

**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 Eighty-Second Meeting
September 9, 2022**

NACCIH Members Present Virtually

Dr. Todd Braver, St. Louis, MO
Dr. Nadja Cech, Greensboro, NC
Dr. Robert Coghill, Cincinnati, OH
Dr. Anthony Delitto, Pittsburgh, PA
Dr. Roni Evans, Minneapolis, MN
Dr. Margaret (Meg) Haney, New York, NY
Dr. Richard E. Harris, Ann Arbor, MI
Dr. Kendi Hensel, Fort Worth, TX
Dr. Girardin Jean-Louis, Miami, FL
Dr. Benjamin Kligler, Washington, DC*
Ms. Lori Knutson, Bentonville, AR
Dr. Helen Lavretsky, Los Angeles, CA
Dr. Wolf Mehling, San Francisco, CA
Dr. Lynne Shinto, Portland, OR
Dr. Justin L. Sonnenburg, Stanford, CA

NACCIH Members Not Present

Dr. Diana Fishbein, Chapel Hill, NC
Dr. Tammy Born Huizenga, Grand Rapids, MI
Dr. Karen Sherman, Seattle, WA

*Ex Officio Member

I. Closed Session

The first portion of the eighty-second 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 170 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 104 scored applications, which requested \$65,950,628 in total costs.

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

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

III. NCCIH Director's Welcome and NCCIH Report

Dr. Helene M. Langevin, director of NCCIH, began by sharing the tragic passing of Representative Jacqueline (Jackie) Walorski (R-IN) from an automobile accident on August 3, 2022. Rep. Walorski was always very supportive of the work of the National Institutes of Health (NIH) and had co-chaired the Congressional Integrative Health and Wellness Caucus. She will be greatly missed.

Recent appointments at NIH include Dr. Monica Bertagnolli, as director of the National Cancer Institute; Mr. Kevin Williams, as director of the Office of Equity, Diversity, and Inclusion; Dr. Nina Schor, as acting deputy director for intramural research; and Dr. Adam Russell, as acting deputy director of the Advanced Research Projects Agency for Health (ARPA-H). At NCCIH, Dr. Patrick Still has joined the Division of Extramural Research (DER) as a program director; previously, he was an NCCIH scientific review officer. Dr. Langevin shared the current NCCIH budget mechanism table with the approved Fiscal Year (FY) 2022 budget and operating plan, which will continue to be adjusted. The FY 2023 President's budget request includes a \$26 million increase for pain research, but it may not be approved.

Awards for funding opportunities under the NIH Bridge to Artificial Intelligence (BRIDGE2AI) program (commonfund.nih.gov/bridge2ai) will be announced soon, and Dr. Langevin will update at the next Council meeting. NCCIH and seven other Institutes, Centers, and Offices (ICOs) cosponsored a Request for Information (RFI), Investigators' Interests in and Barriers to Research Studies on the Health Effects of Cannabis and Its Constituents ([NOT-AT-22-026](#)), which has a deadline of October 15, 2022. Achieve Life Sciences was awarded \$2.5 million in grant funding from the National Institute on Drug Abuse to continue its studies evaluating the use of cytisinicline as a treatment to support cessation of use of nicotine e-cigarettes. Cytisinicline is a plant-based alkaloid with a high binding affinity to the nicotinic acetylcholine receptor.

The NCCIH Clinical Research Toolbox, a web-based repository for investigators involved in NCCIH-funded research, has been redesigned (nccih.nih.gov/grants/toolbox). The toolbox aims to increase the understanding of clinical trials and the related regulatory processes. Extensive new information has been

added, the organization improved, and the design made more user friendly. The redesign was based mainly on feedback provided by Council members and the research community.

Dr. Langevin highlighted multiple publications on studies funded or co-funded by NCCIH:

- Bae M, Cassilly CD, Liu X, et al. [Akkermansia muciniphila phospholipid induces homeostatic immune responses](#). *Nature*. 2022;608(7921):168-173.
- Yildiz S, Grinstead J, Hildebrand A, et al. [Immediate impact of yogic breathing on pulsatile cerebrospinal fluid dynamics](#). *Scientific Reports*. 2022;12(1):10894.
- Chew EY, Clemons TE, Agrón E, et al. [Long-term outcomes of adding lutein/zeaxanthin and \$\omega\$ -3 fatty acids to the AREDS supplements on age-related macular degeneration progression: AREDS2 Report 28](#). *JAMA Ophthalmology*. 2022;140(7):692-698.
- Lindsay EK, Creswell JD, Stern HJ, et al. [Mindfulness-based stress reduction increases stimulated IL-6 production among lonely older adults: a randomized controlled trial](#). *Brain, Behavior, and Immunity*. 2022;104:6-15.
- Olm MR, Dahan D, Carter MM, et al. [Robust variation in infant gut microbiome assembly across a spectrum of lifestyles](#). *Science*. 2022;376(6598):1220-1223.
- Zhang T, Perkins MH, Chang H, et al. [An inter-organ neural circuit for appetite suppression](#). *Cell*. 2022;185(14):2478-2494.
- Kral TRA, Davis K, Korponay C, et al. [Absence of structural brain changes from mindfulness-based stress reduction: two combined randomized controlled trials](#). *Science Advances*. 2022;8(20).

Examples of recent funding opportunities were presented:

- REsearch Across Complementary and Integrative Health Institutions (REACH) Virtual Resource Centers (U24 Clinical Trial Not Allowed), [RFA-AT-23-004](#)—to encourage institutional partnerships between accredited complementary and integrative health institutions and research-intensive institutions, and support of research activities and training for clinician scientist faculty at complementary and integrative health institutions. Projects will focus on NCCIH strategic priorities in symptom management.
- Notice of Special Interest (NOSI): Administrative Supplements for Complementary Health Practitioner Research Experience (Admin Supplements), [NOT-AT-22-010](#)—for administrative supplements to NCCIH-supported awards, enabling complementary health practitioners to have an intensive, supervised complementary and integrative health research experience.
- Research Resource Center To Build an Open-Access Repository and Database for Anatomical and Physiological Correlates of Acupoints (U24, Clinical Trial Optional), [RFA-AT-23-005](#)—for a research resource center to develop and maintain an integrated database and repository for research data on commonly used acupoints in acupuncture-related interventions; to be integrated with other databases of anatomical and physiological data in this field.
- Fostering Mental, Emotional, and Behavioral (MEB) Health Among Children in School Settings: Opportunities for Multisite Trials of Complementary and Integrative Health Interventions

(Clinical Trial Optional), [RFA-AT-23-003](#)—to support multisite clinical trials in school settings to test the efficacy or effectiveness of complementary health approaches for promoting MEB health and preventing MEB disorders in youth.

- Notice of Special Interest (NOSI): Promoting Mechanistic Research on Therapeutic and Other Biological Properties of Minor Cannabinoids and Terpenes, [NOT-AT-22-027](#)—cosponsored by multiple ICOs, to promote research on therapeutic benefits of minor cannabinoids and terpenes found in the cannabis plant.

A list of several additional opportunities was shared:

- Notice of Special Interest (NOSI): Promoting Research on Interoception and Its Impact on Health and Disease, [NOT-AT-21-002](#)
- Notice of Special Interest (NOSI): Fundamental Science Research on Complementary and Integrative Health Approaches, Including Natural Products or Mind and Body Interventions, [NOT-AT-21-006](#)
- Promoting Research on Music and Health: Phased Innovation Award for Music Interventions (R61/R33 Clinical Trial Optional), [PAR-20-266](#)
- Notice of Clarification of Research Examples for PAR-20-266: Promoting Research on Music and Health: Phased Innovation Award for Music Interventions (R61/R33 Clinical Trial Optional), [NOT-AT-22-028](#)

Dr. Langevin also shared several funding opportunities under the Helping to End Addiction Long-term® Initiative, or NIH HEAL Initiative®:

- HEAL Initiative: Pragmatic and Implementation Studies for the Management of Sickle Cell Disease Pain (UG3/UH3, Clinical Trials Optional), [RFA-AT-23-001](#)
- HEAL Initiative: Sickle Cell Disease Pain Management Trials Utilizing the Pain Management Effectiveness Research Network Cooperative Agreement (UG3/UH3, Clinical Trial Required), [RFA-AT-23-002](#) (a reissue)
- Notice of Intent to Publish a Funding Opportunity Announcement for HEAL Initiative: Prevention and Management of Chronic Pain in Rural Populations (UG3/UH3, Clinical Trials Required), [NOT-NR-22-015](#)

Recent events include spring 2022 Integrative Medicine Research Lectures by Dr. Michelle Martin, University of Tennessee Health Science Center, on well-being and the economic burden of disease in cancer patients and survivors, and by Dr. Elissa Epel, University of California, San Francisco, on emotional well-being and the regulation of eating. The 17th Annual NIH Pain Consortium Symposium on June 1–2 had as its theme “Pain Management Through the Lens of Whole Person Health.”

Upcoming events include:

- NCCIH Fellows and Trainees Virtual Workshop: Whole Person Health Research Careers (9/15–16/2022)
- Yet To Be Charted: Lymphatic System in Health and Disease (9/19–20/2022)
- Research Across Complementary and Integrative Health Institutions (REACH) Virtual Resource Centers Technical Assistance Webinar (9/21/2022)
- New NIH Data Management and Sharing Policy: Two-Part Webinar Series (meeting #2, 9/22/2022)
- Functional Neurocircuits of Interoception (NIH Blueprint on Neuroscience) (9/29/2022)
- NIH HEAL Sickle Cell Disease Pain Management Technical Assistance Webinar (10/04/2022)
- Repository and Database for Anatomical and Physiological Ontology of Acupoints, Technical Assistance Webinar (10/06/2022)
- October 19 Third Annual Cannabinoid Principal Investigators Meeting (10/19/2022; by invitation)
- Emerging Natural-Product Novel Methodologies and Technologies, Hot Topic Webinar (11/07/2022)
- The 2022 Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies, by Dr. Laura Stroud, Warren Alpert Medical School of Brown University and The Miriam Hospital (12/13/2022)

Discussion. Dr. Kligler praised the two funding opportunity announcements (FOAs) supporting research capability and capacity among complementary and integrative health practitioners and the request for applications (RFA) on school-based interventions. Dr. Langevin said that former Council member Dr. Patricia Herman led the effort on what is now REACH, which will help clinician researchers in complementary and integrative health submit competitive grant applications and navigate the complex NIH grants environment. Dr. Lavretsky asked about application by schools of music for the virtual resource centers. Dr. Langevin said such schools are welcome to apply as long as the application pertains to music used as therapy. Dr. Emmeline Edwards, director of DER, added that this opportunity is an additional component of NIH’s capacity-building effort on music and health.

Regarding REACH, Dr. Lanay Mudd, DER, said NCCIH is seeking to create at least two virtual resource centers able to reach many different complementary and integrative health institutions. Applicants are required to come in with at least three partnering institutions of differing clinical areas to facilitate connections between multiple disciplines and multimodal research.

Dr. Emrin Horgusluoglu, DER, gave a short overview of the acupoints database funding opportunity. Dr. Langevin commented that the ensuing comprehensive, relational database could become “a Rosetta Stone” in a field of great heterogeneity and a long, diverse history. A major research question is how historical and clinical information translates to physiology. Some acupoints might turn out to be used as “anatomical shorthand.”

IV. The 2023 NIH Data Management and Sharing Policy

NCCIH prioritizes sharing data and making the outcomes of NCCIH-funded research available to all. This session focused on the 2023 NIH Data Management and Sharing (DM&S) policy, its implementation, and how it applies to NCCIH-funded research and data.

A. Implementation Update: NIH Policy for Data Management and Sharing

Dr. Michael Lauer, NIH deputy director for extramural research, presented this update from NIH on its DM&S policy. Data sharing has been a high priority for a long time, including at the highest levels of Government (e.g., in the Cancer Moonshot program and the 21st Century Cures Act). The DM&S policy at NIH goes back to 2003. Comment provided by many other parts of the Government and from the community has been incorporated into its development. The final policy was released in October 2020 and becomes effective in January 2023 (the time in between has been for increasing readiness).

NIH wants data to be shared, including to advance rigorous and reproducible research and promote public trust in research. Dr. Lauer cited several recent reports including a Pew Research Center survey, which found that most Americans believe in data sharing in some ways, and they are more likely to trust scientific research findings if the related data are openly available to the public.

A DM&S plan (including “how, where, and when”) must be submitted with the application for all NIH-funded research. Once the plan is approved, investigators are responsible for complying with it. Not doing so can have consequences, e.g., restrictions, or an impact on future NIH funding. Relevant NIH notices on the new policy include NOT-OD-21-013 on the final NIH DM&S policy; NOT-OD-21-014, -015, and -016 regarding policy supplementary information; and NOT-OD-22-189 on implementation details.

Dr. Lauer explained that scientific data are recorded factual material of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Investigators should plan prospectively for DM&S, and sharing must be done no later than the time of publication or, if the work is unpublished, by the end of the award. Although all data should be managed, all data may not necessarily need to be shared if legitimate restrictions exist. Investigators are encouraged to visit NIH’s new website on DM&S (sharing.nih.gov). All applicants will be asked to provide a budget for DM&S; some costs will be allowable, others will not. NIH hopes to learn more over time about what constitutes reasonable costs for these activities.

There has been a high level of interest in the new policy so far from the research community. Dr. Lauer showed a graphic of steps in plan submission, assessment, and compliance. He discussed NIH’s roadmap on DM&S to 2023 and beyond, including for outreach, policy, and assessment.

Discussion. Dr. Haney asked about costs and repositories, as she obtains extensive behavioral data in her studies that she generally has not uploaded to repositories. Dr. Lauer said that if her files are relatively

small, she could upload data backing up papers to PubMed Central. The next presentation would go into more detail on repositories. Dr. Sonnenburg asked about timing in relation to publication (including preprints) and potential scooping. Dr. Lauer said that the policy is to post at the time of publication—whether with the journal or in another location. Posting is not expected prior to publication (including for preprints).

Dr. David Shurtleff, NCCIH deputy director, asked Dr. Lauer how well the communication effort is going across the extramural community about requirements to comply with the policy. Failure to comply may impact future funding decisions, so it's important for investigators to understand the importance of compliance. Dr. Lauer said that people have become used to other forms of compliance at NIH (e.g., progress reports, public access, and clinical trials registration). He shared Dr. Shurtleff's concern and noted the DM&S policy team works to get these important messages out. Dr. Jean-Louis asked what to do about DM&S if one has multiple publications. Dr. Lauer said the data needed to support a particular publication (e.g., its tables and graphics) are the data that need to be shared. If one has, for example, three papers with evolution in the datasets, the data for each paper should be posted separately. Dr. Harris asked how data sharing takes place for huge datasets as from brain-imaging studies. Dr. Lauer said that different repositories have different data scopes. NIH has set up contracts with several large cloud providers to make cloud storage available for NIH-funded researchers at substantial discounts, as well as some other services such as consulting and high-powered computing.

Dr. Langevin asked about journals that request authors' data plans at the time of submission. Dr. Lauer related an experience in which he submitted a paper and, when asked for his data, let the editor know that he would not be sharing any data until he received a letter of commitment to publish. His paper was accepted, and the subsequent steps did not have problems. As journals often have different policies, a journal's information for authors should be studied, and authors should ask questions if needed.

Dr. Coghill asked what would happen if exploratory analyses are scooped when such analyses would otherwise be part of productivity on the original grant. Dr. Lauer said this concern is real, but over time he has come to believe that the scenario does not happen as much as people think. Those who know the data best are the people who generated it, which gives them a massive head start. The NIH DM&S policy developers would eventually like to see an environment in which if data are shared and subsequently used by someone else, it is "a feather in the earlier group's cap," and credit is given to everyone involved.

B. NCCIH-Specific Implementation of the NIH DM&S Policy

Dr. Craig Hopp, deputy director of DER, gave this presentation on behalf of the NCCIH DM&S Working Group. He noted that this policy is new, and there will be a learning curve for everyone. NIH and NCCIH have previously implemented policy changes to address new needs, and these processes have mostly transpired smoothly. The policy shown by Dr. Lauer might be viewed as the "base model." Institutes and Centers have some flexibility in how they choose to implement aspects of it, e.g., by

layering on additional requirements or listing preferred repositories. NCCIH's working group has chosen not to apply additional requirements or restrictions at this time.

NCCIH has released its [webpage on the NIH DM&S policy](#). Generally, the site mirrors items on the NIH webpage on this topic; in a few places, NCCIH has provided elaboration. An example is a list of questions NCCIH suggests applicants ask themselves and be able to answer when developing a DM&S plan:

1. What data will be created/collected?
2. How will the data be created and collected?
3. What documentation and metadata are needed to accompany the data?
4. How will ethical issues be managed (human subjects, privacy, etc.)?
5. How will copyright and intellectual property be managed?
6. How will data be stored and backed up during research?
7. How will access and security be managed?
8. Which data will be shared, retained, and/or preserved?
9. What is the long-term preservation plan for the data (e.g., which repository)?
10. How will you share the data?
11. Will there be any restrictions on the data sharing required?
12. Who is responsible for the data management?
13. What resources will be required to implement the DM&S plan?

NCCIH has also developed a preferred repositories table. Like Dr. Lauer, Dr. Hopp urged the audience to take advantage of the resources at [sharing.nih.gov](#). As two examples of resources, the [DMPTool](#) is a free, open-source, online application that helps researchers create data management plans, and the [Data Curation Network](#) has participation by numerous university libraries. Dr. Hopp described the following stages of submitting a DM&S plan:

- **Pre-Application:** Applicants should visit the NCCIH and NIH webpages on DM&S. They should follow specific instructions on DM&S in the FOA, if provided, and contact the NCCIH program director if necessary.
- **Pre-Award:** If an award is on the horizon, evaluation of the applicant's plan begins in earnest. It is an iterative process, and there will be multiple opportunities to augment/revise the plan. Having a satisfactory DM&S plan is a requisite for funding. NCCIH staff will undergo training to maintain internal consistency in this area.
- **Post-Award:** Compliance with DM&S will be a term of award and will be evaluated at least annually.

Dr. Hopp encouraged patience from everyone with the new process. Overall, he was confident that it will soon become second nature and ultimately will be rewarding. NCCIH believes that sharing data is the right thing to do, and future generations will benefit from it.

Discussion. In response to a question from Dr. Cech, Dr. Hopp made a comparison to NCCIH's product integrity policy. If an award becomes possible and NCCIH/NIH staff need to communicate with the applicant, they will do so. Dr. Khalsa added that the applicant must submit the DM&S plan with the application, but the plan is not seen or scored by reviewers, who see only the budget information. Dr. Harris asked about data that are found later to be false. Dr. Lauer said one of the salutary effects of data sharing is that some falsified data have been found much earlier than in years past. When such a situation is brought to NIH's attention, NIH follows its standard procedures to handle it. In cases of error, the author(s) might write an addendum, reanalysis, etc. The policies of the repository and/or journal will govern how the changes are presented. In response to a comment by Dr. Wendy Weber, DER, Dr. Lauer discussed the DM&S plan versus the Data Monitoring and Safety Plan (these have the same acronym). The latter plan applies to trials, and the type of plan to be submitted depends upon the type of trial.

V. Determinants of Whole Person Health

Dr. Langevin presented recent developments in NCCIH's progress toward creating a research program on whole person health (WPH). NCCIH has formed a WPH working group at NIH that includes many ICOs that do not have an organ- or disease-specific mission. Further, NCCIH has partnered with stakeholder organizations external to NIH that have missions related to WPH. NCCIH sponsored a workshop last year on methodological approaches for WPH research. A major question at the workshop was how to measure WPH, a much more difficult concept than measurement of a single molecule, disease, or intervention. To address this, NCCIH underwent a process to identify factors and domains that might be used.

In spring 2022, NCCIH issued an RFI inviting input to identify up to 20 determinants that could inform the WPH model by influencing health either positively or negatively. These would encompass biological, behavioral, social, and environmental domains and were requested to be provided as Medical Subject Heading (MeSH) terms when possible. The RFI indicated that the results could ultimately be used to identify a set of common data elements (CDEs) for use across multiple studies.

Dr. Langevin described the response to the RFI as very good: there were 83 respondents, the average number of determinants per respondent was 7, and the total number of unique determinants was 249. There was a high level of correspondence between these determinants and the elements NCCIH has thought and written about for the WPH model.

The working group mapped the most frequently mentioned determinants into four major categories: (1) demographics/genetics, (2) social and environmental determinants, (3) health-related behaviors/lifestyle, and (4) biological outcomes. In addition, for each determinant, the NCCIH team proposed types of data that could potentially be collected such as patient-reported outcomes, geospatial data, wearable (sensor) data, and electronic health record (EHR) and laboratory measurements.

For social and environmental determinants of health, the factors were similar or identical to those in similar models, such as those of health.gov and the National Institute on Minority Health and Health Disparities. NCCIH seeks to not duplicate existing efforts on the social determinants of health but rather to be congruent with them. In the health-related behaviors category, fewer datasets could be found, or they were incomplete. The PhenX Toolkit (funded by several NIH ICOs) of measurement protocols was mentioned. Sleep and stress management are often missing in other models. This seems to be a category where NCCIH could be helpful by integrating all the related determinants.

The biological outcomes category was, in large part, outcomes as measurements taken on people's health. NCCIH wishes to capture physiology as well as behavior. Dr. Langevin highlighted some interesting pieces from the literature and the workshop. For example, [one paper](#) demonstrated how multiple biomarkers could be tracked over time to assess the biological aging trajectory, which is thought to be related to health and, probably, health restoration. A [second article](#) proposed a panel of biomarkers of healthy aging. Dr. Langevin also mentioned a just-published article in [Health Affairs](#) on asking patients about their overall health and well-being.

Dr. Langevin presented a graphic summarizing a framework for WPH. NCCIH focuses on research, and its framework is aimed at measurement, with each determinant/factor linking to specific CDEs. She also presented several other examples of whole health-oriented models that also use a circular, whole-person approach—Whole Health (the U.S. Department of Veterans Affairs [VA]); Total Force Fitness (the Consortium for Health and Military Performance, Uniformed Health Sciences University); Move to Health (the U.S. Department of Defense); Whole School, Whole Community, Whole Child (the Centers for Disease Control and Prevention); and the Circle of Health (VA)—and compared several in a chart, noting that they align very well with NCCIH's WPH framework. The next step will be releasing an RFI early in 2023 asking for the optimal set of CDEs to measure each WPH determinant. The working group will seek to integrate as much as possible with existing models.

Discussion. Dr. Kligler praised this work and looks forward to continued conversation and efforts with NCCIH. The VA holds State of the Art (SOTA) conferences once or twice per year, with one planned for March 2023 on measurement. Dr. Erin Burke Quinlan of DER is on that planning team. Dr. Kligler mentioned the development of a brief tool to assess well-being, the Well-Being Sign (lead developer Dr. Dawne Vogt of the VA) that the VA is pilot testing. Dr. Langevin said she is happy that the VA and NCCIH are meshing their efforts.

Ms. Knutson said she was very happy to see the presentation and the efforts toward measurement. She has heard from a local clinical advisory group of physicians and other health care practitioners that they are asked to be accountable in payment for aspects of WPH because of their effects on disease and illness. However, these providers do not have control over this nor any real way to measure it effectively. In the context of value-based care and WPH, what has been presented by Dr. Langevin is imperative to move this work forward. Ms. Knutson asked whether health beliefs, values, and attitudes are implicit in the domain of social/family/community context because she believes they are fundamental to how people choose their health and how they relate in their community around their

health, including health access and health behavior. Dr. Langevin said that this topic area was challenging for the group, which welcomes feedback about tweaking some of the categories.

Dr. Harris praised the presentation. He asked where pain was located in the model, as it is the major reason people seek health care and impacts many other listed factors. Dr. Langevin responded that pain was almost absent from the RFI responses. However, NCCIH had pain and its management in an earlier version of the model as a separate bubble. Should pain be separate from stress and stress management, or coupled with them? Dr. Harris thinks that a lot of people probably are focused on pain, which likely is a barrier to a WPH approach. Dr. Kligler suggested that many conditions and outside factors impinge on multiple domains, and one model cannot capture them all. Dr. Langevin said NCCIH will continue to look at pain as a determinant.

Drs. Kligler and Langevin commented on inclusion of substance abuse (which is in NCCIH's WPH model; the VA chose to not include diseases in its model). Dr. Lavretsky said, regarding substance use/abuse, that smoking and alcohol are still factors, but now psychedelics, cannabis, and cannabidiol (CBD), for example, are more available and used. Little is known about their impact on WPH. A second factor she recommended including was loneliness, and degree of social support, under lifestyle. All chronic conditions lead to premature, accelerated aging, which has relatively reliable biomarkers that are becoming easier to measure.

Dr. Cech praised the presentation and asked whether there is an interest in molecular measures as indicators of WPH. Could part of development of the model include measurements such as DNA methylation and microbiome measurements? Dr. Langevin said that the framework uses attainable measures, but the list could be expanded as the science progresses. Dr. Shinto spoke positively of the presentation and returned to pain as a topic. When her group sees patients, the numerical-rating scale (i.e., numbers 1 to 10) for pain is recorded as part of vitals. She and Dr. Langevin briefly discussed pain measures in relation to well-being and WPH. Dr. Langevin noted that NCCIH's WPH work is for research; however, it might be adapted eventually for clinical purposes such as for pain measures.

Dr. Sonnenburg complimented this work. Much is happening on measurement in aging and in immune health, and he asked if there will be breadth and flexibility for investigators versus requiring, for example, very specific lists of markers. Dr. Langevin said, from following the conversation in other parts of the NIH on development of CDEs, it appears that what works best is to develop a minimum common data set that captures the major elements. NCCIH is looking for a set upon which everyone agrees, and accessibility must also be considered. Overall, she envisions this effort as being able to evolve, yet preserving a stable core to translate across many studies (i.e., having interoperability).

Dr. Langevin thanked Council for helping shepherd NCCIH's concept of WPH. Several current Council members have been involved in this effort for many years. Key future tasks include analysis of NCCIH's portfolio regarding WPH, and more targeted funding opportunities on WPH.

Dr. Edwards commented that it is wonderful to see this work coming together, and many ICOs have elements of WPH. Dr. Jean-Louis appreciated sleep being well represented.. She suggested that stress,

stress management, and sleep might turn out to be the missing—and key—ingredients for unlocking many behavior changes that researchers seek, but often do not achieve. Dr. Lavretsky was involved in developing the American Heart Association’s new guidelines for heart health, which recommend 7 to 9 hours of sleep and also recommend mindfulness. Dr. Langevin said NCCIH needs to be sure to plug into this guideline and other efforts synergistic with WPH.

Dr. Harris thought this WPH approach could be integrated well at other institutes such as the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Dr. Langevin described her concept that many chronic diseases do not occur suddenly, but rather exist on a bidirectional continuum from a prodromal phase through intermediate stages, and ultimately, the later stage where drugs, surgery, etc., are used. There may be earlier opportunities on the continuum to intervene with behavioral interventions that could influence the disease course.

VI. Reminder of How To Submit Public Comments

Dr. Khalsa reviewed the process for submitting written public comments (detailed in section II above).

VII. Final Comments and Adjournment

Dr. Edwards thanked Council members for a wonderful discussion. Dr. Shurtleff noted in his thanks that the diversity of opinions and ideas of the Council enriches these discussions. Dr. Langevin thanked the Council for their presence and input. Dr. Khalsa thanked the many staff who made the meeting and teleconference possible. The meeting adjourned at 4:00 p.m. ET.

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

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

Helene M. Langevin, M.D.
Chairperson
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