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-Sixth Meeting
January 15, 2021

NACCIH Members Present Virtually
Dr. Belinda Anderson, New York, NY
Dr. Todd Braver, St. Louis, MO
Dr. Robert Coghill, Cincinnati, OH
Dr. Anthony Delitto, Pittsburgh, PA
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[1]
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. Eric Schoomaker, Bethesda, MD[1]

[1]Ex Officio Member

I. Closed Session

The first portion of the seventy-sixth 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 189 applications were assigned to 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 111 scored applications, which requested $492,972,641 in total costs.

II. Call To Order and 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 September 2020 Council meeting were approved unanimously. Dr. Khalsa conducted the annual review of Council operating procedures for NCCIH reports to Council, secondary review of grant applications, review and approval of concepts for research initiatives, adjudication of appeals, and Council involvement in developing, recommending, and setting policy and research priorities. Council approved the operating procedures unanimously.

III. NCCIH Director's Report

NCCIH Director Dr. Helene Langevin began her report to Council by announcing the retirement of Dr. Catherine Meyers, Director of the Office of Clinical and Regulatory Affairs. Dr. Robin Boineau has been named Acting Director of that office. She also noted that Dr. Yisong Wang, program director in the Division of Extramural Research (DER), has left NCCIH for a position at the National Cancer Institute.

In late December 2020, Congress passed and the President signed a spending bill for Fiscal Year (FY) 2021, including for the National Institutes of Health (NIH). NCCIH's appropriation is $154.162 million. Overall, compared with FY 2020, there were modest increases for NCCIH, including for research project grants.

Among NIH news, the NIH Office of Nutrition Research (ONR) has transferred from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to the Division of Program Coordination, Planning, and Strategic Initiatives in the NIH Office of the Director (OD), becoming a trans-NIH effort. This move should enhance coordination of and collaborations in NIH nutrition research. NIH has engaged its Institutes, Centers, and Offices (ICOs) in implementing the *NIH-Wide Strategic Plan: Fiscal Years 2021–2025,* which is in the final stages of approval. The plan prominently features disease prevention and health promotion.

Dr. Langevin noted that NCCIH has been actively continuing its efforts regarding workforce diversity and health disparities research as part of NIH's broader effort. It has formed the NCCIH Health Disparities Working Group, is developing a page on this topic area for the Center's website, and has created the NCCIH Statement on Workforce Diversity and Health Disparities Research.

The U.S. Department of Health and Human Services (HHS) has created a new "Combat COVID" website (combatCOVID.hhs.gov) directed at the public and aimed at engaging four distinct audiences in research. NIH has a new website (COVID19.nih.gov) that provides a central

location for reliable information on COVID-19 research at NIH. NCCIH has participated in a variety of trans-NIH activities and initiatives related to COVID-19, including RADx Underserved Populations (RADx-UP, which focuses on diagnostics), and has led some funding opportunities.

Dr. Langevin highlighted a selection of recent publications on NCCIH-funded research:

- Five NCCIH Division of Intramural Research (DIR) investigators, including Dr. Catherine Bushnell, and their colleagues collaborated on a study about alterations in the default mode network in patients with chronic pain (published in *NeuroImage*).
- NCCIH lead epidemiologist Dr. Richard Nahin led a study on the relationship between pain and cognitive impairment and associations with a variety of health measures (published in *Clinical Journal of Pain*).
- Drs. Alexander Chesler and Marcin Szczot, both from NCCIH's DIR, and their colleagues coauthored an article on the coordination of PIEZO2, sensory neurons, and urothelial cells in urination (published in *Nature*).
- At Massachusetts General Hospital, NCCIH funded a study on dynamic brain-to-brain concordance and the therapeutic alliance between provider and patient in which both participants received simultaneous functional magnetic resonance imaging (fMRI) while an acupuncture treatment was delivered (published in *Science Advances*).
- Another fMRI study, primarily from the Massachusetts Institute of Technology, found that social cravings after acute social isolation and food cravings after fasting evoked similar neural responses in the midbrain (published in *Nature Neuroscience*).
- Drs. Lauren Atlas and Elizabeth Necka, both from NCCIH's DIR, and a Karolinska Institute scientist coauthored an article on metacognitive judgments of pain, particularly participants' certainty levels when rating their pain (published in *Scientific Reports*).
- A special issue of *Trends in Neurosciences* included a review coauthored by several NCCIH scientists, including Drs. Langevin, Wen Chen, and Angela Arensdorf, on the emerging science in the field of interoception.
- Dr. Emmeline Edwards, Director of the DER, and Dr. Della White, a program director in the DER, contributed to two articles in a special issue of the *Journal of Women's Health* on maternal morbidity and mortality, one on perinatal depression and another on the physiological need for calcium, iron, and folic acid during and after pregnancy among women in various subpopulations.

Dr. Langevin highlighted some current and upcoming funding opportunities involving NCCIH leadership or participation such the science of music and health, fundamental science research on mind and body approaches, promotion of diversity in health research, electronic systems to monitor or enhance mind and body interventions (through the Translational Research Innovation Grants To Nurture Initial Translational Efforts initiative [IGNITE] Initiative), research supplements to promote diversity (for grantees of the NIH HEAL [Helping to End Addiction Long-term℠] Initiative), and tools and technologies for studying brain function (through the

Brain Research Through Advancing Innovative Neurotechnologies [BRAIN] Initiative). In addition, NCCIH is participating in three new NIH HEAL Initiative funding opportunity announcements (FOAs) released several days before this meeting.

NCCIH recently held a "Hot Topic Webinar: Implementation Science and Complementary Health Interventions." A team led by program director Dr. Dave Clark has had a paper on implementation science accepted for publication. The executive summary of the HEAL Initiative Workshop on Myofascial Pain held in September 2020 has been posted, accompanied by an NCCIH Director's Message. In October 2020, NCCIH held its first meeting for its grantees working on analgesic properties of minor cannabinoids and terpenes. In December 2020, the annual Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies, "All Health Is Not Created Equal: Where You Live Matters," was given virtually by Dr. Shannon Zenk, the new Director of the National Institute of Nursing Research, and was extremely well attended.

The Sound Health Network will be launched in January 2021. NIH participants include Dr. Edwards, who will lead a segment focused on the therapeutic potential of music, and NIH Director Dr. Francis Collins. In collaboration with the Foundation for the NIH and the Renée Fleming Foundation, NIH will host three panel discussion meetings on this topic in 2021.

Discussion: Dr. Coghill praised the growing rigor of NCCIH-sponsored research and lauded the Center's extramural and intramural investigators. In response to a question from Dr. Haney, Dr. Langevin explained the appropriations decisions process in Congress for NIH and how funds are distributed, including individual appropriations to ICOs for earmarked programs. NCCIH Deputy Director Dr. David Shurtleff welcomed input from Council members and stakeholders on the importance of the Center's work, health problems it seeks to address, and how it would benefit from additional resources.

IV. Update on the NCCIH Strategic Plan: 2021–2025

Ms. Mary Beth Kester, Director of the NCCIH Office of Policy, Planning, and Evaluation, explained that NCCIH expects to publish a draft strategic plan for comment by the end of January 2021. NCCIH hopes the final plan will be published by late spring and be presented at the May 2021 NACCIH meeting. The five objectives in the current draft are: (1) advance fundamental science and methods development, (2) advance research on the whole person and on the integration of complementary and conventional care, (3) foster research on health promotion and restoration, resilience, disease prevention, and symptom management, (4) enhance the complementary and integrative health research workforce, and (5) disseminate objective evidence-based information on complementary and integrative health interventions.

After extensive information gathering and portfolio analysis, NCCIH developed a list of high-priority topics to accompany the strategic plan. The 10 high-priority topics are:

1. **Complementary and integrative management of pain.** NCCIH has focused on research related to chronic pain for the last several years and many programs have been initiated and led by NCCIH alone or in collaborations across NIH and/or with other Federal partners. Identification and/or deeper understanding of mechanisms and therapeutic biomarkers are needed to optimize treatments and predict which individuals or groups most likely to respond.
2. **Complex interactions involving dietary interventions.** There has been relatively little research on the use of dietary supplements as complex mixtures for their health-promoting effects. Innovative strategies are needed to systematically study how natural products affect multiple biological systems. Areas of interest are botanicals, dietary phytochemicals, probiotics, and methods development.
3. **Enhancement of the complementary and integrative health research workforce.** NCCIH supports training and career development of investigators pursuing research topics that are well aligned with its scientific strategic objectives. More details were provided by Dr. Lanay Mudd in her presentation later in the meeting.
4. **Health restoration, resilience, disease prevention, and health promotion across the lifespan.** The usefulness of complementary and integrative health approaches among people who have experienced stressful life as events needs to be investigated. An area of interest is the effectiveness of these approaches as strategies for early interventions among individuals at increased risk.
5. **Implementation science for complementary and integrative health**. To understand the transition from research to practice and policy we need to investigate how to disseminate evidence-based interventions in ways that will provide the most benefit.
6. **Interoception research.** Interoception refers to the representation of the internal world of an organism and includes the processes by which that organism senses, interprets, integrates, and regulates signals from within itself. The processes involved could often serve as therapeutic targets of many complementary and integrative health approaches.
7. **Mechanistic effects of mind and body approaches.** Most mechanistic studies of psychological and physical approaches focus on the neural system, while other physiological, as well as psychological and social systems, remain understudied. NCCIH views fundamental research and discovery of potential biomarkers as critical as well as mechanistic studies of combined multimodal approaches.
8. **Supporting impactful clinical trials of complementary and integrative health approaches.** NCCIH defines “impactful clinical trials” as those that provide evidence to inform clinical practice guidelines and health care policies or provide preliminary data to inform the design of and ability to conduct fully powered clinical trials. An area of interest is randomized, pragmatic clinical trials that enroll a generalizable population from real-world settings and can leverage data from electronic health records.
9. **Whole person research.** NCCIH hopes to emphasize research on multimodal interventions that aim to improve health in multiple interconnected domains: social, psychological, and physical, including multiple organs and systems.
10. **Communications strategies and tools to enhance scientific literacy and understanding of clinical research.** NCCIH is at the crossroads between research and

real-world consumer use. Thus, NCCIH is focused on building understanding of the science of health for among those who use or provide complementary and integrative health approaches, many of which are readily available in the marketplace

Discussion: Responding to a question from Dr. Haney, NCCIH Branch Chief Dr. Wendy Weber provided information on the continuum between efficacy and effectiveness trials. Dr. Shurtleff commented that the pragmatic-explanatory continuum indicator summary (PRECIS) tool is helpful when characterizing NCCIH-supported studies on the pragmatic/explanatory continuum. Dr. Kligler recommended NCCIH be explicit, upfront, and committed about funding pragmatic trials. Dr. Weber said NCCIH has learned much about pragmatic trials, and they will be a part of the Center's new strategic plan.

Dr. Delitto said emphasis on pragmatic trials is critical, but he questioned how health systems could be encouraged to de-implement therapies that compete with nonpharmacologic interventions. Changing behavior is a tremendous challenge, and, in his view, education and financial incentives are not effective. He expressed a desire to see innovative ways for implementing nonpharmacologic approaches. Dr. Edwards commented that NCCIH has been thinking about the science of implementation and de-implementation. The Center is willing to support this research, although it may be controversial. Dr. Evans agreed that education is insufficient to change behavior. Behavior change among and between individuals needs to be examined, where there are multiple levels of behaviors to change. People's motivations should be investigated and NCCIH could advocate for examination of behavioral models across the system.

In response to a question from Dr. Anderson relating to the health research workforce, NCCIH program director Dr. Lanay Mudd said NCCIH is formalizing evaluation of efforts in this area in its strategic plan, as are many other ICOs. Dr. Anderson commented on motivating clinicians to use research evidence for their clinical practice. One effective approach for her has been to encourage acupuncturists to use scientific evidence to build their clinical practice.

Dr. Harris said it took 18 years before he was allowed to treat patients using acupuncture in his institution's hospital. The process takes time and continual pressure. Dr. Sherman said she has learned from the literature that implementation science is very heavy on theory. It appears one must often use a variety of different mechanisms—i.e., be multilevel and multimodal—to get people to change their behaviors and practices. She has usually seen from one or two to five mechanisms in the published studies. Researchers can put many components together and build a case, depending upon what will motivate people in a particular health care system. Dr. Delitto commented that more than time is needed. For example, telehealth was rapidly adopted and expanded, although other factors were involved. Even in an opioid epidemic, the use of nonpharmacologic approaches has not increased. A sense of urgency may be lacking.

Dr. Evans said that collecting contextual data is a very complex task but needs attention by investigators. When moving into dissemination and implementation research, NCCIH needs to ensure contextual data are collected. Dr. Kligler said that the Department of Veterans Affairs (VA) is very active in de-implementation in regard to opioid prescribing. This effort has driven a large-scale uptake of integrative approaches in the VA health care system. He suggested considering partnerships with the VA. Dr. Anderson commented that the financial aspect is very important; for example, the VA has its own financing system for health care. She said slow uptake, ignoring evidence, and associated issues are evident throughout the U.S. health care system. Dr. Langevin said she looks forward to partnering with the National Institute on Aging (NIA) on de-implementation work, including addressing the increasing problem of polypharmacy among older people.

V. NCCIH Enhancement of the Complementary and Integrative Health Research Workforce

Dr. Mudd, who oversees NCCIH's training and career development portfolio, presented an overview of the portfolio, discussed NCCIH's strategic plan objective on this topic, and proposed several workforce development priorities. NCCIH supports a range of research training and career development programs aimed at increasing the number and diversity of well-prepared, skilled investigators with knowledge and expertise in both complementary and integrative health and state-of-the-art research methods. Despite its size, NCCIH offers the same range of training activities offered by larger ICOs.

The following NCCIH FOAs are always available, and all use parent funding mechanisms:

- Individual training (F30, F31, and F32)
- Institutional training (T32 and T35)
- Career development (K01, K08, K23, K99/R00, and K24)
- Administrative Supplements to support diversity, re-entry into the research workforce, or research training/experience for clinician scientists with clinical complementary and integrative health degrees.

The Center also participates in specialized opportunities through various NIH-wide programs such as the NIH Blueprint for Neuroscience Research, the BRAIN Initiative, and NIH Loan Repayment Programs. Within the past year, NCCIH has also supported several diversity-focused programs. The Center spends about $9 million per year on training and career development, about 8.7 percent of its extramural budget, which compares favorably to other ICOs. From FY 2011 to 2019, NCCIH invested more in F, T, and K mechanisms than the NIH-wide average. Most of NCCIH's investment has been in K mechanisms. In its new strategic plan, NCCIH will continue to support enhancement of the complementary and integrative health research workforce and emphasize these three priorities:

Priority 1: Enhance diversity. Current activities include funding opportunities focused on enhancing diversity. Future FOAs could be used to enhance diversity, such as the parent T32 and

T35 programs and the parent R15. Other outreach efforts could include blog posts and NCCIH Training Roadshow presentations tailored to specific audiences. Dr. Mudd highlighted two summer programs (a T35 at the University of California, San Francisco, and an R25 at the University of Michigan) and the NIH Common Fund's FIRST program, which is a new opportunity. She encouraged institutions to apply.

Dr. Mudd presented data on the diversity of NCCIH-supported trainees, with a caveat that NIH does not routinely collect demographic information in applications. Twenty-five percent of trainees appointed to NCCIH-funded T mechanisms are from underrepresented racial/ethnic groups, and 21 Diversity Supplement awards were made to the Center's funded grantees from FY 2016 to 2020. The Center is considering incentives for existing training programs to recruit additional individuals from underrepresented groups.

Priority 2: Enhance clinician science pathways. NCCIH funds opportunities specific to clinician scientists, as well as other opportunities that could be used to support clinician scientist pathways. Dr. Mudd highlighted the Building Research Across Interdisciplinary Gaps training program, a T90/R90 partnership between the National University of Natural Medicine and the University of Washington, and two R15s at complementary and integrative health institutions.

Enhancing current efforts will include outreach activities to bring more attention to existing programs. NCCIH will connect with clinical complementary and integrative health institutions and encourage collaboration across existing training programs. The Center also wants to encourage interdisciplinary collaborations at the institutional level through partnerships between complementary and integrative institutions and research-intensive institutions. For example, NCCIH is considering creating a virtual resource center to provide networking, mentoring, conceptual grant development, institutional review board, and statistical support to investigators at complementary and integrative health institutions.

Priority 3: Enhance career transitions. The NCCIH Fellows and Trainees Workshop is held every other year for F- or T-funded predoctoral and postdoctoral trainees and their mentors. The workshop has not offered formal activities on K awardees' transitions to independence. Dr. Mudd presented data showing that NCCIH K awardees apply for subsequent NIH R01 awards at high rates but do not have as much success as the NIH average. She suggested (1) updating the workshop and roadshow to include material on career transitions, (2) developing a specific virtual workshop/lecture series for K awardees focused on transitioning to independence, and (3) providing more programmatic feedback for resubmission applications. NCCIH is also considering developing new initiatives solely for K awardees to help them create secondary lines of research independent from their mentored research.

Dr. Mudd noted NCCIH has a strong investment in training and career development and that regular evaluation is planned for continual improvement.

Discussion: Dr. Sherman said that a major challenge appears to be less overall NCCIH funding to help investigators make progress in their careers, when compared with other ICOs. She said an analysis of this could inform future efforts. Dr. Mudd said almost 80 percent of the Center's K awardees are involved in clinical research, and she will look into those data in more detail. Dr. Hensel expressed concern that she did not see any data that specified awardees with doctorates in osteopathic medicine. Dr. Mudd said she would check if the M.D. category included people with D.O. degrees. Dr. Hensel said these categories should not be combined. Dr. Langevin commented that this conversation has come up at various NACCIH meetings, and she would like more clarity in this area. She said NCCIH will pay more attention to how people with D.O. degrees are classified and how that community wants to be classified.

In response to questions from Dr. Shinto, Dr. Mudd said NCCIH had previously investigated whether complementary and integrative practitioners were being funded at the same levels as other practitioners, and she recalled that the award percentages were not drastically different, although the application rates differed. Dr. Edwards commented that overall, clinical research grants are not doing as well as basic science grants going from K99 to R00 awards; NCCIH should look at this more closely. Drs. Shurtleff and Langevin also supported this point. It may take time to develop, but if the Center nurtures cross-ICO partnerships, more clinicians may want to do translational research that could be more amenable to a K99 award.

Dr. Shinto said she would like the cross-pollination, such as with the National University of Natural Medicine and the University of Washington, to continue. Dr. Jean-Louis asked about tracking T and F award applicants who did not get funded and comparing success rates and career trajectories with people who were funded. Dr. Mudd said the NIH Office of the Director (OD) has done such analyses NIH-wide and found a strong benefit, for example, of a K award on subsequent success rates. However, this type of analysis would be more difficult for NCCIH because of its smaller size. Dr. Jean-Louis asked Dr. Mudd for data on the rates of underrepresented minorities who applied and were funded. Dr. Mudd said that information is very difficult to obtain because NIH does not collect data on characteristics of applicants. However, data for specific diversity-focused funding opportunities can be examined.

Dr. Anderson asked whether NCCIH is involved in the Support of Competitive Research (SCORE) program. Dr. Mudd said SCORE was a great program led by the National Institute of General Medical Sciences (NIGMS). However, it is being discontinued. Dr. Born asked about opportunities to assign researchers to clinical situations, as she has data and would like to do a pragmatic project. Dr. Mudd said this idea could be proposed as part of a career development award. Dr. Evans suggested working on expanding awareness among complementary and integrative practitioners so they know their options. She encouraged introducing research training earlier in the career paths at institutions. Regarding movement from K to R awards, she said clinical research takes a long time. If NCCIH is moving into dissemination/implementation research, it needs to find good strategies for training people, and she advocated funding a

secondary line of research. She suggested that NCCIH could capitalize on KL2 training programs and focus more on mentor training, which often is a gap.

In response to questions from Dr. Delitto, Dr. Mudd said one of NCCIH's priorities is to ensure its training is well-balanced across topics and across both basic and clinical science. NCCIH supports eight T32 programs across the United States that have a good balance between natural products and mind and body approaches and between basic and clinical science. NCCIH's Fellows and Trainees Workshops bring these scientists together, and more collaboration is happening. NCCIH has supported combined master's and doctoral degree programs in the past as part of a fellowship or training program. Dr. Delitto commented on a doctoral-level entry program for D.C. degrees beginning at his school and recommended organizing and orchestrating such training from the beginning. Dr. Yeh commented that success seems to consist of gaining subsequent NIH funding—an important benchmark—but other measures could give a more holistic view of success, such as funding through external sources or publication paths. Dr. Mudd agreed there are many other metrics that could be considered.

VI. Bioengineering for COVID-19: Rapid Acceleration of Diagnostics

Dr. Bruce Tromberg, Director of NIH's National Institute of Biomedical Imaging and Bioengineering (NIBIB), the hub at NIH for expanding technologies across diseases and disorders, explained that NIBIB's current work includes overseeing the Rapid Acceleration of Diagnostic Technologies (RADx Tech) program, a $500 million effort to significantly increase testing performance, capacity, and accessibility for SARS-CoV-2. NIBIB has many common interests with NCCIH, such as integration of technologies and thinking about biological systems with an engineering approach.

Dr. Tromberg said that a fundamental and unifying belief at NIBIB and across the bioengineering community is the pursuit of computational or mathematical representation of biological processes and systems. Major areas of NIBIB activities are therapeutic devices, engineered biology, imaging technologies, and sensors and point-of-care technologies. The core of NIBIB's work is modeling, computation, and machine intelligence. NIBIB received resources in 2020 that allowed it to drive three COVID-19 initiatives: imaging and artificial intelligence, digital health platforms (e.g., wearables and digital contact tracing), and *in vitro* diagnostic testing technologies.

NIBIB has worked for several years to establish consortia to build databases and repositories and to extract quantitative, reproducible information from images, as well as use algorithms and machine learning/artificial intelligence to validate that information. COVID-19 brought an opportunity to focus on thoracic imaging to gain new prognostic and diagnostic insights. The University of Chicago–led Medical Imaging and Data Resource Center has brought together three professional societies and 23 academic institutions to develop a curated COVID-19 database of chest radiographs and data from computerized tomography scans and clinical trials.

Algorithms will be developed and validated within this network and hopefully approved and cleared by the U.S. Food and Drug Administration (FDA) for dissemination and use worldwide.

For its digital health platform initiative, NIBIB has worked in four major areas: technologies for monitoring and detection, digital contact tracing, integration of platforms with test results, and provision of proof-of-health status. In this pandemic, people need more guidance in real time, and NIBIB is working with app developers help integrate public health guidance into computational models.

NIBIB is on the board for all the RADx programs but focuses on RADx Tech, which emphasizes point-of-care and innovative diagnostics, and the RADx Advanced Technology Platforms (RADx-ATP), which are scaling up existing technologies into manufacturing expansion.

Within 5 days of a $1.5 billion appropriation by Congress to the NIH OD on April 24, 2020, NIH launched an initiative to speed innovation, development, and commercialization of COVID-19 testing technologies at the point of care and in homes. NIBIB rapidly created partnerships across the Government, principally with the Biomedical Advanced Research and Development Authority in HHS, from which NIBIB would also receive another $307 million in funding. The overarching goals have been to expand the number, types, and accessibility of COVID-19 testing technologies and to optimize their performance (e.g., of technological and operational features to better match them to the many different community needs). NIBIB has contributed to the increase in testing from about 250,000 tests per day at the launch of RADx to about 2 million tests per day by January 2021. This testing does not include the millions of rapid antigen tests that have not been collected and followed.

RADx enabled NIBIB to expand its Point-of-Care Technologies Research Network (POCTRN), established several years ago. The network uses a flexible, rapid process to conduct reviews, provide funding, and enhance technology designs at key stages of development. The POCTRN architecture has allowed rapid review and brought a flexible funding mechanism as well as expertise in the evaluation, testing, and validation of technologies. NIBIB's "structures within the structure" allowed for the creation of very large contracts and quick dissemination of funds.

The center of the NIBIB structure is the RADxTech/ATP innovation funnel, which is operated similarly to a venture fund. Dr. Tromberg described current projects and said more projects are in the pipeline. NIBIB has also provided smaller funding amounts to about 50 promising early-stage projects through NIH's Small Business Education and Entrepreneurial Development, a proof-of-concept network within the NIH OD.

NIBIB's work has been very focused on point-of-care technologies and making them accessible, but there are differences in cost and speed between point-of-care nucleic acid tests and viral antigen tests. NIBIB has sought to close this gap by investigating pooling the tests from a social pod. Dr. Tromberg also described challenges, such as enabling tests to be put into a cell phone

reader, creating within-app symptom surveys, developing instructions, creating imaging to facilitate reading and interpretation, and maintaining the security of connection regarding proof-of-health status.

For RADx Tech and RADx-ATP, implementation has been a major problem. Millions of tests per day for home use are coming, and optimizing that use pathway is critical. Effective economic, regulatory, and reporting structures to support the entire screening and surveillance enterprise have not been established. Digital health platforms will be expanded. In addition to the pooling concept, a new class of technologies is being developed that is not based on previous testing platforms, which will help bridge a performance gap. NIBIB is very engaged in supporting partnerships with clinical studies to gain better guidance on how to use tests.

Dr. Tromberg noted NIBIB is a relatively small Institute, but it has spent about $1 billion in less than a year. This has remarkably expanded NIBIB's visibility and responsibility. Fortunately, the path has aligned well with the Institute's vision and mission, helped galvanize their community, and linked NIBIB with many more communities.

Discussion: Dr. Langevin described this work as very exciting and said NCCIH will have to think about technology development. Dr. Tromberg said he would be happy to disseminate NIBIB's model and technology. He responded to a question from Dr. Delitto by saying that in the past year NIBIB has called out to the entrepreneurial and innovation community on a scale that would not have been possible 5 years ago. There are now about 140 bioengineering departments across the country; many are engaged in innovation and development activities with companies and responded to NIBIB's call. Dr. Sonnenburg asked whether NIBIB had any lessons learned to offer from the past year, including how to be more nimble, be ready for the next pandemic, and accelerate the NIH pace toward discovery. Dr. Tromberg said these questions are being asked across the NIH leadership. At NIBIB, structures were used to expand a system and build in efficiency. By adding nonprofit organizations to supplement both the network and contracts, funds were obtained and awarded quickly through subcontracts. NIBIB also benefited from the Government's COVID-19 contracting guidelines. Elements from the experience can be recapitulated, even in the basic science arena. Dr. Tromberg also suggested having a low barrier to access and assembling a group of true experts around a concept to hone it.

VII. Concept Clearance: NIH Health Care Systems Research Collaboratory

Dr. Weber, Chief of the Clinical Research in Complementary and Integrative Health Branch, DER, presented a concept for a trans-NIH initiative to continue the NIH Health Care Systems Research Collaboratory program and its leadership. Currently, Dr. Langevin and Dr. Richard Hodes, Director of NIA, lead the program.

The goal of the Collaboratory program is to strengthen the national capacity to implement cost-effective large-scale research studies that engage health care delivery organizations and patients

as research partners. The program established a coordinating center in 2012 that provides national leadership and technical expertise. The Collaboratory was initially supported by the NIH Common Fund. In 2017, it transitioned to cofunded support for the coordinating center from the Common Fund and participating ICOs, and to funding from participating ICOs for the trials and implementation science studies.

The overall aim of the Collaboratory program is to provide a framework of implementation methods and best practices that will enable many health care systems to participate in pragmatic research. Research conducted in partnership with health care systems is essential to strengthen the relevance of research results to real-world health care practice. Successful approaches and best practices established through this initiative should have a major impact on clinical research in the United States. The Collaboratory is also well-suited for testing how readily practice guidelines can be implemented in health care systems and for assessing outcomes of implementation across a broad range of patient subgroups. Since 2012, 21 trials have been supported through the Collaboratory program, involving the Common Fund and 15 NIH partners. These trials have been conducted across the United States at more than 850 clinical sites of 20 health care systems, with more than 800,000 participants.

The purpose of the present concept is to support the continuation of the Collaboratory for an additional 6 years. An initiative would provide continued support of the coordinating center through a limited-competition FOA and a set of pragmatic trials or implementation science research studies conducted in partnership with at least three health care delivery systems. Projects and the coordinating center will ultimately make the data, tools, resources, and lessons learned available to facilitate a broadened base of research partnerships with health care systems.

Continued support of the Collaboratory would offer benefits to NCCIH, such as encouraging studies of how to integrate effective complementary health approaches into care delivery models, multimodal interventions, and potentially, whole person health outcomes. The Collaboratory also would create an excellent learning opportunity for trainees and new grantees to transition to this type of research. The Collaboratory has served as a model for other initiatives and programs, such as the NIH–Department of Defense–VA Pain Management Collaboratory.

Dr. Weber recommended that interested viewers visit the Collaboratory's webpage "Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials" (https://rethinkingclinicaltrials.org), which contains extensive information in the form of publications, videos, tools, white papers, and guidelines, in addition to information on all the funded trials and the coordinating center.

Discussion: Dr. Coghill inquired about overlap with the Patient-Centered Outcomes Research Institute (PCORI). Dr. Weber said PCORI is another source of funding, and the Collaboratory always checks to avoid overlap with PCORI. In response to a question from Dr. Anderson, Dr. Weber said each ICO will be able to include its own areas of interest. For NCCIH, the area of

interest will reflect its strategic plan, for example, whole person health and multimodal interventions. Dr. Anderson said choosing appropriate outcome measures will be a challenge. Dr. Weber said most trials allow patient-reported outcomes to supplement electronic health records.

The concept was cleared unanimously.

VIII. Public Comment

Dr. Khalsa noted that because this meeting was entirely virtual, the public could submit comments to him by email (partap.khalsa@nih.gov) or hard-copy letter; his contact information is on the NCCIH website. Comments may be up to 700 words, which is considered roughly equivalent to a 5-minute oral comment. One public comment has been received as of January 29, 2021.

From: mescoach@aol.com <mescoach@aol.com>
Sent: Friday, January 29, 2021 2:37 PM
To: Khalsa, Partap (NIH/NCCIH) [E] <khalsap@mail.nih.gov>
Subject: Advisory Panel Meeting (Public Comment)

Nursing works collaboratively with the public, organizations and governments on all areas of healthcare. They are deeply involved in the caring of the whole person. The State of the World's Nursing 2020 Report (WHO,2020) urges relevant stakeholders to strengthen nursing leadership to ensure nurses continue to play an influential role in decision making in order to contribute to health and health care systems.

There is widespread recognition among the public of nursing supporting complementary and integrative models of care. More specifically, academic nursing programs across the country are adopting curriculum to include coursework on holistic nursing. Despite this recognition, there has been little financial support to further ensure that nurses and nursing validate interventions and direct research agendas on integrative care. Maximizing the historical underpinnings of nursing, strongly points to nursing as the leader in integrative care. Their sphere of influence is global, as evidenced in particular during the COVID-19 pandemic. Competencies which lead to health protection, support nurse coaching as well as integrative modalities. Improving practice at point of care and informing policy are influenced by scientific research that begin with retention and recruitment of registered nurses for all sectors of healthcare. Strategies to develop nurse leaders and faculty researchers through NCCIH funding provide a systematic way of analyzing the contributions of nurses in this field of endeavor. Potential areas of research using the American Holistic Nursing Association Scope and Standards of Practice will allow further inquiry, diversity of perspectives and a more united collective voice for the ongoing contribution of integrative care.

In designating 2020 as the Year of the Nurse and the Midwife, WHO recognized the vital role of nurses and midwives in contributing to universal health coverage and called for increased investment in the nursing and midwifery workforce to achieve the United Nations (2015)

Sustainable Development Goals. The need to think global and act local continues in 2021 and a strong research agenda will be required to track nursing's contribution to these goals.

Respectfully submitted,

Dr. Mary Elaine Southard, DNP, RN, APHN-BC-HWNC-BC
Integrative Care Consulting and Coaching, LLC
Scranton, PA

IX. Adjournment

Dr. Langevin thanked all who were present and noted that NCCIH reads and evaluates all suggestions and comments. The meeting was adjourned at 4:05 p.m.

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

4/13/2021

X Partap S. Khalsa

Signed by: Partap S. Khalsa -A

Helene Langevin -S

Digitally signed by Helene Langevin -S
Date: 2021.04.15 16:21:09 -04'00'

Partap S. Khalsa, D.C., Ph.D., D.A.B.C.O.
Executive Secretary
National Advisory Council for Complementary and Integrative Health

Helene Langevin, M.D.
Chairperson
National Advisory Council for Complementary and Integrative Health