

**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-FIRST MEETING
February 7, 2014**

NACCAM Members Present

Dr. Brian Berman, Baltimore, MD
Dr. Donald Brater, Indianapolis, IN¹
Dr. David Borsook, Waltham, MA
Dr. Daniel Cherkin, Seattle, WA²
Dr. Alice Clark, University, MS^{1,2}
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Tracy Gaudet, Washington, DC
Dr. Jane Guiltinan, Seattle, WA
Dr. Frances Henderson, Jackson, MS
Dr. Steven Hersch, Charlestown, MA¹
Dr. Janice Kiecolt-Glaser, Columbus, OH¹
Dr. David Kingston, Blacksburg, VA
Dr. John Licciardone, Fort Worth, TX²
Dr. Richard Niemtzow, Clinton, MD
Dr. Philippa Marrack, Denver, CO
Dr. Lloyd Michener, Durham, NC
Dr. Deborah Powell, Minneapolis, MN²
Dr. Lynda Powell, Chicago, IL
Dr/ Eric Schoomaker, Bethesda, MD¹
Dr. Chenchen Wang, Boston, MA

SPEAKER

Dr. Gervasio Lamas, Miami Beach, FL

¹Ad-hoc

²Telephone

NACCAM Members Not Present

Dr. Scott Haldeman, Santa Ana, CA

NIH Staff Present

Lynn Adams, ORWH, NIH
Barbara Sorkin, ODS, NIH
Diane Hannemann, OD, OSP, OSMR, NIH

Members of the Public

Erica Froyd
Miles Brawn
Tyler Cymet

I. Closed Session

The first portion of the forty-fifth 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 315 applications were assigned to NCCAM. Of these, 225 were reviewed by NCCAM, 90 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 93 applications, requesting \$29,757,598 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 June 2013 meeting and the October 2013 teleconference meeting were approved unanimously.

III. NCCAM Director's Report

Dr. Briggs began her report to Council by welcoming the new Council members. She then discussed the NIH budget. The Fiscal Year (FY) 2014 budget is slightly more than \$30 billion, substantially below the sequester amount in 2013. A slide on national spending in six major countries for scientific research and development from 2012 to 2013 showed that spending fell in the United States. NCCAM's budget pattern has tracked with that of NIH. NCCAM's budget for FY 2014 is \$124.3 million under the January 2014 omnibus appropriations bill, which is lower

than the President's proposed budget (\$129 million) but an increase over post-rescission/sequestration (\$120.8 million).

For the benefit of new Council members, Dr. Briggs gave an overview of NCCAM's budget and its mechanisms and the Center's history, legislative mandate, mission, vision, and portfolio. NCCAM's legislative mandate does not really define complementary and alternative medicine, which has created a large gray zone. One useful concept when thinking about this topic and research priorities has been integration—i.e., what health practices are either likely to be or are being integrated into health care systems. Related to this, NCCAM also considers questions of what medical students should learn and health policy. The NCCAM portfolio is broad, but the largest funding category by condition is chronic pain and by treatment type is botanicals. The Center is the largest single funder of research on complementary health practices at the NIH (in FY 2013). A graphic of NCCAM's four-stage pipeline model for addressing research questions was explained.

In July 2012, Dr. Catherine Bushnell was recruited to be NCCAM's new Scientific Director and launch the Division of Intramural Research's new program on the brain's role in perceiving, modifying, and managing pain. Since then, she has been recruiting outstanding young investigators to perform mechanistic studies related to pain. The Division's other recent activities include animal protocols, clinical protocols, journal publications, and a pain-related seminar series.

NCCAM has been leading implementation of the NIH Health Care Systems Research Collaboratory, which is working to strengthen research methods in real-world effectiveness studies. The methods to be developed will enable learning, inform larger-scale studies in outcomes and effectiveness research, and build "PCORI readiness" (i.e., for the Patient-Centered Outcomes Research Institute). Among its activities, the Collaboratory has released two Requests for Applications (RFAs) and made awards for five potentially high-impact Pragmatic Trial Demonstration Projects. There is potential for Collaboratory-PCORI partnership. Dr. Briggs has been appointed by NIH Director Dr. Francis Collins as the NIH's representative to the steering committee of the PCORI-funded National Patient-Centered Clinical Research Network. PCORI increasingly emphasizes listening and talking to patients and bringing them into dialogue about research questions; this is also relevant to NCCAM, with its focus on practices widely used by Americans. Dr. Briggs expressed appreciation for Council's help to strategically shape NCCAM's research agenda and range of research questions so that they may be sensitive to challenges faced by patients, providers, and policymakers.

Dr. Briggs announced that she and former Deputy Director Dr. Jack Killen had a Viewpoint article published in the August 21, 2013, issue of *JAMA: the Journal of the American Medical Association*. New senior appointments at the NIH were announced. The legislative update included the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative; the \$100 million set-aside to the National Institute on Aging for Alzheimer's research; the President's FY 2015 budget proposal, to be delivered to Congress in early March; and the strong interest evident on Capitol Hill in mindfulness meditation. Dr. Robert Califf of Duke University delivered NCCAM's annual Stephen E. Straus Distinguished Lecture in the Science of Complementary Health Therapies, "A New Fabric for Clinical Research: Application to the Pain Problem." The Office of Communications and Public Liaison (OCPL) has been active in

developing new approaches in science literacy efforts, social media, and other technologies such as e-books and responsive Web design. Dr. Briggs announced three new Council working groups that will address strengthening collaborations with the U.S. Department of Veterans Affairs (VA) and the U.S. Department of Defense (DoD); strategic planning for the NIH Intramural Division, part of an NIH-wide effort; and effectiveness research on mind and body interventions.

Discussion. A question was asked as to how NCCAM is addressing the many treatments that may be cost effective but involve a time commitment that may not be practical. Dr. Briggs responded that the foremost question should be whether the treatments are effective. NCCAM and NIH have not tended to take on analysis of the tradeoffs in the economic piece of the question. The NIH has traditionally viewed detailed economic analysis as an area in which it does not have the in-house expertise for oversight, although that does not mean that such questions do not get placed on the table nor that the kind of data to address them should not be collected. For the policymaking and payment aspects of economic studies, the NIH encourages partnership with other funders.

IV. The NIH Initiative on Enhancing Research Reproducibility and Transparency

Dr. David Shurtleff, NCCAM Deputy Director, presented on the NIH's initiative to enhance the reproducibility and transparency of research findings. This was described as a widespread problem in all areas of research; at present, the NIH is focusing on preclinical research. Examples of problems include difficulty replicating published data and insufficient or deficient reporting of methodological approaches. Dr. Shurtleff noted that an article by Dr. Collins and NIH Principal Deputy Director Dr. Lawrence Tabak on this topic appeared in the January 30, 2014, issue of *Nature*.

The Institute and Center (IC) Directors consider this topic to be of serious concern. The National Cancer Institute and National Institute of Neurological Disorders and Stroke have held stakeholder workshops on it, and Dr. Collins has formed an ad hoc group to address it. That group has identified the three major underlying issues as poor training, poor evaluation, and perverse reward incentives—for example, incentives for researchers to publish results only in top-tier journals and/or too quickly, which could arise from pressure to obtain the next grant.

The ad hoc group has developed five core principles to address these issues: raise community awareness, enhance formal training, improve the evaluation of applications, protect science's integrity by adopting more systematic review processes, and increase stability for investigators. Specific recommendations map back to these principles and will be implemented by all ICs. For example, the NIH is developing a pilot course from the Office of Intramural Research on study design; once tested and proven effective, it would be made available to all extramural researchers and trainees. Overall, the effort is having an impact, Dr. Shurtleff said, as can be seen, for example, in some prominent journals' significant changes to process. Some ICs are pursuing projects related to this initiative, and Dr. Shurtleff offered five ideas for activities NCCAM could consider.

Discussion. Discussion topics included how to define replication; what is replicable; the feasibility of full, true replication; and challenges related to animal models, such as finding optimal models and translating results of studies. Replication is difficult to standardize and incentivize. The amount of preclinical paperwork for investigators is already burdensome, without adding more. Dr. Briggs noted that all the issues brought up by the discussants are also ones that the NIH has heard.

V. Chelation Therapy in Coronary Artery Disease: The Trial to Assess Chelation Therapy

Dr. Gervasio Lamas, a cardiologist and the chairman of medicine at Mount Sinai Medical Center, Miami Beach, Florida, presented on a recently completed, NCCAM-cosupported, multicenter, double-blind clinical trial on which he is principal investigator. The Trial to Assess Chelation Therapy (TACT) tested a complementary approach that has a 58-year history and is in wide use to treat heart disease.

The TACT participants, at 134 sites in the United States and Canada, were 1,708 adults aged 50 and older who had suffered a heart attack at least 6 weeks before enrollment and had a baseline creatinine level of 2 or lower. They were randomly assigned to receive a two-part treatment modeled after the chelation therapy approach most used in the United States. For one part, the active intervention was an intravenous solution centering on the molecule disodium ethylene diamine tetra-acetic acid (EDTA), which was compared with a placebo solution. For the other part, a high-dose regimen of 28 vitamins and minerals, taken as three pills twice per day, was compared with placebo pills. Thus, the study was multifactorial with four treatment arms.

The infusions numbered 40 and lasted at least 3 hours apiece, with the first 30 given weekly followed by 10 maintenance treatments 2 to 8 weeks apart. Even though more than 55,000 infusions were given, compliance rates were high. Most participants also took standard medicines for heart attack survivors. They were followed for a minimum of 1 year and up to 5 years. The team assessed a primary composite endpoint of major adverse cardiovascular events: recurrent heart attack, stroke, hospitalization for angina, coronary revascularization, and death from any cause.

In this population receiving optimal therapy, for the primary endpoint, the active chelation treatment produced a relative risk reduction of 18 percent compared with placebo, which constituted a modest benefit. The individual endpoints did not occur with sufficient frequency for statistical significance, but the hazard ratios were all less than 1. Two subgroup analyses showed that: (1) The same essential result occurred whether study sites were complementary and alternative practices or conventional practices, and (2) benefits were notably high among participants who self-identified as having diabetes.

The high-dose vitamin regimen somewhat reduced cardiovascular events (11 percent, which was not statistically significant) compared with placebo. This reduction carried over to the combination of chelation plus oral vitamins. When the combination of active infusion plus active vitamins was compared with the combination of placebo plus placebo, there was an enhanced reduction of clinical events (HR [95 percent CI]: 0.74 [0.57, 0.95], $P=0.016$); this was of

sufficient magnitude to be clinically significant (5-year number needed to treat=12). The subgroup with diabetes—a very high-risk group of heart attack survivors—demonstrated higher benefit from chelation to a degree that was clinically significant, including a 41-percent reduction in cardiovascular endpoints and 43-percent reduction in total mortality.

Dr. Lamas proposed that the effect size creates a crossroads situation: whether to implement the treatment, replicate the study, and/or perform basic science to understand mechanisms. All these options have risks and challenges. He proposed a clinical trial to replicate the results in the population with diabetes and vascular disease, extend eligibility to peripheral artery disease, and explore mechanisms, especially the heavy-metals hypothesis.

Discussion. Dr. Briggs provided some NIH history on TACT. Both NCCAM Founding Director Dr. Stephen Straus and the National Heart, Lung, and Blood Institute (NHLBI) then-Director Dr. Claude L'Enfant were involved in the initial decisions to fund the study. From the start, the trial has been a close partnership between NCCAM and NHLBI, with costs borne essentially 50-50. For the past 5 to 6 years, NHLBI has had primary oversight of the trial. Dr. Elizabeth Nabel, former NHLBI Director, convened an expert panel of cardiology experts to review the TACT study. That committee strongly recommended study completion. Dr. Briggs praised Dr. Lamas's leadership of the trial and the coordinating center at Duke University.

A member asked whether, given the high burden of infusion on patients and the medical system, future study could use an oral approach. Dr. Lamas said that an oral approach would have to be provided if the treatment were to be generalized, as the cost otherwise would be extreme. The infusions largely stop by 18 months, and it appears that the statistical curves may continue to separate; thus, there could be some legacy to the infusions. Given the findings on reducing cardiovascular events and improving survival, he does not think it would be difficult to convince many more patients to undergo this kind of regimen.

In response to a question about number of infusions, Dr. Lamas noted that all aspects of the study were designed after receiving input from chelation practitioners, including sufficient number of infusions. The practitioners initially recommended 50 but considered 40 acceptable. The topic of toxicity was brought up. Dr. Lamas said that the team checked calcium 10 times during the rapid-infusion phase and selected length of infusion time based on calcium level corrected for albumin; e.g., if that level was under 8, there was no infusion. Only one patient acquired symptomatic hypocalcemia. Asked whether it could be determined from urine exactly what is being excreted (including heavy metals) and the best number of infusions, Dr. Lamas responded that although the team had not been funded for obtaining biological samples, it would be critical to do so in the future. Essential heavy metals needed in the body, such as copper and chromium, were repleted orally. A question concerned the role of heavy-metal exposure from the environment. Dr. Lamas observed that people do have heavy metals in their bodies from the environment, e.g., from leaded gasoline (legal years ago) and metal pipe solder. There was agreement it would be important in future work to find ways to measure this aspect more closely.

Dr. Briggs said that NCCAM is engaged in discussions with NHLBI and the National Institute of Diabetes and Digestive and Kidney Diseases about next steps. She agreed with the need to understand what is being excreted in urine but cited study replication as a core need. She added that although Dr. Lamas did not present the epidemiology data suggesting that heavy-metal

toxicity may be a factor in cardiovascular disease, some of these data appear suggestive and offer hints of particular susceptibility for diabetics.

VI. Council Operating Procedures

Dr. Goldrosen reviewed Council operating procedures, including processes for NCCAM reports to Council, secondary review of grant applications, approval of concepts for research initiatives, and handling of appeals from applicants. Council unanimously passed a motion approving the operating procedures as presented.

VII. NCCAM's Approach to Clinical Studies

Dr. Emmeline Edwards, Director of the NCCAM Division of Extramural Research, led a presentation on NCCAM's oversight of clinical research. She opened by sharing NIH's definition of clinical trials and discussing general NIH considerations for trials, including research priority setting, potential return on investment, requirements relating to application content and review criteria, and trial monitoring.

Major issues being discussed at NIH about clinical trials include too-small size, non-timely starts, inadequate recruitment numbers, mixed aims, high costs, and, often, unpublished results. One report on the problem of unpublished results appeared in the *New England Journal of Medicine* on February 20, 2014, by Dr. David Gordon, et al.; NCCAM's trials fit with that picture. The Center is actively working with investigators to form strong partnerships from the start, including the need to publish, even if a finding is negative.

Dr. Wendy Weber, Program Director, delivered the second part of the presentation. She noted that NCCAM supports a higher percentage of clinical studies (56 percent in FY 2013) than the NIH average (40 percent), and strong oversight and good stewardship of that work is very important for the Center. She explained that the number of R01 awards has been increasing and the number of R21 awards has been decreasing over time.

NCCAM has assembled its own Clinical Trials Working Group, which issued three recommendations for shaping NCCAM's clinical trials portfolio: (1) develop new initiatives to support clinical trials in priority areas; (2) encourage planning grants and feasibility studies before supporting large-scale trials; and (3) leverage trans-NIH initiatives for clinical trials that align with NCCAM priorities.

The public is highly interested in mind and body interventions and uses them at a high rate. Dr. Weber proposed a six-stage model for mind and body studies, expanding upon NCCAM's existing four-stage model for the translational pipeline. This multistaged approach is necessary, she said, for full development and testing of nonpharmacologic approaches, followed by movement into dissemination and implementation. NCCAM's goals for this portfolio are that the research is focused and aligned with the Center's Strategic Plan; is conducted at the appropriate stage based on current evidence; is statistically powered to assess clinically meaningful

outcomes; is realistic in timeframes and budgets; and tests hypotheses that will guide future research. Challenges to be addressed include applications that are not always aligned with NCCAM priority areas, investigators who propose mixed mechanistic and efficacy study designs, and standard NIH review criteria that emphasize innovation. Solutions were proposed to each challenge.

Dr. Weber closed with NCCAM's proposal for a strategy. One part consists of new initiatives for mind and body trials that support studies across the staged model and test in priority research areas for NCCAM, such as pain management. Relevant, specific review criteria would be used to assess proposed trials' feasibility, methods, and impact. Secondly, NCCAM would continue to support mechanistic studies via separate initiatives and parent R01/R21 funding opportunity announcements (FOAs).

Discussion. It was recommended to involve patients and providers in study design. The characteristics of populations for study must be stated precisely, and motivation for change should be included. Polarized reviews can be a problem and are an area in which Council can help. Systematic reviews are valuable, including for identifying research gaps. Better ways of measuring health, well-being, and wellness are needed, as are ways to study how to keep people from crossing over to injury and disease. The trajectory for health and well-being is not synonymous with the trajectory for preventing and managing disease. Nonpharmacologic approaches to pain management are a compelling area to consider in building carefully up to trials. The best control group should be chosen for any given question (versus always using an attention control); ideally, it should be best in class, even if consisting of a combination of approaches.

VIII. Scientific Priorities for NCCAM's Natural Products Portfolio

Dr. Craig Hopp, Program Director, presented a proposal that he developed, along with Dr. Edwards and Program Directors Drs. John Williamson and Carol Pontzer, for the restructuring of NCCAM's natural products portfolio. This effort was also shaped by numerous internal and external meetings and evaluations of NCCAM and NIH investments in this area. The natural products portfolio, currently about half of the Center's extramural investment, was very broad in its early years. The proposed reshaped portfolio is more focused and is built around four integrated priorities. Dr. Hopp summarized current efforts under those priorities and offered several examples of initiatives that could be developed.

The first priority is interactions—i.e., how natural products interact with each other, pharmaceuticals, the microbiome, and genetics/epigenetics. Data show that natural products, alone and together, can act at many levels and with synergy. Complex interactions can be at the heart of their perceived benefits and risks. Cutting-edge technologies can make better characterization possible. The topic of interactions is a major public health issue that uniquely fits NCCAM's mission and priorities, requires a focused, systematic effort, and has the potential for a very high impact on patient care.

The second priority is methodologies, both new ones and the integration and improvement of existing ones. NCCAM would drive the research forward by supporting innovative leaders and approaches to address current limitations. Methods to improve chemical characterization and biological characterization and address yield and supply challenges are major needs.

The third priority is exploration—priorities three and four are of lower profile and represent more “down the road” interest. NCCAM would encourage high-risk, high-reward investigation that takes advantage of global biodiversity, would require multidisciplinary research that is outside the box, and would want to see cutting-edge tools employed.

The fourth priority is resilience. Although the public uses dietary supplements mostly for health maintenance and disease prevention, very little research has addressed their contribution to resilience. An array of model systems is being developed to examine resilience, and NCCAM could hold a workshop to explore such models and opportunities related to natural products. In closing his talk, Dr. Hopp said that addressing all these priorities will require a more hands-on approach and that this greater focus would yield a smaller “garden” but one that hopefully has more impact on moving the field ahead.

Discussion. In response to questions about further focusing interactions research, Dr. Hopp said that NCCAM would focus on pharmacokinetic interactions. Dr. Briggs added that NCCAM, after separate planning sessions, now envisions a two-part approach: (1) having continued openness to innovative mechanistic work on new transporters that may be an important basic piece and (2) focusing on a small number of natural products and narrow-therapeutic-index-category drugs that they might modulate, in an approach to optimize methods. A very large body of literature shows diverse approaches, but no standards for prioritizing which outcomes are likely to be clinically significant. Applicants will be encouraged to propose a strategy for best practices in studying these interactions, taking a small set of important cases. Dr. Briggs described the two biggest priorities in moving ahead with interactions research as strengthening the methodology and figuring out the best first steps.

Another question concerned participation by the U.S. Food and Drug Administration (FDA) in NCCAM’s efforts on interactions. Dr. Briggs responded that two FDA staff have been participating in NCCAM-sponsored meetings and are highly supportive of approaches to develop best practices, in part because the FDA would eventually benefit.

Resilience was also raised as a topic, including its definition. It was recommended that NCCAM not limit its thinking and efforts on resilience to the concept of disease states. Dr. Briggs expressed that resilience is important, and she is optimistic about the potential to promote it through mind and body practices; she is less optimistic in this respect concerning natural products, as even healthier eating is a “tough sell.” The last discussion topic was advanced technology, including the mining of huge datasets (e.g., of health care networks), building large open-access databases as exist in the chemistry field, and supporting cost-effectiveness in studies.

IX. Updates From NCCAM Staff

1. NIH and the BRAIN Initiative

Dr. Shurtleff presented an overview of NIH/NCCAM participation in the BRAIN Initiative launched in April 2013 by President Obama. BRAIN is designed to revolutionize understanding of the human brain by accelerating the development and application of innovative technologies. The science is ready for these challenges, Dr. Shurtleff said. The NIH is investing \$40 million in the effort in FY 2014. The NIH Advisory Committee to the Director convened a working group of experts, the BRAIN Working Group, which delivered an interim report containing nine recommendations of high-priority research areas for FY 2014.

NCCAM is a member of the NIH Blueprint for Neuroscience Research, which has formed project teams built around themes in the interim report. Dr. Shurtleff is a member of the team on overall coordination. Working extremely rapidly, the Blueprint and participating NIH ICs were able to release six related FOAs in December 2013: three focusing on circuit-level analysis, two on the cellular level of analysis, and one on next-generation imaging. The BRAIN initiative, Dr. Shurtleff concluded, has the potential for wide-ranging benefits.

Discussion. Dr. Briggs stated that this area has much potential for NCCAM's portfolio. The Center is investing in imaging, with a key focus on better understanding the modulation of pain—e.g., by emotional states—and if the research methods are significantly improved, that will aid this effort.

2. Nonpharmacologic Approaches To Managing Pain and Comorbid Conditions in U.S. Military Personnel, Veterans, and Their Families

Dr. Kristen Huntley, Program Director, reported on NCCAM's efforts to encourage research in this topic area. Currently, the Center is using a phased approach: Phase 1, consisting of PA-12-160; Phase 2, of PA-13-075; and Phase 3, currently at midpoint, of three linked RFAs: AT-14-003, -004, and -005. These focus on nonpharmacologic approaches to managing pain and comorbid conditions and are partnerships with the National Institute on Drug Abuse and the VA. NCCAM intends to commit \$2 million in FY 2014 to this effort and award three to four new grants. The major areas of emphasis are pilot and feasibility studies (R34 mechanism), clinical trials and intervention studies (R01), and health services and observational studies (R01). Dr. Huntley also noted NCCAM's participation in the R34 mechanism of RFA-DA-13-013, under which two grants were awarded.

A work group will be formed on this topic within Council to advise on strategies to strengthen collaborations with the DoD and the VA and on potential development of a research initiative. NCCAM will continue to work on building collaborations. The Center remains focused on a mission of supporting research that could ultimately improve health and alleviate suffering.

Discussion. Dr. Briggs commented that this area is one that is highly visible and of great public interest and potential. It will continue to be discussed with Council. In some ways, she said, a real-world experiment is taking place as complementary approaches are incorporated into military health care, with some approaches having evidence and others lacking it.

3. Twitter and Twitter Chats: NCCAM's Best Practices and Lessons Learned

Ms. Alyssa Cotler, Director of OCPL, described activities led by her office pertaining to Twitter, a social networking and microblogging service. NCCAM's Twitter chats take place approximately monthly for 1 hour. The underlying purposes include to provide science-based resources and information directly to an interested, engaged public; hear participants' questions and viewpoints directly; position the Center as the authoritative source of science-based information; and raise that information's profile, not only to chat participants but also to their followers. Another key reason is collaboration—NCCAM has had very fruitful collaborations with other NIH components and nongovernmental organizations that provide added subject expertise. With social media, the most mileage is gained through engagement, and momentum builds over time. Ms. Cotler explained the process of planning, promoting, and conducting chats and evaluating their impact using metrics.

Discussion. Dr. Briggs noted that NCCAM uses rigorously reviewed text as sources in these chats, and key messages include the importance of seeking out research and data when making health care decisions. Dr. Briggs stated that these chats are having substantial impact. She sees a question for NCCAM as how to engage stakeholders and thinks that the Center will gradually learn the extent to which social media can be part of that effort.

4. The Arts in Palliative Care for Symptom Management: Funding Opportunity Concept

Dr. Briggs noted that NCCAM has had an ongoing dialogue with the National Endowment for the Arts on the role of arts therapies in health. Out of this dialogue, she said, NCCAM has developed a plan for a collaborative initiative. She introduced Dr. Lee Alekel, Program Director, who presented a funding opportunity concept that would be a partnership between NCCAM, the National Institute on Nursing Research (NINR), the Office of Research on Women's Health, and the Office of Behavioral and Social Sciences Research. Its purpose would be to foster research on the potential for arts-based approaches to enhance palliative care for individuals living with multiple symptoms related to chronic or terminal illness. This concept fits squarely within NCCAM's portfolio, Dr. Alekel said, because of the Center's strategic goal to advance the science and practice of symptom management.

In 2011, NINR led a 3-day workshop cosponsored by NCCAM with other NIH partners, "The Science of Compassion: Future Directions in End-of-Life and Palliative Care." One of the unaddressed issues in palliative care that emerged from this event was the integration of mind and body approaches. The rationale for Dr. Alekel's concept is that the arts have the potential to prevent, ameliorate, or help treat symptoms and health-related conditions, and research is needed to understand the role of the arts in optimizing palliative care strategies.

Preliminary evidence from quite small studies suggests that arts interventions in patients with chronic diseases have a link to reduced levels of pain, stress, anxiety, and fatigue, as well as improved psychosocial and quality-of-life outcome measures. However, research is needed to build a stronger evidence base for the role of the arts in palliative care for symptom management and to integrate palliative care effectively into health care practices.

Discussion. Two members of Council said they had previously been skeptical about this topic but are now supportive, one from personal reports and the other from preparing a recent literature review. Dr. Alekel mentioned that, among the arts, music has the most evidence to date.

X. Public Comment and Adjournment

No public comments were offered.

The meeting adjourned at 4:00 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

Josephine Briggs, M.D.
Chairperson
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