

**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 SIXTY-NINTH MEETING
February 8, 2019**

NACCIH Members Present

Dr. Belinda Anderson, New York, NY¹
Dr. Lynn DeBar, Seattle, WA¹
Dr. Roni Evans, Minneapolis, MN
Dr. Diana Fishbein, University Park, PA
Dr. Steven George, Durham, NC
Dr. Joel Greenspan, Baltimore, MD
Dr. Richard Harris, Ann Arbor, MI
Dr. Bin He, Pittsburgh, PA¹
Dr. Kendi Hensel, Fort Worth, TX
Dr. Patricia Herman, Santa Monica, CA
Dr. Susmita Kashikar-Zuck, Cincinnati, OH
Dr. Jean King, Worcester, MA
Dr. John MacMillan, Santa Cruz, CA
Dr. Cynthia Price, Seattle, WA¹
Dr. Eric Schoomaker, Bethesda, MD
Dr. Justin Sonnenburg, Stanford, CA¹
Dr. Barbara Timmermann, Lawrence, KS
Dr. Gloria Yeh, Boston, MA

¹By Telephone/Video-conference

NACCIH Members Not Attending

Dr. Tracy Gaudet, Washington, DC

Speakers

Dr. Rosalind King, Bethesda, MD
Dr. Lisbeth Nielsen, Bethesda, MD
Dr. Eve Reider, Bethesda, MD
Dr. Wendy Smith, Bethesda, MD

Federal Staff Present

Olga Brazhnik, NCATS, NIH

Members of the Public

Dawn Langley Brady

Mindie Flamholz

Pat Kobor

Sarah Scruggs

Richard Zarrella

I. Closed Session

The first portion of the sixty-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 139 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 61 scored applications, which requested \$21,030,395 in total costs.

II. Call to Order and Annual Review of Operating Procedures

The open session was convened at 10:00 a.m. by Dr. Partap Khalsa, NACCIH Executive Secretary. The minutes of the October 2018 Council meeting were approved unanimously. Dr. Khalsa presented the annual review of Council operating procedures, which include NCCIH reports to Council, secondary review of grant applications, concepts for research initiatives, appeals, and Council's role in policy and research priorities. Council approved the operating procedures unanimously.

III. NCCIH Director's Report

NCCIH Director Dr. Helene Langevin delivered her inaugural report. She praised Center staff for their helpfulness during her transition and Dr. David Shurtleff and Dr. Wendy Weber for their leadership as Acting Director and Acting Deputy Director, respectively, during the year following Director Emeritus Dr. Josephine Briggs's departure. Dr. Langevin described the state of the Center as strong. She welcomed new Council members Drs. Evans, Fishbein, Harris, Hensel, and Sonnenburg. Among new NCCIH staff are Program Director Dr. Della Brown White and Scientific Review Officer Dr. Jessica McKlveen, and staff departures include Drs. Linda Duffy and Slava Soldatenkov who are retiring, and Dr. Mark Pitcher who has moved to the University of Bridgeport.

In legislative news, most of NIH, including NCCIH, was funded and remained in operation during the recent partial Federal Government shutdown. NCCIH received its 2019 appropriation on time this year, which has been very helpful for planning. NIH has submitted its Fiscal Year (FY) 2020 congressional justification for clearance and awaits the President's budget. The Agriculture Improvement Act of 2018 (P.L. 115-334, known as "the Farm Bill") removes hemp-derived products from Schedule I. There are many legislative details to be worked out, but this change holds promise for future research on cannabinoids.

Dr. Langevin reviewed NCCIH's budget mechanism table. The Center received a budget increase from FY 2018 to 2019, resulting in an increase in the amount spent on research project grants and total research grants. Because the Center is small, cofunding and vibrant exchange with collaborators are critical to expanding reach, and staff work to develop collaborative relationships.

Several examples of impactful NCCIH-sponsored research results were presented, including studies of the PIEZO2 gene's mediation of light touch sensation in mice and humans; neuroprotection from two components of coffee in models of Parkinson's disease and dementia with Lewy bodies; massage for knee osteoarthritis; and findings from the 2017 National Health Interview Survey on the use of yoga and meditation by U.S. adults.

NCCIH is an active participant in a large-scale, trans-NIH initiative, Helping to End Addiction Long-term (HEAL). The Center is working hard to identify and fund research on its own and with partners on nonpharmacologic approaches to address opioid misuse and/or pain. The Center is well positioned to develop related initiatives because these have been priority areas in its Divisions of Extramural Research (DER) and Intramural Research, especially with regard to pain. The Center has three current HEAL-related Requests for Applications (RFAs), AT-19-004, -005, and -006. A congressional bill (H.R. 6) intended to help fight the opioid epidemic includes language referring to approaches studied by NCCIH.

NCCIH is also committed to furthering research into how listening, performing, and creating music could enhance wellness and serve as a therapy for neurological disorders. The current funding opportunity announcements (FOAs) on music and health, NS-19-008, NS-19-009, and AT-19-001, are part of the Sound Health initiative, a partnership between NIH and the John F. Kennedy Center for the Performing Arts.

The 2018 Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies was given by Dr. Tracy Gaudet, executive director of the Office of Patient Centered Care and Cultural Transformation at the U.S. Department of Veterans Affairs and a member of Council. A symposium on advancing research on natural products as treatments for pain took place at NIH on February 6. It was cosponsored by NCCIH, the National Institute on Neurological Disorders and Stroke, and the National Center for Advancing Translational Sciences (NCATS).

“Translating Fundamental Science of Acupuncture into Clinical Practice—for Cancer Symptom Management, Pain, and Substance Abuse” will be the topic of a workshop co-organized and -sponsored by NCCIH and the National Cancer Institute. The DER has been holding a series of technical assistance webinars for potential grant applicants. The Center’s Integrative Medicine Research Lecture Series in spring 2019 features three lectures on the theme “Microbes in Our Gut: Emerging Insights on Health and Disease.” On September 23, 2019, NCCIH will celebrate its 20th anniversary with a symposium featuring the 2019 Stephen E. Straus Lecture, to be presented by Dr. Lorimer Moseley, professor of clinical neurosciences and Foundation Chair in Physiotherapy at the University of South Australia. The day will also feature presentations and posters by NCCIH-supported extramural and intramural investigators.

Dr. Langevin offered some reflections on her vision for NCCIH and referenced the remarks her predecessor, Dr. Josephine Briggs, had offered at the October 2017 NACCIH meeting. Dr. Langevin shared a quote from a *New York Times* article by David Brooks, “At the Edge of Inside.” The quote briefly, stated that people on the “edge of inside,” i.e., who within their group or organization “work at the boundaries, bridges, and entranceways,” have some distinct advantages. She applied this idea to NCCIH as a change agent within NIH, a role that carries certain strengths and responsibilities. NCCIH can and should be bold and take risks, as by supporting investigation of treatments and ideas that are bold and unconventional while upholding scientific integrity.

In addition, NCCIH should be integrative. That integration has multiple dimensions, including across:

- Conventional and complementary therapeutic modalities (a part of this dimension is to address the whole person)
- The health and disease spectrum
- The lifespan.

Some of these themes appear in NCCIH’s current strategic plan. In describing how they relate to one another, Dr. Langevin began with the dominant model in medicine—an organ-specific disease model that has its origins in the 19th century and works very well for certain conditions such as infections. “Health,” however, is understood very differently and can be thought about both specifically, e.g., heart health, and more holistically. The term “biopsychosocial” is often used in talking about a whole-person approach to health. The “disease” and “health” models do not talk to each other well. In addition, Dr. Langevin proposed that a piece has been missing between them: “unhealth,” which may be defined as “lack of health or vigor.” She used a metaphor of a plant in the states of health, unhealth, and disease. The transition back and forth between health and unhealth may be dynamic and reversible but the transition to disease less so.

The medical model is focused on controlling and eradicating disease, and we are very good at this. “Disease prevention” and “health promotion” inhabit a much broader space and spectrum. The preventive spectrum is divided into primary, secondary, and tertiary prevention, and Dr. Langevin

described each. She emphasized that not enough attention is paid to health restoration and recovery, perhaps because of the availability of powerful drugs. In the historical literature prior to discovery of antibiotics, one sees more attention paid, for example, to a convalescent period after illness, including attention to diet and the pace of resuming physical activity, so that full health may be regained and relapses avoided. Overall, we need more attention now on return to health, in clinical practice and in research.

These questions are important for NCCIH because complementary and integrative health care inhabits the spectrum of health, unhealth, and disease. Its modalities are important not only for symptom management but also disease prevention and health restoration. NCCIH has room to do more research in the latter two areas. Unlike plants, people can modify their own behavior to become healthier in mind and body, but research in this area lags far behind that in disease.

Dr. Langevin closed by stating that she sees great potential for integrating research on whole-person health across NIH. Health promotion and disease prevention are front and center in the NIH strategic plan. One important way that NCCIH could be a positive change agent within NIH is to work with the other institutes and centers (ICs) in integrating research efforts on health—a theme reflected in this Council meeting’s symposium on well-being.

Discussion. Dr. Eric Schoomaker expressed support for Dr. Langevin’s vision and talked about people’s inherent capacities to heal (which we have not tapped into enough) and to grow through exposure to adversity and unhealth. Students learn in medical school to be oriented to pathology, not health. Dr. Langevin agreed, adding that even prevention efforts point toward disease. Restorative mechanisms exist but have not been studied as much. We should not be limited to “what could go wrong?” but also study “what could go better?”

Dr. Jean King commented that we don’t talk enough about the success stories—are there ways we could improve health behaviorally to be able to talk about resilience? Dr. Langevin mentioned “spontaneous remission” and commented that healing must take place for this to happen—what is that healing, and what did the person do to make it happen? Dr. George asked whether Dr. Langevin could anticipate how study designs might change to capture the kind of complexity she described. Dr. Langevin said that one can have complexity in either direction. Disease and health are complex, and with the right measures one can probably look at restorative mechanisms, e.g., in resolution of inflammation.

IV. NCCIH Triennial Report on Human Subjects in Clinical Trials

Dr. Catherine Meyers, Director of the Office of Clinical and Regulatory Affairs at NCCIH, presented her report on the Center’s compliance with NIH policy on inclusion guidelines. Dr. Meyers opened with a history of women and minorities in NIH-funded clinical research. NIH established a policy in 1986 for inclusion of women in clinical research, which was made into law in the NIH Revitalization Act of 1993. The goal of that policy is not to satisfy quotas for proportional representation based upon census

data but to conduct research so that findings will be generalizable to the U.S. population. The number of women, men, and representatives of racial/ethnic subpopulations included in a study depends on (1) the scientific question addressed in the study and (2) the prevalence among subpopulations of the condition under investigation. Data are reported by investigators in their annual progress reports. Following the 21st Century Cures Act (2106), NIH reporting requirements changed. Dr. Meyers discussed the three major requirements: to report (1) on a triennial basis rather than the prior biennial basis; (2) by relevant age categories (also called “inclusion across the lifespan” at NIH, and there has been a revision of the inclusion of children policy); and (3) with data disaggregated by research area, condition, and disease categories.

Dr. Meyers presented tables of data from FYs 2016 to 2018 (with some earlier data back to 2010) on all clinical research and Phase III trials for the Center, including with respect to inclusion of women and minorities. In the past several years, the Center has not supported many Phase III trials, as much of the portfolio has been more focused on earlier phase evidence generation on interventions. Participation of women has stayed about the same, at about 50 percent or more. Enrollment of minority participants has markedly increased compared, e.g., with the years 2010 to 2014, but some earlier large-scale studies were conducted in settings that did not collect data on participant race/ethnicity. NIH is paying attention to this factor, and Dr. Meyers noted that the number of “unknowns” has been dropping.

NIH’s approach for reporting categories of age and research area, condition, and disease were described as works in progress. For research area, condition, and disease, the existing system is the Research, Condition, and Disease Categorization (RCDC) process. NIH is working on how to provide this information to Congress and the public going forward. Maintaining patient confidentiality is a consideration as some of the numbers in categories are very small. A trans-NIH group is working on the details of the age categories.

Discussion. Dr. Kashikar-Zuck, who works with children and adolescents, asked whether NIH will update the inclusion table soon. Dr. Meyers replied that the format for that information is an active topic for the workgroup. The tables will have more complexity to include lifespan, and there is interest across the Government in harmonizing the way agencies and their components collect and present it. Overall, NIH is aware of the problems that investigators are having with these forms, and Dr. Meyers expects a wave of revision.

Dr. Meyers’s report was unanimously certified by Council.

V. Concept Clearance: Interdisciplinary Training Programs for Complementary and Integrative Health

NCCIH Program Director Dr. Lanay Mudd presented this concept. Training and career development for professionals in complementary and integrative health research is included in the current NCCIH

strategic plan. In 2015, Council formed a working group that produced a report, including recommendations, on development of the clinician-scientist workforce (<https://nccih.nih.gov/sites/nccam.nih.gov/files/Workforce-Development-Working-Group-Report.pdf>).

The concept's goal is to support partnerships at an institutional level for an interdisciplinary training program, in the process specifically addressing the working group's recommendations. Ultimately, NCCIH hopes to increase the number and quality of clinicians trained to conduct rigorous research in the Center's priority topic areas. Clinical research is becoming a team activity, and thus multiple disciplines need to be represented on teams and multiple types of mentors offered. Under an initiative, there could be programs that include both research-intensive institutions and other institutions focused on clinical training of complementary and integrative health practitioners and that offer multidisciplinary mentorship.

The concept would support existing efforts as well as allow development and use of new avenues. NCCIH has supported interdisciplinary programs in various ways over the years, such as the U19 and R25 programs, but these were not specifically focused on training clinician-scientists. More recently the Center has added T90s/R90s and a supplement program to some KL2s from NCATS, but those programs are young and their success not fully known as yet. NCCIH may need to add other options.

Discussion: Dr. Greenspan asked whether this concept is a “reboot,” and Dr. Mudd replied that it would help NCCIH continue to support pathways such as the R90/T90 while also allowing it to consider new pathways to improve the pipeline. To a question about whether there has been input from institutions, Dr. Mudd said she has done much outreach on the Center's current training programs at institutions, studied what has worked or not worked, talked with Council member Dr. Yeh, and been contacted by the community. She has found that the interest exists to support this type of training, and one way of training may not suit everyone.

Dr. Yeh suggested that this concept would potentially allow use of several different mechanisms, e.g., additional slots or spots that could be appended to existing T32 programs. Dr. Schoemaker suggested that the term “transdisciplinary” would better capture what this concept aims at, vs. “multidisciplinary” or “interdisciplinary,” and Dr. Mudd said she would consider which term(s) are used going forward. Dr. Price asked whether Dr. Mudd had any evaluation data on trainees' perceptions of utility of such programs and mentioned the T90 program at the University of Washington and the National University of Natural Medicine. Dr. Mudd said it could be an option to continue support under that initiative, but the first 5 years of any training program are difficult; four trainees in the program have finished it to date, and they are all involved in research now, which is a strong early showing. However, there are 10 more trainees who have not finished the program yet. Dr. Mudd offered to follow up more with Dr. Price if desired.

In response to a question from Dr. George on eligibility, Dr. Mudd said she had been thinking of institutions mainly focused on clinician training in complementary and integrative health. In response to questions from Dr. Fishbein, Dr. Mudd provided a more detailed look at the concept's goal and what the process and results would look like. Dr. Fishbein added a hope there would be work in concert to establish awareness of complementary practices as evidence based, so that clinicians can understand the need for rigorous research. Dr. Langevin described Dr. Mudd's concept as "almost a little laboratory" NCCIH would like to create for exploring, trying different approaches, and seeing what works best. She described the endeavor of creating clinician-scientists in this field as very challenging.

Dr. Wendy Weber, Chief of the Clinical Research in Complementary and Integrative Health Branch in DER, clarified that this concept's purpose is to fund research and the training of researchers, not clinical training. It should also be kept in mind that NCCIH is part of NIH, and the concept's goals will be to build the pipeline of people able to do this research, compete for active grants, and expand the evidence base. Dr. David Shurtleff, Deputy Director of NCCIH, said that NCCIH should have its options open on ways to accomplish the goals and should receive input from Council as representatives of the community. Research will drive the practice and rigor of what NCCIH does. Dr. J. King said that in her long experience training clinician-scientists, she has seen a need for developing cohorts so that trainees can share challenges, start research projects together, etc. Dr. Mudd agreed and noted that NCCIH held its first workshop for trainees and fellows 2 years ago, with the second one coming in fall 2019.

Dr. MacMillan asked whether botanical/natural product scientists could be eligible for the future opportunities, and Dr. Mudd responded that while the concept was originally conceived as training for people with clinical degrees, NCCIH could consider this. Dr. Langevin mentioned that at NCCIH's natural products workshop two days before, an expressed need was to pair up people who have knowledge of complementary and integrative health systems, herbal medicine, etc., with natural product chemists. Dr. Price encouraged funding T32 grants, as she found her T32 very helpful. Dr. Yeh also commented positively on T32s and noted there are multiple pathways to success.

Several members offered additional comments on being, teaching, and/or working with clinician-scientists—for example, having to see patients less or not at all is often part of the equation, and while wearing so many hats on the job is difficult, valuable research ideas can emerge from it. Dr. Khalsa noted that developing clinician-scientists has been of interest and concern to NIH; in related reports, there has been a consistent theme of multiple pathways to get there and multiple models of success. Dr. Langevin noted a need for mentors and role models to help people learn and do the job.

The concept was passed unanimously.

VI. Symposium: NIH Research on Well-Being

Dr. Emmeline Edwards, Director of the DER, opened the afternoon session by explaining that NCCIH has been developing an initiative on emotional well-being. This fits with several of the Center's priority

areas: self-care, promotion of healthy behaviors, and healthy lifestyle. Representatives of other ICs that have been working with NCCIH are the invited speakers.

Office of Behavioral and Social Sciences Research (OBSSR), NIH

Dr. Wendy Smith, Associate Director of OBSSR, described OBSSR's mission and its role as an Office within the NIH Office of the Director. OBSSR seeks ways to stimulate its mission and support its IC partners, often takes a 20,000-foot view, and covers broad content areas. Dr. Smith briefly discussed *U.S. Health in International Perspective: Shorter Lives, Poorer Health*, a 2013 report from the Institute of Medicine (now National Academy of Medicine) co-commissioned by OBSSR and illustrating the latter's strong interest in enhancing health.

In one of her publications, Dr. Smith defined "health" as the state of the physical being (one's body and how it functions) and "wellness" as one's perception of that state (i.e., one's experience of it). She suggested adding "thriving" to Dr. Langevin's trio of health, unhealth, and disease. OBSSR has studied "blue zones": pockets of people who live especially long lives and have very limited disease. The National Geographic Society has done key research in this area. Dr. Smith offered examples of these healthy groups in Greece, Costa Rica, Japan, Italy, and California (Loma Linda). What contributes to their health and wellness? Some common themes are purposeful physical activity; purpose (a reason to live); stress relievers built into each day (such as a nap or a social hour); diet, including the context in which one eats; social connections; sleep; sun; and a sense of humor. OBSSR is trying to drill down to factors that (alone or in combination) could be modifiable and applied to the broader United States over the lifespan. All the variables involved are complex. Part of the landscape consists of studies that have been going on for years or decades.

OBSSR also considers how it can stimulate and support work in this topic area across NIH. Sample questions include: What topics are "pop flies"? How can various NIH perspectives be integrated? What are some major public health crises where the Office could contribute? Dr. Smith described her Office's participation and/or leadership in activities related to the NIH response to the opioid crisis. OBSSR is beginning to explore some public-private partnerships.

National Institute on Aging (NIA), NIH

Lisbeth Nielsen, Ph.D., Chief of the Individual Behavioral Processes Branch, presented on subjective well-being (SWB) research at NIA. Well-being is central to the NIA mission and is highlighted in its strategic plan. What is SWB? The definition she offered is "how people experience and evaluate their lives and specific activities and domains in their lives" (National Research Council, 2013). Three broad domains of well-being have been widely accepted in the literature: experienced well-being (in-the-moment states), evaluative well-being (global judgments of how life is going), and eudaimonic well-

being (involved with ideas of meaning, purpose, and personal growth). Dr. Nielsen also provided examples of methods and approaches for capturing these SWB components:

- Experienced well-being: in survey research, daily diary methods such as those used in the Midlife in the United States (MIDUS) Study, and the Day Reconstruction Method, used in several large national surveys such as the Health and Retirement Study (HRS)
- Evaluative well-being: single item measures, as used in the HRS; the 5-item Satisfaction With Life Scale; and Cantril's Self-Anchoring Ladder
- Eudaimonic well-being: the Control, Autonomy, Self-realization, and Pleasure Scale (CASP-19) and the Ryff Measure of Psychological Well-Being.

Regarding the utility of employing these kinds of measures, Dr. Nielsen noted that (1) if we do not measure well-being, we do not know whether we are improving it; (2) the measures have a relation to distinct but integrated goals in psychology and economics; and (3) in the context of biomedical studies of aging, well-being is of interest both for its causal role and as an end in itself. She gave examples of NIA's investments in this topic area such as the Edward R. Roybal Centers for Translation Research in the Behavioral and Social Sciences of Aging, and an FOA in 2011 that NIA and NCCIH cofunded, RFA-AG-11-003. NIA has been interested in building data resources for the research community, as through its support of large U.S. and international surveys and guidelines. One topic that has been little studied is cultural differences in how people value the same sorts of experiences.

Dr. Nielsen gave examples of NIA-funded study results. On recent areas of interest, she referred to summaries of several NIA-supported meetings: a "Workshop on Positive Psychobiology" in March 2013; a "Subjective Well-Being Measures in Interventional and Observational Studies in Older Individuals" workshop in March 2015; and a meeting on "Developments in the Day Reconstruction Method and Related Methods" in January 2015.

Discussion. In response to a question from Dr. Khalsa, Dr. Nielsen explained that there is also "objective well-being" (which been discussed, e.g., by the Sarcozy Commission and some large United Nations panels). Ways to measure it include objective measures of health, life circumstances, and community features. Dr. Edwards asked how to differentiate emotional well-being and SWB. Dr. Nielsen suggested starting with making a distinction between the experienced component versus the evaluative component, which are very different processes. In response to a question from Dr. Langevin about measures of self-reported health, Dr. Nielsen said that the literature on quality of life assessments and well-being assessments appears to have some overlap and evolution. There is a quality-of-life research society, and the conversations so far on this topic have mainly been between economists and psychologists.

Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH

Dr. Rosalind King, Associate Director for Prevention, presented on NICHD's research on emotional well-being. She opened with comments on NICHD's history and mission. A model by developmental psychologist Urie Bronfenbrenner illustrated the common perspectives of NICHD's grantees. A main point was that individuals are embedded in dynamic, multilayered contexts. Emotional well-being comes up in many parts of NICHD's portfolio. Examples of extramural and intramural projects were shared in the areas of reproductive health, child development, and adolescents and social media. The field of developmental psychology has had a strong influence on the portfolio. NICHD is also the home of the National Center for Medical Rehabilitation Research network.

The Institute is undergoing a strategic planning process for 2020 to 2024 and has issued a related Request For Information. Dr. King selected three of the six priority research themes so far in which emotional well-being may be most relevant: "Setting the Foundation for a Healthy Pregnancy and Lifelong Wellness," "Identifying Sensitive Time Periods to Optimize Health Interventions," and "Improving Health During the Transition From Adolescence to Adulthood." NICHD has been thinking about potential IC partners, including NCCIH, for work within its themes.

Discussion. Dr. Khalsa asked whether the speaker had any further comments regarding study of the timing of childhood difficulties in relation to possible later effects. Dr. King replied that the field appears to be interested in puberty and "tweens," and the latter group is understudied. Dr. Harris brought up the Adolescent Brain Cognitive Development (ABCD) Study and asked whether its dataset could be mined, unhealth outcomes introduced, and/or funding opportunities explored. Dr. King replied that her IC has introduced an FOA in this area. In response to a question about studies of complementary and integrative approaches for well-being in the NICHD portfolio, Dr. King mentioned that most of these studies have been in pediatrics, and there is room to build connections. Many pediatricians have mentioned emergency departments as a place to intervene. Dr. Fishbein asked whether NICHD is interested in resilience in early life (e.g., at ages 4 to 6 years) and adolescence. Dr. King replied that her IC does have that interest in several of its branches. She has seen more attention to gene-environment interactions, but the samples so far have been small. Dr. Nielsen mentioned the Midlife Reversibility of Risk Associated with Early Life Adversity network and the interest in trying to understand more about the casual chains of risk and the potential windows of malleability/plasticity in people later on. Several ICs are interested in this.

National Institute on Mental Health, NIH

Dr. Eve Reider, Associate Director of Prevention Research in the Division of Services and Intervention Research and a former NCCIH program director, spoke on "NIMH and Well-Being: A Prevention Perspective." She opened with an overview of the prevention science research perspective, including

approach and how prevention interventions work. A life-course, social-field concept/perspective developed by S.G. Kellam was shown. Dr. Reider explained that prevention discipline works with levels of risk of the target group or individual. It has been learned that preventive interventions can positively affect children's biological functioning and may have beneficial effects on a broad array of behaviors. Examples included a family bereavement program and a randomized, controlled study of effects of an experimental parenting intervention on diurnal cortisol rhythms in a group of infants referred to Child Protective Services.

NIMH has contributed to prevention science in many ways, e.g., by funding the development and testing of theory-based, developmentally focused interventions designed to prevent mental, emotional, and behavioral disorders. At present, NIMH funds theory-based developmentally focused prevention research, with a focus on populations at increased risk. It uses an experimental therapeutics approach and supports clinical trials designed to explicitly address whether the intervention engages the target(s)/mechanism(s) presumed to underlie the intervention effects. NIMH is also interested in (1) understanding how advances in technology contribute to the development, testing, and implementation of preventive interventions; (2) a better understanding of what interventions work, for whom, and under what conditions; (3) funding prevention research focused on the implementation of interventions at scale with fidelity by trained providers in existing infrastructures; and (4) use of innovative methodology in the design and implementation of prevention trials. An example of an NIMH priority topic relating to well-being is suicide prevention.

Examples of potential ways forward for NIMH in well-being are to understand (1) what preventive interventions work best, for whom, and under what conditions; (2) well-being as an outcome of preventive interventions and how it relates to reducing risk for mental health disorders; (3) the target mechanisms of preventive interventions in improving well-being and reducing risk for mental health disorders; and (4) resilience and its relationship to well-being in the context of the prevention of mental health disorders. Many domains of functioning in the Research Domain Criteria (RDoC) may be relevant. Dr. Reider also announced a new FOA: RFA-MH-20-110, Secondary Data Analysis to Examine Long-Term and/or Potential Cross-Over Effects of Prevention Interventions: What Are the Benefits for Preventing Mental Health Disorders? (R01 Clinical Trial Not Allowed). The participating ICs are NIMH, NCCIH, and the Office of Research on Women's Health. NCCIH intends to commit \$500,000 in total costs in FY 2020 to fund one award.

Discussion. Dr. Fishbein raised a question about the new RFA regarding measurement of outcomes, including with regard to crossover effects. In her reply, Dr. Reider discussed long-term outcomes and suggested that she has often seen researchers choose to add little items (vs. full measures) from among the items they have available. She referenced a symposium on psychosis behaviors, at the American Psychological Association conference in 2018, to check for scales and items. Dr. Shurtleff asked whether the concept of well-being is part of discussions at NIMH for sustaining mental health long-term and as a preventive strategy for prodromal states. Dr. Reider said that generally it is not; prevention is a

focus, and there are opportunities to look at how focusing on well-being and mental health relates to prevention of mental health disorders.

Dr. Khalsa asked whether rankings of measures of well-being can be used to elucidate whether there is a need to intervene with prevention approaches. Dr. Reider said that this is an answer that we need and studying it in children would be different from studying it in adults. Dr. R. King commented that we need to encourage capacity in everyone to promote wellness because unexpected things happen in life, and even people who appear to be doing well can be negatively impacted. Dr. Schoomaker asked whether the Army's Study To Assess Risk and Resilience in Servicemembers—Longitudinal Study (STARRS-LS) is informing work by Dr. Reider and her colleagues. Dr. Reider said she does not know that dataset well but could obtain the information; she could also try to find out whether any participants in the STARRS cohorts received preventive services in early life and if so whether related impact has been studied. She suggested to Dr. Schoomaker that if the military were to increase its training offerings in skills with broad effects (e.g., life skills and resilience), these would be useful additions to its single-focus skills trainings (e.g., on drug abuse).

Dr. Edwards reminded Council of NCCIH's existing high-priority topics in emotional well-being: ontology, mechanisms, and biomarkers; prevention research; and technology and outcome measures development. Dr. Schoomaker shared several statistics comparing the United States to similar nations on health and well-being. He added that no matter how much science or investigation is done, if people who make policy are not willing to shift their focus, it is simply an intellectual exercise. Can a way be found, as through implementation science, to achieve a shift? Dr. Edwards agreed and added that the long-term goal would be the evidence base, movement toward implementation science, and helping to shift the paradigm of policymakers. Dr. Nielsen commented that this area is of interest in the policy economics world; in doing the science that we do, to the extent that the measures are available, and we measure the specific things that matter most, then our science can potentially be part of those discussions. Dr. R. King added that people may not always be sure that NIH is the right place to go for this kind of work.

Dr. Harris asked whether a self-reported measure exists that could serve to benchmark how well a person is. Dr. Edwards responded that NCCIH sees potential in developing a tool like the Patient-Reported Outcomes Measurement Information System (PROMIS) to capture various facets of well-being and for use across a number of states. Dr. Khalsa asked whether there is a biological and/or neurological substrate for well-being. Dr. Harris responded that he sees this question as uncharted territory but fertile ground for investigation; his own feeling is that some of it is biological. Dr. Edwards referred to models of success presented at NCCIH's emotional well-being workshop in April 2018. Dr. Nielsen agreed that the topic mentioned by Dr. Harris is a ripe area. There is little on it, and in the positive psychobiology meeting mentioned above, people grappled with it. Historically, there has been more focus on disease or on stress biomarker(s). Dr. Richard Nahin, NCCIH Lead Epidemiologist,

commented that investigators in the MIDUS study may be looking at neurological substrates of well-being.

Dr. Smith cautioned to keep in mind that when one looks at a certain kind of biomarker, it is being viewed in a particular person, at a particular time, in their particular place and culture, etc. It may change over time. Dr. Fishbein said that she would like to know if there is a biomarker that would persist through various life stages and situations and could also inform people in creating not just interventions but environments that would foster well-being (e.g., through connectivity). Dr. Langevin encouraged looking beyond mental/psychological/brain-based processes to the physical body (e.g., a person's posture, movement, etc.) in the search for biomarkers of wellness. Dr. Yeh supported "not forgetting about the body" and suggested exploring whether NIH's All of Us program has mineable data for looking at well-being over long time periods.

Dr. Shurtleff asked for more granularity with respect to how well-being correlates with various aspects of disease prevention and health promotion, later suggesting extending investigation into the environment (e.g., work, school, and community settings). Dr. Nielsen commented that her field thinks well-being is a malleable target, and it is known to be linked to health outcomes; she gave examples of important scientific questions and possible measures. She mentioned the interest in strength-based interventions (i.e., that draw upon a person's capacities for strength). Dr. Price suggested heart rate variability as a potential biomarker to investigate. Dr. R. King offered to provide information on the Work, Family & Health Network project. Dr. Reider noted that some examples exist of using evidence-based prevention interventions, combined with a complementary health approach—e.g., in studies by John Lochman and Carolyn Boxmeyer, and in the United Kingdom's MYRIAD Project. Dr. Edwards said that broadening NCCIH's interest into employment and school settings would offer more opportunities for public-private partnership. Dr. Schoomaker mentioned the Total Force Fitness model of the Department of Defense and encouraged being holistic and well-being focused in measurement and examination of outcomes.

Dr. Herman asked whether there is more that NCCIH could do around this topic than it has in the past so that efforts could take more hold. An example would be to place an intervention in a context beyond, "Here's another treatment for heart disease." Dr. Edwards agreed that framing efforts well is a challenge. Dr. Yeh added as another idea the topic of burnout; it is a costly problem in the private sector, for example, but has been little studied in that setting. NCCIH could appeal to the interests of corporations and encourage partnership with the public sector.

Dr. Shurtleff added more topic ideas such as social media, cyberbullying, social isolation, social anxiety levels, and the workplace setting. He agreed with searching for places where NCCIH could intervene in an impactful way on well-being. Dr. R. King mentioned that capturing and measuring social media use is an area of great need. The NIH-funded ABCD Study may have some items on social media use. Dr.

Smith supported the idea of focusing on where the opportunities are now (and where NIH is being asked to respond) with respect to major current and upcoming public health problems.

Dr. Nielsen commented that social well-being is essential for people to feel that their life has purpose, meaning, and value, and in old age, it is predictive of some medical outcomes. NIA is looking for partners interested in the topic of work, the workplace, and aging; there will be a meeting at the National Academies for planning purposes, including toward a larger initiative. Dr. Reider noted that the National Academy of Medicine has a large initiative on clinician burnout and well-being. Dr. Langevin wondered whether people have been experiencing “social unhealth” and whether that concept could be a useful one. At the close of the symposium, Dr. Wen Chen, Chief of the Basic and Mechanistic Research in Complementary and Integrative Health Branch in DER, announced a workshop, “The Science of Interoception and its Roles in Nervous System Disorders,” in April 2019 on the NIH campus. NCCIH is the workshop’s planning lead.

Public Comment and Adjournment

Ms. Mindie Flamholz, of Baltimore, MD, described her work, including her belief that the body and its organ systems hold emotions that need to be released, and described some of her experiences with “healing sounds” and energy work. She recommended that the field of medicine move toward more personalized medicine.

The meeting was adjourned at 3:20 p.m.

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

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