DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR COMPLEMENTARY
AND ALTERNATIVE MEDICINE

NATIONAL ADVISORY COUNCIL FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE
MINUTES OF THE FIFTY-SECOND MEETING
June 6, 2014

NACCAM Members Present

Dr. Brian Berman, Baltimore, MD
Dr. David Borsook, Waltham, MA
Dr. Daniel Cherkin, Seattle, WA
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Tracy Gaudet, Washington, DC
Dr. Jane Guiltinan, Seattle, WA
Dr. Scott Haldeman, Santa Ana, CA
Dr. Frances Henderson, Jackson, MS
Dr. Steven Hersch, Charleston, MA
Dr. Janice Kiecolt-Glaser, Columbus, OH
Dr. David Kingston, Blacksburg, VA
Dr. John Licciardone, Fort Worth, TX
Dr. Philippa Marrack, Denver, CO
Dr. Lloyd Michener, Durham, NC
Dr. Deborah Powell, Minneapolis, MN
Dr. Lynda Powell, Chicago, IL[1]
Dr. Eric Schoomaker, Bethesda, MD
Dr. Chenchen Wang, Boston, MA

[1]Telephone

SPEAKER

Dr. James Anderson, Bethesda, MD

NACCAM Members Not Present

Dr. Donald Brater, Indianapolis, IN
Dr. Richard Niemtzow, Clinton, MD

NIH Staff Present

Barbara Sorkin, ODS, NIH
Edward Culhane, OLPA, NIH

Members of the Public
Jason Crosby
Sarah Dick
Julia Dollinger

I. Closed Session

The first portion of the fifty-second meeting of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) 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 218 applications were assigned to NCCAM. Of these, 122 were reviewed by NCCAM, 96 by Center for Scientific Review. Applications that were noncompetitive, not discussed, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 98 applications, requesting $44,605,698 in total costs.

II. Open Session—Call to Order

The open session convened at 10:00 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order. The minutes of the February 7, 2014, meeting was approved unanimously.

III. NCCAM Director's Report and Name Change Discussion

Dr. Briggs welcomed new Council members Drs. Craig Brater, Steven Hersch, Janice Kiecolt-Glaser, and Eric Schoomaker. NCCAM staff news included the recent appointments of Dr. Partap Khalsa as Deputy Director of the Division of Extramural Research, Dr. John Williamson as Chief of the Basic and Mechanistic Research in Complementary and Integrative Health Branch, and Dr. Wendy Weber as Chief of the Clinical Research in Complementary and Integrative Health Branch. Dr. John Glowa, Program Director, is retiring. Highlights of NIH news included the opening of the new Porter Neuroscience Research Center, where NCCAM's main laboratories are located; NIH's partnership in the new Interagency Pain Research Portfolio database; the NIH Accelerating Medicines Partnership; and the Dalai Lama's visit to NIH.

NCCAM is functioning under the Fiscal Year (FY) 2014 omnibus appropriations bill, with a budget of $123.8 million. Dr. Briggs explained the NCCAM budget mechanism table. The President's FY budget request for 2015 calls for a modest increase to $30 billion for NIH and $124.5 million for NCCAM; however, those amounts are not back to pre-sequestration levels. The actual buying power of the NIH budget has largely been in decline since 2004 except for a brief bump at the time of stimulus funding. The sequester law is still in effect, calling for continued reductions over a 10-year period, and it is possible that NIH's buying power could decline again. Recently, some appropriation hearings have

involved Dr. Collins and a small number of Institute and Center (IC) Directors, and several congressional activities on the theme of innovation have taken place.

On April 30, Dr. Briggs and Council member Dr. Tracy Gaudet were among participants in the Senate Committee on Veterans' Affairs hearing on "Overmedication: Problems and Solutions." Dr. Briggs noted that NCCAM is seeing substantial public interest not only at the VA but in other settings regarding the problem of overmedication and the need for new pain-management strategies.

NCCAM is a major cofunder of curriculum materials on pain being developed by the National Institute on Drug Abuse (NIDA) for health students and professionals. The first module is online and includes some information on integrative approaches. A Trans-NIH Sleep/Pain Workshop, held May 29-30 and put together by Program Director Dr. Lee Alekel and a trans-NIH group, discussed research priorities.

Dr. Briggs discussed the need for data standards, recommending a recent Perspective in *The New England Journal of Medicine (NEJM)* by R. Kush and M. Goldman [2014;370(23):2163–2165] on this topic. Dr. Briggs praised the leadership of Dr. Partap Khalsa, who, with Dr. James Panagis of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and with guidance from former NCCAM Deputy Director Dr. Jack Killen, organized the NIH Pain Consortium's Task Force on Research Standards for Chronic Low Back Pain. The Task Force's report, including a draft set of research standards, is now available on the Pain Consortium Web site, and a related manuscript is being published by a number of leading journals.

Dr. Briggs also discussed a paper in *Science Translational Medicine* by S. Kam-Hansen, et al. [2014;6(218):218ra5] on labeling, placebos, and pain, and a review in *NEJM* led by NIDA Director Dr. Nora Volkow [2014;370(23): 2219-2227] on the adverse effects of using marijuana. The NIH's portfolio on medical marijuana is modest, Dr. Briggs said, but richer on marijuana's two primary bioactive compounds: tetrahydrocannabinol (THC) and cannabidiol (CBD). NCCAM leadership is considering this important and complex topic and will be working to shape its role, including through drug-interaction studies. At this point, Dr. Briggs invited discussion, and a member thanked her for her informative updates.

Dr. Briggs then opened the topic of a proposed change to the Center's name. A discussion on this topic began at NCCAM a year ago, and a Council working group was formed. However, this year's climate has been a better one in which to take up this complex issue, in part because of greater budgetary certainty for NCCAM. Dr. Briggs shared the original legislation creating NCCAM, which contains the three words "alternative," "complementary," and "integration" (thus, "integrative" also applies). The term "alternative" was in use for all these practices at the time NCCAM was founded and was part of the name of NCCAM's predecessor, the NIH Office of Alternative Medicine. Dr. Briggs noted that "alternative" is commonly, although not exclusively, used to refer to use of practices that are sometimes discouraged by the conventional medical profession. "Complement" and "complementary" entered the field at about the time this legislation was passed.

NCCAM studies metrics on Web searches, which have shown that "alternative", is widely used by the public at large, "integrative" is increasingly being used, and "complementary" is not much used. Dr. Briggs added that many of the health practices incorporating these approaches into health care increasingly use "integrative." One example is the Consortium of Academic Health Centers for

Integrative Medicine, which consists of about 45 medical schools having programs that study the kinds of approaches that NCCAM studies; none uses the term "alternative." She added that "integrative" is being commonly used in military health facilities, nursing homes, and hospices to refer to these approaches. Furthermore, during NCCAM's strategic planning process about 4 years ago, it emerged that NCCAM should focus on approaches that have potential to be considered for integration into care. Therefore, she said, integration has become part of NCCAM's vocabulary to talk and think about what the Center does.

Dr. Briggs reported that when she gives seminars to groups, she is commonly asked, "Why don't you [NCCAM] change your name?" Early on, the Center thought legislative action would be needed to do so, but upon further study it became clear that a name change would be possible through administrative action, with certain constraints—e.g., the new name should not reflect a change in mission, and certain conditions must be met such as providing a process for stakeholder input. NCCAM has provided that process, consisting of the present Council meeting, the February 2013 Council meeting, and a mechanism for public comment via the Web site from May 16 to June 6, 2014. NCCAM has proposed the National Center for Research on Complementary and Integrative Health as the new name but is also open to other proposals.

To date, NCCAM has received more than 500 public comments. About two-thirds have favored the name change, although some have offered suggestions of tweaks to wording. Some comments indicate that a name change would improve clarity on the actual mission and reflect more accurately both current health care and health-care research. About one-third of the public comments have been negative. Many have been from a number of long-term critics of the Center and its existence, and themes have included whether the Center's mission is of value and what the costs involved would be. The NCCAM Director of Communications has estimated that the cost of a name change would be approximately $35,000 for signage, changes to the Web site, etc.

In terms of wording, there has been strong support for including "integrative" and "research" in the new name. Comments on "complementary" have been mixed: it was included because it would show an evolution of the name and could reduce some ambiguities, but it is also historical and not widely used by the public. Using "medicine," "health," or "health care" has been debated. Dr. Briggs and the NCCAM staff favor "health" or "health care," since, in this field, many of the practitioners are not physicians and self-care is emphasized.

Discussion on Name Change. There was enthusiastic support for a name change. The proposed name was seen as an improvement over a name that has an historical legacy and can be confusing. One question was, "What is complementary and integrative health?" "Integrative" was cited by many as a strong positive, in that it would reflect where the field is, in many cases, and where it is going. One member noted that patients prefer to go to one location where the best options are available in an integrated fashion, rather than pursuing a variety of complementary practices in different locations. It was commented that name changes are difficult and it is better to lean forward than be in an "in-between state." It was reported that the VA just went through a similar naming project and chose "integrative health." One member recommended overall systems thinking in which the best evidence is the most important factor, not distinctions between these terms; divisiveness was a concern. Using "integrative," with or without "complementary," could open the door to looking at health from every possible angle (genes, social determinants of health, etc.).

Two members expressed support for the idea of the term "health practices," while another member thought it too narrow for the broad approach conceived. A member stated that "health" is preferable to "health care" because the former is much broader and implies more action in ways other than through the health care system. "Research" was mostly considered unnecessary, for reasons of length and the NIH context.

Views were mixed on whether to keep "complementary." On the positive side, it was stated, for example, that there is concern in the complementary practitioner community that those who are not physicians will feel excluded without "complementary" in the name. Dr. Briggs commented that research has found that most of the practices in NCCAM's mission are used based on the individual's decisions and in a complementary mode. On the negative side, it was expressed that "complementary" should be dropped because of length, a negative connotation in the broader scientific community, and where the field is heading. There were several comments in support of the name as "The National Center for [or "on"] Integrative Health." The few comments made about "alternative" supported dropping this word.

In response to a question about the possibility of changing from a Center to an Institute, Dr. Briggs said that "Center" is a good fit, not only because of NCCAM's size but because NCCAM tries to be a Center that brings together things happening across NIH. A member noted that a name change would present an opportunity to open the door more widely when looking at the research portfolio.

IV. Overview of the First Decade of the NIH Roadmap/Common Fund

Dr. James Anderson, Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the NIH Director, presented an overview of the first decade of that Division and the NIH Common Fund. Both were created in the NIH Reform Act of 2006, he said, as a way for NIH to work across all the ICs and as recognition that the NIH Roadmap had been successful.

The Common Fund, Dr. Anderson said, is a true trans-NIH activity, a way to take an idea and turn it into a trans-NIH implementation plan, and an approach to managing science. It has no specific mission, but rather is a process of organization and delivery. Common Fund projects start with ideas from the research community, and DPCPSI's Council of Councils has found that many of the best project ideas come from the ICs. The Fund and DPCPSI often work with coordinating committees with cross-NIH membership to reach understanding and collaboration about research activities and how priorities can be set collaboratively.

Dr. Anderson explained the criteria for potential Common Fund projects (which are similar to NIH Roadmap criteria), including that they should be novel; transformative; catalytic, short term, and goal driven, with specific deliverables; synergistic and enabling to the ICs; requiring a high level of trans-NIH strategic coordination; compelling to stakeholders; and positioning NIH as unique. Strategic planning of Common Fund programs is done in two phases and takes about 18 months.

In FY 2014, the Common Fund appropriation is about $540 million, which supports about 30 large programs ranging from very basic science to clinical work. The Common Fund does not award funds directly but instead to the ICs that oversee the projects. An ideal Common Fund project is to develop a

field or a tool that will enable others to come in and begin doing R01-type research. Even the most basic projects must demonstrate a strong ability for translation to human health. About one-third of the funding goes to investigator-initiated projects, such as the NIH Pioneer Awards. An analysis of the Pioneer Awards Program over 4 years found that its approach to funding increases innovation.

Three examples of successful Common Fund projects were highlighted. First, Dr. Anderson noted that The Human Microbiome Project generated resources that enabled researchers to comprehensively characterize the human microbiota and analyze their role in human health and disease. Dr. Briggs reported on the next two projects. The Patient Reported Outcomes Measurement Information System (PROMIS), led from the beginning by NCCAM and NIAMS, is a system of well-validated, precise instruments for assessing patient-reported health status with respect to symptoms and quality of life. PROMIS instruments have a mean of 50 percent, allowing for easier interpretation than with many other tools, and are now available in multiple languages and countries.

The NIH Health Care Systems Research Collaboratory seeks to strengthen the ability of the research enterprise to work in partnership with health care systems and transform those partnerships so that more rigorous research can occur in settings of real health care delivery. NCCAM is the funding agency for the Collaboratory and has performed all the administrative work as well as much of the scientific work. Dr. Briggs commented that although there have been challenges with the Collaboratory, substantial progress is being made. She added that having the Patient-Centered Outcomes Research Institute (PCORI) in the research world has been a positive development, and PCORI is very interested in the Collaboratory and its seven projects.

Dr. Anderson closed by announcing two Common Fund projects for FY 2015. "Accelerating Translation of Glycoscience: Integration and Accessibility" will focus on a topic—glycans—that is understudied and underappreciated but central to much of biology. "4D Nucleome" will address how overall chromosomal organization affects gene use.

Discussion. It was asked how the NIH Pioneer Awards fit into the Common Fund. Dr. Anderson noted that the Pioneer Award Program is part of the Common Fund, and was originally an experiment coming out of the NIH Roadmap on ways to stimulate innovation. He added that the Pioneer Award Program has been very rigorously evaluated, determined to be successful, and offered to the ICs. Some ICs have developed their own, similar programs. He and Dr. Briggs invited input from Council on whether the Pioneer Awards should stay within the Common Fund or undergo experimentation with a different mechanism. Dr. Briggs noted that the IC Directors are discussing whether to develop new mechanisms as alternatives to R01s, a topic sometimes simplified as "people versus projects." For example, NIH's intramural efforts are more focused on finding outstanding people than on a pre-review of exactly what their projects will be. She said that NCCAM has been happy to pick up the funding for at least one Pioneer Awardee per year, and they are exceptional scientists. She added that this is an example of tough issues around finding the necessary balance between investigator-initiated and program-led work and that one benefit of the Pioneer Awards has been to bring innovative scientists together.

V. 2014 Update on the NCCAM Intramural Research Program

Dr. M. Catherine Bushnell, Scientific Director of the Division of Intramural Research (DIR) and Senior Investigator in the Division's Pain and Integrative Neuroscience Branch, presented an update on DIR

over the past year and its strategic vision process. In 2013–2014, DIR has been growing, including by adding three tenure-track faculty members: Drs. Alexander Chesler (through the NIH Stadtman Program), Yarimar Carrisquillo, and Lauren Atlas. Dr. Chesler's lab aims to follow the flow of information from the moment it is detected by a primary afferent terminal, through the spinal cord/brainstem, to targets in the brain and to understand the changes that occur after injury and inflammation. Staff works to find the critical nodes in the circuits where therapeutic intervention has the best chance to thwart and/or reverse the progression of chronic pain. In Dr. Carrisquillo's lab, the main goal is to identify anatomical, molecular, and cellular mechanisms that underlie pathological pain states, with a focus on the amygdala. Dr. Atlas, who will join NCCAM in July 2014, will use brain imaging and sensory testing in humans to address the role of psychological factors in pain processing. She will apply computational learning models to pain perception and image analysis to address the neural mechanisms of expectancy and context-based pain modulation in healthy people and chronic pain sufferers.

Other new staff includes a nurse practitioner, and a Ph.D. physicist who is an imaging analysis expert. A medical officer (M.D.) will likely join the group as well. The program has three rooms in the Clinical Research Center and its basic lab in the new Porter Center. The Division has been divided into the Laboratory of Clinical Investigation Branch, which has two sections, and the Pain and Integrative Neuroscience Branch, with three sections. In addition, NCCAM contributes services of an acupuncturist, Dr. Adeline Ge, to the Clinical Center. Lab improvements in the Clinical Center have included adding a mock magnetic resonance imaging (MRI) scanner, which is important in pretesting, and transcranial magnetic stimulation as a physiological probe.

Dr. Bushnell discussed the intramural strategic planning being done across NIH under a directive from Dr. Collins, who has posed the question, "What should the NIH Intramural Research Program look like in 10 years, and how should we get there?" Thus, that program is preparing its first draft strategic plan, to be completed by mid-December 2014. In preparing its part of this plan, NCCAM has assembled a mandated review group, co-chaired by Dr. Briggs and Dr. Allan Basbaum of the University of California, San Francisco (UCSF). Its members are Council member Dr. David Borsook; Dr. Susan Folkman of UCSF; Dr. Maiken Nedergaard of the University of Rochester; Dr. Markus Heilig of NIDA and the National Institute on Alcohol Abuse and Alcoholism; and Dr. David Shurtleff, NCCAM Deputy Director. The group has had a teleconference and a face-to-face meeting. The Chairs of the NIH Boards of Scientific Counselors, the NIH Scientific Directors, and the IC Directors also have had a joint meeting. This varied input will inform the final NIH intramural report.

Dr. Bushnell detailed findings from the NCCAM review group meeting. The first major area is how to delineate what goes on in NCCAM's extramural versus intramural programs. The panel recommended that NCCAM continue to examine the balance between mechanistic and clinical work and how the division can inform, and be informed by, the work of the extramural community. Dr. Briggs noted that the panel found the three programs synergistic, and Dr. Bushnell agreed, adding that they are very interactive. Dr. Bushnell reported a panel member recommendation that the program not only use the National Institute of Neurological Disorders and Stroke Board of Scientific Counselors to evaluate faculty members, but have its own external review group to evaluate the program.

A Council member asked what gap the program fills and what its goal is. Dr. Briggs explained the background of NCCAM's program becoming a focal point for the NIH pain program and that Dr.

Bushnell is in the process of articulating answers to these questions in the strategic plan. In brief, much of extramural pain research has focused on peripheral nociception, with questions around central circuits receiving much less attention. A concern was expressed about setting up a program that is successful and then losing the need as extramural researchers step in. Dr. Bushnell said the program's emphasis is nonpharmacologic modulation of pain, which gets little attention or study—it is difficult to study higher-order brain circuitry—not pharmacologic modulation. Integration of human and animal work allows the tackling of hard questions. She added that there must be a balance for the staff between high-risk projects and more doable projects. Another member commented that this group has unique opportunities because of continuity.

Another panel recommendation was that the Division should strengthen its clinical roots—e.g., by creating opportunities for investigators to understand challenges of clinical care and interact directly with patients and practitioners caring for patients. The Clinical Research Center provides a unique opportunity for this. Dr. Bushnell noted that the medical officer she hopes to bring on is very interested in this, e.g., through giving patient presentations to basic scientists. She added that this clinician already has collaborations under way with various groups at the Clinical Research Center. Dr. Briggs noted as an advantage of the Clinical Center the ability to spend generous time with patients. Another Council member asked about interaction with military hospitals, such as the Walter Reed National Military Medical Center. Dr. Bushnell said that NCCAM and Walter Reed have begun talking and are mutually interested in collaboration. There was a question on how to communicate with DIR about the mechanistic work at the member's own institution. Dr. Briggs said it is a challenge to integrate what is happening at external institutions researching pain compared with NCCAM's program, and communication could be made more systematic.

The next discussion point concerned what would be most appropriate to study in the intramural program compared with the extramural program. Dr. Briggs said that the review group recommended considering whether an intervention or line of inquiry has the potential to provide mechanistic insight. She added that another point concerned the reproducibility of data in terms of applicability to this environment: the panel would like to see an environment in which negative studies are published as much as positive ones, and there is a readiness to take on unexpected results. Although publishing is important for young scientists, the culture should not be so pressured that it is difficult to also meet the highest scientific standards.

Another panel recommendation was to develop a mentoring program. Dr. Bushnell said that she thinks this is critical, and she is working on a more formalized plan for the tenure-track scientists. A further recommendation by the panel was to understand differences between rodent and human brain circuitry, and Dr. Bushnell said that the group is well situated to do so and is very interested in it. In response to the panel recommendation to develop relatable, concise messages about the program, Dr. Bushnell said the group is working on a mission statement that is formal and clear and that Council's input will be important. The program indeed plans to take a leadership role in the trans-NIH pain community, e.g., through the Pain Consortium, invited speakers, and possibly a Pain Day at NIH.

Discussion. Dr. Briggs said that the strategic planning project will wrap up soon and Council will see the draft plan. A member brought up how to promote this program's process and observed that it seems to contain three domains: (1) clinical studies; (2) the translational domain, which must be related to complementary approaches; and (3) basic science. He added that trying to get everyone to think in that

kind of integrated way would be very helpful. Dr. Bushnell agreed, noting that these domains do talk to each other and she plans to have ways to keep that integration going. Dr. Briggs added that NIH intramural programs do not have to have exactly the same box around what they do, and some of the work in influential, impactful NIH programs has been fundamental. She said she feels similarly about pain research—that NCCAM should not be in the pharmacology business, where there does not seem to be a void, but should include study of how central circuits' functioning in pain appears relevant in multiple ways to complementary and integrative approaches. She does not insist that all intramural projects be tightly tied to that box, but Council needs to keep discussing how the work best fits with mission. Dr. Bushnell noted that she plans to craft a program that can best be done in the NCCAM/NIH environment and is broadly related to NCCAM's mission.

A member commented that this program could be an opportunity to loosen the tethers somewhat from complementary approaches and take the science where it goes—including to fundamental questions about pain—and to see the program take more of a general leadership role in pain research. Another member recommended that NCCAM figure out ways to have information exchanges more often between its intramural and extramural scientists, e.g., through webinars. Dr. Bushnell's presentation at the International Research Conference on Integrative Medicine and Health 2014 was praised.

VI. Update on Chelation Therapy Activities

Dr. Alekel updated the Council on activities related to the Trial to Assess Chelation Therapy (TACT), including a concept for clearance. TACT results were presented at the NACCAM meeting of February 7, 2014. Dr. Alekel briefly recapped several major TACT results, including the noteworthy findings in the diabetes subgroup (about one-third of participants). Participants with diabetes experienced a marked reduction in cardiovascular disease endpoints, especially those who had peripheral vascular disease.

Dr. Alekel noted that NCCAM proposes to take what has been learned from TACT and do a similar study in partnership with the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Institute of Environmental Health Sciences (NIEHS). The new study would seek to replicate TACT findings in people with diabetes. It would use a sample enriched with patients with peripheral vascular disease and with women and minorities (underrepresented in the first trial) and would emphasize noncomplementary-health (i.e., conventional) sites. Outcomes of interest include cardiovascular events, safety outcomes, quality of life, pain, and cost-effectiveness. NIH would encourage that urinary minerals be assessed in relation to disease-related biomarkers, to explore potential mechanisms by which EDTA chelation therapy might exert its effects in diabetics.

Discussion. A member expressed support and asked about NCCAM's financial contribution. Dr. Briggs responded that the cost estimate is not yet final, but preliminary discussions indicate that NHLBI and NCCAM would be equal partners; negotiation is still taking place with NIDDK. Final numbers will not be known until further in the planning process, but the investment may be about $1.5 million for the first year and $4 million to $5 million over subsequent years, shared by three ICs, Dr. Briggs said. The working hypothesis is that heavy-metal toxicity underlies these results; NIEHS would support the heavy-metal studies. Dr. Briggs added that the first trial had 150 participating physicians and recruitment was a very laborious process, partly because some providers were either strongly for or against chelation therapy and were uncomfortable randomizing patients. She thinks a consensus exists

regarding appropriate equipoise for the new trial, certainly at the conventional sites, and that recruitment will be easier.

Another commenter supported the new study and added that emerging evidence appears to indicate that heavy-metal levels in underserved communities may be a major reason for higher levels of disease in those communities. Dr. Briggs said that if the phenomenon seen in TACT is robust and shows a high correlation with heavy metal–level burden, it would ultimately give a strong preventive message. There was a question whether heavy metals include metals in implants. Dr. Alekel said she does not know, but it appears from the literature that lead, mercury, and cadmium seem to be the prime heavy metals that could be targeted and also some transition elements involved in oxidative stress. Dr. Goldrosen asked for a vote on clearance of this concept, and 16 votes were in favor.

VII. Update on the National Health Interview Survey

Dr. Richard Nahin, Senior Advisor for Scientific Coordination and Outreach, and Barbara Stussman, Survey Statistician, co-presented on the survey supplement on complementary health approaches that NCCAM funded and co-designed in the 2002, 2007, and 2012 editions of the National Health Interview Survey (NHIS).

Ms. Stussman opened by noting that rigorous national surveys such as the NHIS are used at NCCAM to help inform the Center's research agenda/strategic plan. NHIS is a large, nationally representative, in-person survey conducted in American households by the National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC). In 2002, the supplement on complementary approaches had a section on adults only; in 2007, it had an adult section and a limited section on children; and in 2012, the adult and children's sections were nearly identical. Each edition has yielded data on about 35,000 adults and (when included) about 15,000 children ages 4 to 17 years. In each household surveyed, one randomly selected adult answers a range of questions related to his or her own health and health care, and in households with children, this adult acts as a proxy for questions about one child in the household.

The NCCAM-supported survey supplement covers the prevalence/frequency of use of complementary approaches during the 12 months prior to the survey (and, in 2012 for natural products, the prior 30 days), whether they were used for one or more specific health condition(s), reasons for use, whether the respondent told a conventional health care provider about the use, and out-of-pocket costs.

Ms. Stussman explained the development process for these complementary health supplements, which includes a literature review, feedback from the community on previous surveys, expert panels/workshops, interviewing/focus groups, and quantitative analysis of previous data. Among the findings from interviews, for example, were that the primary components of wellness were considered to be finding balance, being centered, and being optimally healthy.

Among the changes made to the 2012 questionnaires (compared with 2007) were restricting followup questions on yoga, tai chi, and qi gong to only those using meditation and/or breathing exercises as a component of these techniques; expanding the list of nonvitamin, nonmineral dietary supplements (NVNMDS); changing the wording "herbal supplements" to "herbal or other nonvitamin supplements"; developing a concept of wellness and adding a large set of wellness-related questions; expanding the

child survey (now the most complete survey ever on this topic); asking more questions about disclosure to health care providers; breaking down meditation by type (mantra, mindfulness, and spiritual); and surveying whether all, some, or none of the cost of these approaches was covered by insurance.

After Ms. Stussman laid the groundwork, Dr. Nahin presented an initial look at the 2012 NHIS data. First, he addressed the question of whether the use of complementary approaches has changed over time. While the NHIS questionnaires for the 3 years were not identical, where questions are very similar across years, some trends could be observed. The prevalence of use of mind and body approaches saw approach-specific changes over time. The largest increase was in use of yoga, a finding that held across all age and racial/ethnic groups. The overall use rate of NVNMDS in the prior 30 days stayed about the same in 2012 as in 2007, but changes occurred over time in the prevalence of use of specific supplements, including ginkgo, ginseng, echinacea, melatonin, glucosamine/chondroitin, and fish oil/omega-3s. Similar types of patterns in prevalence and sales were also found for a number of supplements and could possibly be interpreted as related to the release of scientific study findings.

A second topic addressed by Dr. Nahin was whether use of complementary approaches varied among nine U.S. geographic regions. A number of regional differences were seen for individual modalities and for complementary approaches overall. The Mountain States region had both the highest overall prevalence and the highest approach-specific prevalence—a finding that surprised the researchers, although Dr. Nahin noted that many supplement companies are located in that region and marketing may have an effect. The West North Central region was second for overall use of complementary health approaches, another surprising finding, Dr. Nahin said. Southern states had the lowest prevalences for both overall and approach-specific use. Dr. Nahin will deliver a much-expanded version of this talk at NIH on June 9.

Discussion. A member commented that in 2002 overall use of complementary therapies was about 38 percent and in 2012 about 33 percent, and asked if this is a trend. Dr. Nahin responded that this originated from differences in the survey; NCCAM and CDC authors have a paper now under review in which they recalculated 2002 and 2012 data only for items that compare "similar to similar"; when they did so, the rate was quite flat, with only a slight bump in 2007. Upcoming publications will discuss data on adults, children, costs associated with these therapies, and insurance coverage. Dr. Briggs noted that the NHIS data files are publicly available on the Web and are used by many academic researchers.

It was asked whether there was any variation in the incidence of back and neck pain in people who use or do not use complementary approaches. Dr. Nahin mentioned a paper he and colleagues have under review that looks at condition-specific costs from the 2007 data, including pairings. He reported a substantial overlap, although not 100 percent, between people reporting both back pain and neck pain. Another member noted that part of NCCAM's mandate is to provide information to help consumers make evidence-based decisions and asked whether information being disseminated by NCCAM and others is leading to changes over time seen in the NHIS data. Dr. Nahin responded that his team will soon submit a paper on the 2007 data and on responses to questions on why people did not use certain therapies, if they had reported not using them. Dr. Briggs added that how NCCAM assesses the value of its information resources is a very important question, and Council should return to it at a future meeting.

A member asked whether the survey team talked to the Department of Defense and the VA when developing the supplement, and Dr. Nahin said they did not. The member noted that large-scale surveys are done in this field, acceptability of complementary approaches in the military community may exceed that of the population at large, and it would be worth being able to compare the data. Another member suggested examining the National Ambulatory Medical Care Survey. Dr. Nahin responded that the survey team added questions on complementary approaches to that survey in 2012, and the data will become available to his team and CDC colleagues for analysis sometime this summer. Dr. Briggs commented, in response to a question about different types of complementary-approach users, that NCCAM thinks the most interesting analyses from the NHIS data involve different individual modalities and not the amalgamated data, which combine all kinds of users.

VIII. Updates From NCCAM Staff

1. Peer Review Meeting Formats

Dr. Dale Birkle Dreer, Chief of NCCAM's Office of Scientific Review (OSR), opened her presentation by explaining that NIH has embarked on a project to enhance its peer review process, and part of that process is evaluation and continual improvement. Dr. Dreer then presented information on peer review meeting formats that the Center for Scientific Review (CSR) and NIH ICs use to conduct the first level of peer review. First, she discussed the core values of NIH peer review: expert assessment, transparency, impartiality, fairness, confidentiality, integrity, and efficiency. All reviews must adhere to these values, and she gave examples of means for ensuring that they are upheld—e.g., through a conflict of interest policy; common review criteria to be applied equitably to all applications; and different review meeting formats. In addition to meeting core values, NIH must meet certain legal requirements regarding the peer review process.

Dr. Dreer described and presented the advantages and disadvantages of the five formats OSR uses for review meetings: face-to-face, teleconference, internet-assisted, video-assisted, and editorial (two-stage) reviews. A table, based in large part on CSR data on a 1-year period ending in March 2014, depicted the different formats and their application capacities, relative staff burdens, and costs per application. Dr. Dreer noted that while cost and efficiencies are very important factors, they are not the only factors. Each type of review meeting has limitations and advantages, and a limitation in one format may be an advantage in another. The NCCAM Office of Scientific Review chooses the review format that it determines will result in the best reviews of the applications. She anticipates continuing to hold face-to-face meetings, yet also taking advantage of newer technologies as much as possible to improve efficiency, while maintaining the other core values of peer review at NIH.

Discussion. It was asked whether, with the new multi-application system, any data exist on increases in resubmissions. Dr. Dreer responded that applicants can still have only one resubmission and that it will take at least a year to find out whether there are any increases. A member expressed support for OSR and CSR looking at better ways to hold reviews but also concern about fairness in terms of adequate time for discussion. Another member supported the idea of two-stage reviews. Dr. Dreer said that part of NCCAM's mission is to have exchange with the scientific community and even if applicants do not get funded, they still receive valuable feedback.

2. NCCAM Research Training Portfolio

Dr. Alberto Rivera-Rentas, Program Director, updated Council on NCCAM's research training portfolio. The Center's goal in this area, which ties to Strategic Objective 4 in the NCCAM Strategic Plan, is to increase the number, quality, and diversity of well-prepared and skilled investigators with knowledge and expertise in complementary and integrative health. Dr. Rivera-Rentas explained the funding mechanisms used for research training at NIH and presented graphics of the programs available at various stages of training and career development. He summarized NCCAM's vision and expectations—for example, awardees are expected to develop skills across multiple areas, including scientific knowledge, creativity, research, grantsmanship, and the business of science.

Dr. Rivera-Rentas discussed the programs that NCCAM offers in each category and gave examples of program announcements. New funding mechanisms for NCCAM include TR90/R90, F31 Parent, F31 Diversity, and Predoctoral F30 (dual-degree). NCCAM participates with the NIH Loan Repayment Program, a valuable resource that encourages outstanding health professionals to pursue careers in biomedical, behavioral, social, and clinical research.

Two graphics illustrated the funds and their distribution associated with NCCAM's training/career-development awards. NCCAM provides its own policy guidance for various types of research training programs. Some recurrent challenges with training/career development applications have included the degree of alignment with NCCAM's strategic plan and research priorities; stand-alone clinical studies proposed without adequate resources; natural product projects lacking adequate product assurances (for example, an Investigational New Drug application, where appropriate); available resources insufficiently detailed; inexplicit mentor support statements; unsupportive institutional environment; and/or unclear institutional commitment.

NCCAM's training/career development program conducts an active outreach effort to applicants and potential applicants through teleconferences, the NCCAM Web site, presentations at meetings, webinars, and the NCCAM Research Blog. In the future, Dr. Rivera-Rentas will be seeking input from Council on outreach efforts. Dr. Briggs noted there may be a Council working group on this topic. No comments or questions followed this presentation.

IX. Public Comment and Adjournment

No public comments were offered.

The meeting adjourned at 3:45 p.m.

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

Martin Goldrosen, Ph.D.
Executive Secretary
National Advisory Council for
Complementary and Alternative
Medicine

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