Criswell, director of NIAMS, opened her presentation by providing background on her IC. Since she began her role as director, she has been getting to know her fellow IC directors and discussing areas of mutual interest and potential collaboration. She gave an overview of NIAMS's history, mission, budget, and support of intramural and extramural research programs (many of which are conducted in partnership with other ICs such as NCCIH).

NIAMS's strategic plan for 2020 to 2024 focuses on five broad areas of interest: systemic rheumatic and autoimmune diseases; skin biology and diseases; bone biology and diseases; muscle biology and diseases; and joint biology, diseases, and orthopedics. Each area represents a tremendous public health burden. Most of the diseases are chronic and are associated with significant chronic pain and disability. Many affect women and minorities disproportionately. The plan also highlights four cross-cutting scientific themes: shared mechanisms in health and among diseases; patient-centric approaches to health and disease; health and disease in diverse populations; and precision medicine for arthritis and musculoskeletal and skin diseases, to tailor care to patients.

One example of a past successful collaboration between NIAMS and NCCIH is the Patient-Reported Outcomes Measurement Information System (PROMIS[®]), funded through the Common Fund. This has been a groundbreaking project in the area of self-reported outcomes and today is a rich, highly inclusive resource for clinicians, researchers, and patients.

NIAMS's activities to address musculoskeletal pain include the Osteoarthritis Initiative (OAI), which was active between 2001 and 2016 and was carried out with several ICs (including NCCIH) as well as industry and the Foundation for the NIH. Today, it has one of the largest and perhaps most important datasets in the history of osteoarthritis (OA) research. Dr. Criswell presented examples of findings on exercise and diet in the context of osteoarthritis (OA). NIAMS is planning a workshop on health disparities in OA.

The NIAMS-funded Meniscal Tear in Osteoarthritis Research (MeTeOR) trial has been comparing outcomes of treating this common condition (in knee OA) with arthroscopic surgery or physical therapy (PT). Dr. Criswell explained that it is acceptable to try PT first, according to patient preference. It is important to note, however, that one-third of the patients in this study who had PT alone underwent surgery within 6 months, which suggests that PT is not preferable for some patients. The researchers are now conducting a 12-year follow-up study, which is expected to yield additional information on the disease and the relative risks and benefits of the two treatments. Dr. Criswell next discussed two of NIAMS's investments in fibromyalgia research, the Fibromyalgia Integrative Training for Teens (FIT Teens) randomized controlled trial and the University of Michigan Fibromyalgia Center of Research Translation (CORT).

Next, Dr. Criswell discussed projects under HEAL, including the Back Pain Consortium (BACPAC) Research Program, which is led by NIAMS. Within BACPAC, the Biomarkers for Evaluating Spine Treatments (BEST) clinical trial is designed to inform a precision medicine approach to chronic low-back pain.

A new HEAL initiative, RE-JOIN, is being led by NIAMS and is an NIH-wide initiative. Other examples of NIAMS partnership activities included:

- The current funding opportunity on developing quantitative imaging and other relevant biomarkers of myofascial tissues for clinical pain management (NCCIH-led)
- The Integrative Management of Chronic Pain and Opioid Use Disorder for Whole Recovery (IMPOWR) Research Centers
- The HEAL Workshop on Myofascial Pain held in September 2020 (NCCIH-led)

- Three projects within the HEAL effort on Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM)
- The Lumbar Imaging with Reporting of Epidemiology (LIRE) pragmatic trial

The Accelerating Medicines Partnership® (AMP®) program is a public-private partnership that includes NIH, the U.S. Food and Drug Administration (FDA), multiple biopharmaceutical and life science companies, and nonprofit and other organizations to transform the current model for developing new diagnostics and treatments. AMP partners share the goal of increasing the number of new diagnostics and therapies for patients and reducing the time and cost to develop them. The program aims to improve understanding of therapeutically relevant biological pathways and validate information that could be relevant for the development of multiple therapeutics.

Dr. Criswell shared some results of one of the initial AMP projects that NIH launched in rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) (the AMP RA/SLE program). Partners were NIAMS, the National Institute of Allergy and Infectious Diseases, and nonprofit and industry organizations. The program has been very innovative, examining the cell types, gene expression patterns, and signaling molecules that play a role in one or both diseases.

Dr. Criswell described the second program, AMP Autoimmune and Immune-Mediated Diseases (AMP AIM), which launched in 2021 and is designed to broaden and build upon AMP RA/SLE. The disease foci are RA, SLE, psoriasis, psoriatic arthritis, and Sjögren’s syndrome. Investigators will seek to index and map cells and pathways in these diseases and to discover how they interact through new analytics, to identify specific and shared disease mechanisms. Two RFAs were released, with awards to be announced in February 2022.

NIAMS, like NCCIH, has developed proposed programs in pain research for FY 2022 in case the funding bill passes. Dr. Criswell commented that she and her colleagues are quite optimistic about the future of pain research at NIAMS and NIH and are confident the results will ultimately benefit individuals and their families who are living with and impacted by musculoskeletal pain.

Discussion: Dr. Langevin thanked Dr. Criswell for her overview of the broad interests of NIAMS, including areas of collaboration with NCCIH, past, present, and potentially in the future. Dr. Criswell said she is very excited about the many opportunities moving forward. Dr. Delitto was pleased with NIAMS/NCCIH collaboration to date and saw potential for much more. Dr. Harris asked whether NIAMS and NCCIH could work to offer specific funding opportunity announcements (FOAs) bridging both integrative and more conventional treatments instead of the current siloed approach. Dr. Criswell said patients want to access anything across the spectrum of options that could help them. Dr. Mehling commented that at least three meeting participants present are part of BACPAC. Dr. Criswell praised BACPAC investigators for how they have managed and kept moving forward during the pandemic.

Dr. Sherman asked if Dr. Criswell anticipates BACPAC going from the preliminary stage through to implementation, and could NIAMS/NCCIH partner on this? Dr. Criswell said yes and said that it is fortunate that HEAL supports BACPAC. She sees HEAL as being well funded in the years ahead.

Dr. Langevin asked whether the AMP approach to look at cellular mechanisms could be extended to other musculoskeletal conditions. Dr. Criswell said accessing disease tissues was a critical goal in the first AMP program but is very challenging. She foresees that there will be easier ways to undertake it, including across more diseases and possibly even in the clinic. Datasets being developed across multiple diseases will be an important resource for understanding common pathways and moving from discoveries in one disease to implications and ramifications for others.

V. Introduction to a Concept of Whole Joint Health

In what she termed a philosophical discussion, Dr. Langevin presented a vision of a model of whole joint health as a follow-up to NCCIH’s work on whole person health, which is the emerging theme in NCCIH’s strategic plan for 2021 to

2025. The whole person health model is conceived to help people restore their health in multiple interconnected domains (behavioral, biological, social, and environmental) and places health and disease as endpoints on a continuum. Movement on this continuum is bidirectional, and there are many points at which one can restore or improve health and function. Adding “person” to “whole health” is important, because within the biological realm many systems in the body are often studied apart from one another.

With regard to the musculoskeletal system, a few examples of factors that impact joint health include the status of a person’s joints, muscles, and bones (biological level); what kind of physical activity they do (behavioral level); and whether they can exercise safely outdoors or indoors (social, environmental levels). In addition, factors that impair or do not promote better health should be considered.

The whole joint health concept is similar to that of whole person health. Joints have many different components that are not always integrated optimally in research or patient care. While some structures are unique to specific joints, for example, the articular disc in the temporomandibular joint or the meniscus in the knee, there are components that are common to all joints, such as cartilage, synovium, joint capsule, ligaments, tendons, and associated muscles. Identifying and studying these joint components in a way that could be translated across all joints could be very useful. Dr. Langevin proposed creating a more universal or generic structure for thinking about joints and introduced the idea of a “joint unit” that would include these components, as well as their vasculature and innervation.

NCCIH has a separate initiative that will look at developing biomarkers for myofascial pain; this would also be relevant to understanding joints. Knowing more about diagnosing and treating myofascial trigger points might be very useful in managing joint pain. There may be a relationship temporally between what goes on in the supporting structures and the articular surfaces. Dr. Langevin explained the mobility of tissues and imbalances related to joint mechanics. Weak muscles, stiff connective tissues, misaligned joints, and malfunction and degeneration of supportive structures could lead to damage to the articular surfaces. In short, what is transpiring regarding the outside of the joint and the supporting structures could be important in understanding why joints degenerate and could aid in prevention.

If a whole person health view of joint pain could be developed, it would include factors that can contribute to a vicious cycle such as worsened posture, obesity, increased stress and muscle tension, and depression. Using whole person health, one might be able to intervene earlier to try to prevent, improve, and perhaps even reverse pathology, moving away from the “disease” end of the continuum toward health.

Examples of interventions include improving diet; enhancing physical activity, posture, and stamina; reducing kinesiophobia (the fear of physical movement and activity); retraining (as in loosening up stiff connective tissues, strengthening weakened muscles, and correcting posture); incorporating localized manual therapies, physical therapy, and movement therapies; and improving access to therapies and exercise. Addressing the different components of joint pain from the whole person to the cartilage could help improve our understanding of how to prevent joint problems, improve joint health, and progress toward the goals of RE-JOIN. If this model could be achieved, it could possibly also be applied to other body systems (e.g., whole digestive health) and serve as a blueprint.

Discussion: Dr. Criswell said the presentation illustrates a tremendous opportunity and the collaboration of different ICs at NIH. Dr. Evans praised the concept, particularly the psychosocial aspects. Its approach and that of whole systems are important for all chronic health conditions and are congruent with many approaches in complementary and integrative health. Dr. Sherman praised the concept and saw it as providing a framework for development of the best sets of therapies. Improving our understanding of the biology may help inform first-line treatments and customize treatment plans.

Dr. Khalsa asked Council whether they had comments on teaching and researching whole joint health. Dr. Delitto said there is a need to begin to explore the evidence and that there is an opportunity to develop whole-body interventions and

compare them to interventions that are not necessarily effective but are overutilized. Ms. Knutson applauded the concept and linked it to the clinical environment and value-based payment. She noted that the timing could not be better as payors are moving toward a whole person view over the lifetime. Dr. Sonnenburg asked about the possibility of using the whole joint health concept as a template for future expansion. Dr. Langevin said that NCCIH recently held a workshop on whole person health research, including how to think about interconnected systems. There are some systems known already to be integrated and interact with the whole body, whereas for others, more needs be learned.

Dr. Lavretsky commented regarding teaching an integration/whole person approach. COVID and post-COVID have made this kind of approach necessary, and in research and care, there can be reconstruction and refocusing to be more collaborative. Dr. Hensel said the approach fits well with osteopathic medical schools—an approach that is not siloed, but rather is about “intermeshing” between systems. Dr. Evans suggested thinking about more integration of people from different disciplines in education and research opportunities, not just integration within single disciplines. Dr. Criswell asked how NCCIH would approach development of the evidence base to inform understanding and ultimately implementation, and whether there any examples. Dr. Langevin appreciated that NIAMS took a big first step by leading the first, fundamental question: mapping the sensory neurons. She then described steps in a possible process and mentioned BACPAC, which will be informative and helpful in many ways.

Dr. Harris shared some thoughts based on his work in BACPAC and on the BEST trial, doing brain imaging and various interventions. They are using phenotyping with different interventions as probes to see which patients respond to them, and then going back to anatomy and biomarkers. Dr. Sherman would not expect to see metabolomics or brain imaging performed in the clinic for typical patients, but perhaps this might change in the future. Dr. Criswell said that imaging is expensive, but when one looks at long-term costs, investing in phenotyping upfront might at times make sense. Dr. Langevin recommended that researchers persist, not become discouraged, and think about the kinds of phenotyping that are missing as well as gaps in ways we look at and measure the body.

A discussion followed about palpation and manual therapies. Dr. Langevin noted there is no objective measurement of palpation and of what one palpates, but palpation could inform decisions about using other tools such as ultrasound and magnetic resonance imaging. Dr. Hensel gave an example of the use of butterfly ultrasound in osteopathic education. Dr. Mehling said that palpation is a neglected skill in conventional medical schools compared to imaging, and that hands-on education is important. Dr. Delitto did not see palpation returning to allopathic medical schools, although it is used in some other health professions. Dr. Harris stressed touch as critical for healers and the healing process and suggested more research on gua sha healing and cupping. Dr. Mehling said there is increasing interest among his university’s medical students in integrative approaches and massage. Dr. Sherman proposed several sample questions originating out of her experience in acupuncture trials.

Dr. Langevin commented that the pendulum in the domain of pain started to swing about 30 years ago from focusing on the peripheral tissues to focusing on the nervous system. Now there is a need to reconnect the brain to the rest of the body, especially in musculoskeletal pain. Dr. Harris recommended having interventions that target multiple levels and areas concurrently.

VI. Update on NCCIH Pain Funding Opportunity Announcements

Dr. Emmeline Edwards, director of the DER, presented a brief overview of plans that NCCIH has developed to expand its pain program. The aim is to address gaps in the portfolio and leverage opportunities for collaboration with other ICs and other Federal agencies. National study reports show that pain is a major public health problem in the United States. For example, more people live with chronic pain than cancer, heart disease, or diabetes combined. A large percentage of these people have severe limitation of function.

Dr. Edwards highlighted NOT-NS-22-057, Multi-Institute Interest in Pain Research, released on December 27, 2021, and sponsored by NCCIH and six other ICs, to alert the community about the multi-IC interest in pain research and in training programs to build the workforce in this area.

Complementary and integrative management of pain is one of the 10 top scientific priorities in NCCIH's strategic plan. Cutting-edge areas include:

1. Advancing understanding of multisystem pain mechanisms and phenotypes (e.g., myofascial pain) and common comorbidities
2. Elucidating mechanisms underlying overlapping pain conditions
3. Increasing the focus on health disparities in pain and greater inclusion of women, racial and ethnic minorities, and underserved populations in clinical trials/studies on pain
4. Expanding the evidence base on the efficacy and effectiveness of complementary and integrative approaches for pain management
5. Increasing understanding of the multisystem mechanisms underlying the effects of complementary and integrative approaches on pain
6. Leveraging HEAL and other NIH-wide and trans-agency programs to identify therapeutic biomarkers for complementary and integrative health approaches on pain
7. Improving methods for incorporating effective complementary and integrative approaches into standard care to treat pain and decrease the unnecessary use of opioids

Dr. Edwards described two Notices of Special Interest (NOSIs) that were published in November 2021 and open at the time of this meeting: NOT-AT-22-003, Administrative Supplements for NCCIH Grants to Support Pain-Focused High Priority Research Areas, and NOT-AT-22-007, NCCIH High Priority Pain Research.

Dr. Edwards detailed some current research gaps in the NCCIH pain portfolio:

- Basic/mechanistic, translational, or clinical research on pain related to sickle cell disease
- Basic and mechanistic understanding of myofascial pain
- The fundamental science of biophysical force-based interventions to prevent or manage chronic pain
- Identifying novel therapeutic targets of pain for nonaddictive natural products
- The science of music therapies to enhance pain management
- Multicomponent pain management intervention development
- Trials of complementary and integrative interventions delivered remotely or via mHealth

She gave examples of recent funding opportunities on pain in which NCCIH is involved, including:

- RFA-AT-22-006, NIH-DOD-VA Pain Management Collaboratory – Pragmatic and/or Implementation Science Demonstration Projects (UG3/UH3, Clinical Trial Required)
- Under HEAL, there were:
 - RFA-AT-22-003 - HEAL Initiative: Developing Quantitative Imaging and Other Relevant Biomarkers of Myofascial Tissues for Clinical Pain Management (R61/R33, Clinical Trial Required)
 - RFA-AT-22-004 - Heal Initiative: Pragmatic and Implementation Studies for the Management of Sickle Cell Disease Pain (UG3/UH3, Clinical Trials Optional)
 - RFA-AT-22-005 - HEAL Initiative: Sickle Cell Disease Pain Management Trials Utilizing the Pain Management Effectiveness Research Network Cooperative Agreement (UG3/UH3, Clinical Trial Required)

- RFA-NS-22-002 - HEAL Initiative: Advancing Health Equity in Pain Management (R61/R33, Clinical Trial Required)
- RFA-NS-21-029 - HEAL Initiative: Planning Studies for Initial Analgesic Development [Small Molecules and Biologics] (R61 Clinical Trial Not Allowed)
- RFA-NS-21-015 - HEAL Initiative: Team Research for Initial Translational Efforts in Non-addictive Analgesic Therapeutics Development (U19 Clinical Trial Not Allowed)
- RFA-NS-21-016 - HEAL Initiative: Planning Studies for Initial Analgesic Development Initial Translational Efforts [Small Molecules and Biologics] (R34 Clinical Trial Not Allowed)
- RFA-NS-21-010 - HEAL Initiative: Development of Therapies and Technologies Directed at Enhanced Pain Management (R43/R44 Clinical Trial Required)
- HEAL Data2 Action (HD2A) Program - a set of four interrelated RFAs to promote the synthesis and real-world application of existing data and to guide and monitor improvement in service delivery to prevent or treat opioid use disorder and pain
- RFA-DA-22-049, -050, -051, -052 - Innovation research grants to be supported by three resource centers

Dr. Edwards strongly encouraged researchers to visit the NCCIH and HEAL websites regularly, as new listings are frequently posted. Other HEAL FOAs highlighted were:

- RFA-DA-22-047 (R01): for improvement of service delivery in the area of polysubstance use
- RFA-DA-22-048 (R34): for pilot and feasibility trials to improve prevention and treatment for polysubstance use
- RFA-DA-22-043 (R24 research networks) and RFA-DA-22-034 (R34 planning grants for efficacy and effectiveness trials): for recovery support services for individuals treated with medications for opioid use disorder
- RFA-DA-22-046: To study harm reduction policies, practices, and modes of delivery for people with substance use disorders
- RFA-DA-22-045 (R21 Exploratory) and RFA-DA-047 (R01): To study data and methods to address urgent needs to stem the opioid epidemic

These RFAs are in place in case NCCIH does receive the influx of funding for pain research. Dr. Edwards applauded her staff, who have worked very hard on very short notice to conceive and develop impactful FOAs. She said there is much interest, well justified, in pain research, and NIH has taken many steps to address some of the issues and provide research opportunities in multiple domains.

Discussion: Dr. Cech asked whether the strategy is to take advantage of existing initiatives or create new ones. Dr. Edwards responded that NCCIH has adopted a multipronged approach, for example, by starting with administrative supplements. The timeline overall is ambitious, but if the extra funding is received, NCCIH has little choice.

VII. 2022 NCCIH Triennial Report on Compliance with Inclusion Guidelines

The NIH director is required to provide a report to Congress every 3 years on the state of NIH-supported biomedical and behavioral research, including on adherence to the NIH Policy on Inclusion of Women and Minorities in Clinical Research. The goal of the policy is not to satisfy quotas for proportional representation based upon U.S. Census data, but rather to conduct research so that the findings will be generalizable to the U.S. population. The number of women, men, and/or representatives of racial/ethnic subpopulations included in a study depends upon the scientific question the study addresses and the prevalence among subpopulations of the condition under investigation. Data are reported by investigators in their inclusion enrollment report within their annual progress report.

Dr. Boineau presented data on 3 years (2019 to 2021) of NCCIH clinical research—including on domestic enrollment, extramural and intramural research projects, and all clinical research and Phase III trials. Data were submitted the preceding year—e.g., data labeled in the presentation as “FY 2021” were submitted to NIH in FY 2020. Key data include the following:

- The total enrollment in NCCIH clinical research went from 9,343 total participants in 2019 to 15,850 in 2020 and 49,100 in 2021. The percentage of women enrolled was very close to 50 percent in all 3 years.
- Within all NCCIH clinical research for these 3 years, total minority enrollment was about 25 percent each year. The Hispanic/Latino population (6 percent in 2019 and 2021 and 8 percent in 2020) was proportionately small compared with the non-Hispanic population.
- In NCCIH intramural clinical research studies, total enrollment grew from 344 in 2019 to 1,407 in 2020 and 2,102 in 2021. Minority enrollment was 64 percent in 2019, 32 percent in 2020, and 38 percent in 2021. Female enrollment was 56 percent in 2019 and 45 percent in both 2020 and 2021.
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The COVID-19 pandemic may have affected study recruitment numbers in the FY 2020 and 2021 data. Dr. Boineau emphasized that NCCIH continues to support increased participation of women and minority populations in NCCIH-funded studies. New resources are available on the NCCIH and NIH websites to enhance diversity in NIH/NCCIH research, such as the [NIH UNITE Initiative](#) and an NCCIH Hot Topic Webinar in April 2021, “[Engaging Diverse Communities in Complementary and Integrative Health](#).” The [NIH Research, Condition, and Disease Categories \(RCDC\) Statistics Report](#) website enables the public to review NIH-funded research. Listings are in research, disease, or condition categories. Users can drill down for more detail, such as sex/gender, ethnicity, and race.

Discussion. Dr. Coghill asked how NCCIH will handle situations of ongoing studies that have declining study enrollment due to COVID-19. Dr. Boineau responded that NCCIH anticipates that the pandemic will have broad and deep effects. She noted that NCCIH asks researchers questions such as: “What is your main research question? What are you doing to answer that question? What funds do you have to answer it?” NCCIH can then help researchers look at options and determine how they can complete the study. NCCIH may have access to funding that could help researchers in this situation, but the Center is not able to cover every need. Dr. Edwards said that this conversation has been an ongoing one between program staff and investigators. NCCIH has had maximum flexibility but wants to preserve integrity of the research. Staff has brainstormed with investigators to guide them and help them develop useful strategies. Some researchers whose studies have been affected by COVID-19 have been able to transition to remote interventions.

VIII. Recognition Ceremony for Retired and Retiring Council Members

Three Council members had completed their terms shortly before this meeting: Drs. Belinda Anderson, John MacMillan, and Gloria Yeh. Dr. Barbara Timmermann would complete her term at the end of this meeting. Dr. Langevin honored them and thanked them for their outstanding service and contributions to NCCIH and the field of complementary and integrative health. Drs. Anderson, Timmermann, and Yeh were present for the ceremony, and they offered brief remarks.

IX. Concept Clearance: NCCIH High-Priority Pain Research

The United States is in a public health emergency related to the opioid misuse and addiction crisis, first declared in 2017 by Acting Secretary of Health and Human Services Eric D. Hargan. In addition, the country has an ongoing public health emergency of pain. Although Congress gave NIH a large appropriation that became the HEAL Initiative, unfortunately there has not been major progress in the opioid epidemic. The Centers for Disease Control and Prevention recently estimated 100,306 drug overdose deaths in the United States in the 12-month period ending in April 2021—an increase of almost 30 percent from the year before. With the possibility of receiving additional funding for pain research in the budget that is currently going through Congress, NCCIH is interested in developing an initiative that would directly contribute to ending the opioid crisis through improved pain management and nonpharmacologic, nonaddictive approaches.

The goals of this concept are to accelerate pain research, address the underlying causes of the opioid misuse crisis, extend existing efforts into FY 2023 and beyond, and fill gaps in the current NCCIH portfolio. Its objectives are: (1) basic/mechanistic, translational, or clinical research on pain related to sickle cell disease; (2) basic and mechanistic research on myofascial pain; (3) fundamental science of biophysical force-based interventions to prevent or manage

chronic pain; (4) studies identifying novel therapeutic targets of pain for nonaddictive natural products; (5) the science of music therapies to enhance pain management; (6) multicomponent pain management intervention development; and (7) trials of complementary and integrative interventions for pain management delivered remotely or via mHealth. The overall goal is to address the opioid misuse crisis. NCCIH would utilize this opportunity to fill in gaps in its portfolio and support projects currently in progress. For example, NCCIH's myofascial FOA under HEAL is for clinical research, but the present concept would include basic and mechanistic research related to myofascial pain.

The concept was approved by all voting-eligible members. There were no questions or comments.

X. Final Comments and Public Comment

Dr. Khalsa reviewed the process for submitting public comments. Dr. Langevin thanked all the members and speakers, commenting that the past year has been "one like no other." She recognized that the amount of information presented at this meeting about FOAs could be overwhelming in some ways, but that the important thing to remember is that if there are additional funds for pain research, it will be an opportunity to fund a missing piece—i.e., other opportunities across the ICs that could not be funded through HEAL given its specific focus. Whatever the outcome regarding the funding bill, NCCIH will continue to do the best that it can with the resources that it has.

XI. Adjournment

The meeting was adjourned at 4:20 p.m. ET.

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