

**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 TWENTY-EIGHTH MEETING
September 5, 2007**

NACCAM Members present

*Dr. Paul Aisen, Washington, DC
Dr. Lori Arviso Alvord, Hanover, NH
Dr. Stephen Barnes, Birmingham, AL
Dr. Carlo Calabrese, Portland, OR
*Dr. Lupo Carlota, Memphis, TN
Dr. Fabio Cominelli, Charlottesville, VA
Dr. Silvia Corvera, Worcester, MA
Dr. Jeanette Ezzo, Baltimore, MD
Dr. Joan Fox, Cleveland, OH
Dr. Margery Gass, Cincinnati, OH
*Dr. Michael Irwin, Los Angeles, CA
Dr. Ted Kaptchuk, Boston, MA
Dr. Bala Manyam, Odessa, FL
Dr. Joel Pickar, Davenport, IA
Dr. Bruce Redman, Ann Arbor, MI
*Dr. Herman Taylor, Jackson, MS
Dr. Frank Torti, Winston Salem, NC
Dr. Stefanie N. Vogel, Baltimore, MD
*Dr. Larry Walker, University, MS

*Ad hoc members

NACCAM Members not present

Dr. Madhulika Agarwal, Washington, DC
Dr. Sheldon Cohen, Pittsburgh, PA
Sec. Michael Leavitt, Washington, DC
Dr. Richard Niemtow, Clinton, MD
Dr. Danny Shen, Seattle, WA
Dr. Elias Zerhouni, Bethesda, MD

NIH Staff Present

Ms. Andrea Collins, National Cancer Institute
Mr. Dan Cilo, NCCAM Clearinghouse
Dr. Timothy Hays, Office of the Director

Ms. Suzanne Niemeyer/ NCCAM Clearinghouse
Ms. Maggie Petersen, NCCAM Clearing House
Dr. Marni Silverman, National Institute of Mental Health
Ms. Linda Southworth, National Cancer Institute
Dr. Christine Swanson, Office of Dietary Supplements
Ms. Jenna Zhang, Office of Extramural Research

Members of the Public

Virginia Bader
Carol Callaway
Christine Choate
Marcia DeFalco
Eileen Francis
Aviad Haramati
Cristopher Herrera
Laura Honesty
Janet Kahn
Erin Loomis
Lynn Marble
Martha Menard
Georgia Persinos
Julie Phan
Stephen Shannen
Rachel Soloveichik
Shawn K. Stout
Ana Tavakoli
Tamara Thompson-Johnson

I. Closed Session

The first portion of the 28th 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 263 applications were assigned to NCCAM. Of these, 214 were reviewed by NCCAM, 49 by Center for Scientific Review. Applications that were noncompetitive, unscored, or were not recommended for further consideration by the scientific review groups were not considered by Council.

Council agreed with staff recommendations on 156 applications, requesting \$ 51,429,207 in total costs.

II. Open Session—Call to Order

The open session of the NACCAM meeting convened at 1 p.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meeting on June 1, 2007, were approved.

Dr. Goldrosen noted that the next Council meeting is scheduled for Friday, February 1, 2008.

Dr. Goldrosen introduced Dr. Jack Killen, who was recently named Acting Deputy Director of NCCAM. Dr. Killen is standing in for Dr. Margaret Chesney, who is on temporary assignment with the NIH Office of Behavioral and Social Sciences Research (OBSSR).

Dr. Killen introduced Dr. Ruth Kirschstein, Acting Director of NCCAM, who joined the meeting via telephone. Dr. Kirschstein welcomed participants and visitors to the meeting.

Dr. Killen welcomed four ad hoc Council members: Dr. Paul S. Aisen, Dr. Lupo T. Carlota, Dr. Michael R. Irwin, and Dr. Larry A. Walker.

III. Report From the Acting Deputy Director

NCCAM Organizational Update

Dr. Killen noted the departure of Dr. Marc Blackman, Division of Intramural Research, and Dr. Chesney's temporary assignment with OBSSR. He also welcomed Jean McKay to her position as Director of NCCAM's Office of Policy, Planning, and Evaluation.

Legislative Update

Dr. Killen reported that Dr. Kirchstein, along with directors of four other NIH institutes and centers, testified before the Senate Committee on Appropriations' Subcommittee on Labor, Health and Human Services, Education, and Related Agencies on June 22, 2007. After providing an overview of recent NCCAM activities, Dr. Kirschstein responded to Senators' questions on administrative and scientific matters ranging from statutory requirements for the composition of NACCAM to the effect of genetic variation on an individual's response to CAM therapies. Dr. Killen noted that the subcommittee members showed a high level of interest and engagement during Dr. Kirchstein's testimony.

Stakeholder Dialogue

Dr. Killen reported that more than 150 people participated in the day-long NCCAM Stakeholder Dialogue on June 20, 2007, on the NIH campus in Bethesda, Maryland. Participants represented complementary and alternative medicine (CAM) schools; CAM and conventional professional associations; research, academic, and training institutions;

patient organizations; and industry groups. During a general session and breakout sessions on research, research training, and outreach, participants commented on NCCAM's activities and priorities. A summary of comments is available at nccam.nih.gov/dialogue.

Loan Repayment Program

Dr. Killen discussed NCCAM's participation in NIH's Loan Repayment Program. The program aims to recruit and retain independent research investigators, especially new investigators, by helping to repay all or part of their educational loans. In FY 2007, NCCAM was assigned 26 loan repayment applications. Based on peer review, NCCAM funded 13 of the applications; 6 funded candidates have CAM doctoral degrees.

AHRQ Meditation Report

Dr. Killen described the results of an Agency for Healthcare Research and Quality review of the research literature on meditation practices for health, funded by NCCAM in January 2005. The review identified 813 studies. It found some evidence of health benefits from meditation; however, firm conclusions on the effects of meditation practices for health cannot be drawn based on the available evidence. More rigorous research is needed. NCCAM will use the AHRQ study results to guide future funding of meditation research and to develop a workshop on research issues.

Budget Update

Dr. Killen discussed NCCAM budgets for FY 2007 and FY 2008. The budget authority for FY 2007 (which ends September 30, 2007) is \$121,371,000. Anticipated reductions in the original appropriation—the Labor/HHS rescission and NIH Roadmap contribution—did not take place. For FY 2008, the President's budget request places NCCAM's net budget at \$121,699,000; the proposed House budget is \$123,380,000; and the proposed Senate budget is \$124,213,000. House and Senate negotiations will take place before a final bill is sent to the President.

IV. NIH Research, Condition, and Disease Categorization

Dr. Goldrosen introduced Dr. Timothy Hays, Director of the NIH Research, Condition, and Disease Categorization (RCDC) Project, which is located within the Office of the Director of NIH. Dr. Hays described RCDC, an electronic system that will sort all NIH research investments into approximately 360 standardized categories. The new system will more clearly and efficiently report NIH research spending to Congress and the public and will facilitate research portfolio analysis. NIH will introduce RCDC to the public in summer 2008 and will launch the system on the NIH Web site in February 2009, using FY 2008 projects.

V. Concept Review: CAM Approaches in the Management of HIV Disease and Its Complications

Dr. Killen introduced Dr. Carol Pontzer, NCCAM Program Officer, Division of Extramural Research and Training. Dr. Pontzer presented a concept for an NCCAM initiative to stimulate research on CAM interventions that are frequently used in the management of HIV disease and the complications associated with antiretroviral therapy (ART).

HIV-positive individuals on ART are significant users of CAM. Recent surveys have estimated that 47 to 74 percent of HIV-positive individuals in the United States have used some form of CAM intervention. Dietary supplements and mind-body therapies predominate these interventions, which are used for a variety of reasons. The high rate of CAM use in HIV-positive individuals warrants a greater understanding of its safety and efficacy. Dr. Pontzer provided examples of potential topics for study.

Dr. Pontzer noted that this research concept is consistent with the NCCAM Strategic Plan and the proposed 2009 Trans-NIH Plan for HIV-Related Research. It will address the relatively low numbers of investigator-initiated research applications in this area and will continue the use of requests for applications (RFAs) to bolster NCCAM's commitment to HIV-related research.

The proposed initiative will use the R01 funding mechanism; applications will be funded beginning in FY 2009. Pilot and developmental studies (R21s) can be submitted under existing funding announcements.

Discussion

In response to a question from Council, Dr. Pontzer reiterated that projects previously funded under the R21 mechanism would be eligible for R01 funding under the new initiative. Dr. Killen indicated that the initiative would also attract new applicants. Dr. Killen also clarified that funds would be set aside in the NCCAM budget for this initiative, and Dr. Pontzer explained that NCCAM would work in partnership with the NIH Office of Aids Research.

Council passed a motion to approve the project concept.

VI. Concept Review: Outcomes, Cost-Effectiveness, and the Decision Process To Use CAM

Dr. Killen introduced Dr. Richard Nahin, NCCAM Senior Advisor for Scientific Coordination and Outreach. Dr. Nahin presented a concept for an initiative to stimulate observational studies to evaluate the efficacy and cost-effectiveness of CAM approaches as used in the community and to understand how patients and providers decide to use CAM.

The proposed initiative involves health services research (HSR). HSR examines how people get access to health care, how much care costs, and what happens to people as a result of this care.

HSR is important to NCCAM and the CAM field for several reasons. First, HSR methodology can help explain what drives CAM use, at the individual level and the population level. In addition, with strategic investment in HSR, data on cost and outcomes of CAM use could become available from practitioners, insurance plans, and health maintenance organizations. Finally, HSR's observational methods can examine complex CAM interventions in real-world settings, offering an alternative to expensive randomized, controlled trials.

HSR is an area of emphasis in NCCAM's 2005 Strategic Plan, which offers recommendations for HSR on cost, outcomes, and the decision process. A 2005 Institute of Medicine (IOM) report makes similar recommendations. From FY 2002 through FY 2006, NCCAM funded a total of 26 R01 and R21 grants for HSR; the number declined from 11 in 2002 to 5 in FY 2006. In 2002, the largest HSR funding share went to research on the decision to use CAM; by FY 2006, that share had declined to zero, while funding for research on who uses CAM increased.

The rationale for the proposed initiative is to help NCCAM take greater advantage of scientific research opportunities offered by current public use of CAM. The initiative will encourage research on how CAM therapies function in actual health care settings. It will emphasize observational studies and secondary data analyses. Recommendations for specific research topics will be developed from NCCAM's Strategic Plan and the 2005 IOM CAM report.

The proposed funding mechanism is limited to R01 applications only. Pilot and developmental studies (R21s) can be submitted under existing funding announcements.

Discussion

The proposed restriction to R01 applications was discussed, and Dr. Nahin reiterated that applications for R21 HSR funding may be submitted under existing announcements. The relative proportions of R01 and R21 HSR grants funded in the past were discussed, along with questions about the review process and potential review by NIH's Center for Scientific Review, which has dedicated study sections on HSR.

Council passed a motion to approve the project concept.

VII. NCCAM Symposium: Initiatives and Funding for CAM Studies of Back Pain

Use of CAM for Back Pain

Dr. Killen introduced Dr. Partap Khalsa, NCCAM Program Officer, Division of Extramural Research and Training. Dr. Khalsa provided background information about

the use of CAM for back pain and summarized previous NCCAM-funded research on back pain and current initiatives available to investigators.

The 2002 National Health Interview Survey revealed that the U.S. public used CAM for back problems more than for any other condition. The survey also showed that chiropractic, yoga, and massage (common therapies for back-related disorders) were among the top five CAM interventions used by the public.

Although NCCAM's funding for the musculoskeletal and pain research portfolio has been significant, the portion spent on back pain has been relatively small. This investment, however, has generated important discoveries. Most of NCCAM's expenditures on back pain research have used R01/P/U funding mechanisms rather than the R21 (developmental/ exploratory) mechanism. For back pain research, of the five CAM domains delineated by NCCAM, the body-based and manipulative interventions domain has received the most funding. Within that domain, the largest expenditures have been for research on spinal manipulation. Dr. Khalsa noted that expenditures were not always driven solely by NCCAM's priorities, but also reflected the profiles of the applications received.

Dr. Khalsa outlined NCCAM's active initiatives related to back pain, including the Biology of Manual Therapies; Developmental Centers for Research on CAM; Centers of Excellence for Research on CAM; Mechanisms, Models, Measurement, and Management in Pain Research; Basic and Preclinical Research on CAM; and an Exploratory/Developmental Grant for Clinical Studies of CAM.

Are Popular CAM Therapies Effective for Low Back Pain?

Dr. Khalsa introduced Dr. Daniel Cherkin, Associate Director and Senior Scientific Investigator, Center for Health Studies, Group Health Consortium, Seattle, Washington. Dr. Cherkin's presentation was in three parts: a "world premier" of initial results from the SPINE Trial, a large, NCCAM-funded study of acupuncture for chronic low-back pain (LBP); a summary of his organization's research on massage and yoga for LBP; and announcement of new clinical guidelines for treatment of LBP.

The SPINE Trial. Dr. Cherkin briefly reviewed the background that led to NCCAM funding for the SPINE (Stimulating Points to Investigate Needling Efficacy) Trial. The study was designed to answer three questions: Is individualized acupuncture more effective than standardized acupuncture in treating chronic LBP? Is real (needle) acupuncture more effective than simulated acupuncture? Is acupuncture superior to usual care?

Dr. Cherkin described the study design (including patient selection, study treatments, usual care, and outcome measures) and preliminary results. The study met recruitment goals and had high patient adherence to protocols, high followup rates, and few adverse events.

The SPINE Trial found that individualized acupuncture was not more effective than standardized acupuncture for chronic LBP, real acupuncture was not more effective than simulated acupuncture, and all acupuncture treatments were superior to usual care. The researchers concluded that acupuncture was effective for chronic LBP, but its effectiveness was not due to the insertion of needles. They believe it is possible that noninsertive stimulation of acupuncture points works. The trial highlighted the potential importance of nonspecific effects of treatments for healing. Remaining questions include the following: Are nonspecific effects less valid than specific effects? If so, to whom (patients, clinicians, researchers, payers) are they less valid?

Studies of massage and yoga for LBP. A study published in 2001 found that therapeutic massage was an effective treatment for persistent back pain. It was superior to both self-care materials and acupuncture after 10 weeks of treatment and superior to acupuncture at 1 year. In addition, therapeutic massage reduced medication use. A 2005 study found that 12 sessions of Viniyoga reduced back-related dysfunction more than an exercise program at 12 weeks and more than a self-care book at 12 and 26 weeks.

A current NCCAM-funded study of massage for chronic LBP aims to determine whether relaxation (Swedish) massage is effective and whether focused structural massage (myofascial, neuromuscular) is more effective than relaxation massage. Another current NCCAM-funded study on chronic LBP is testing whether yoga is superior to usual care and to conventional exercise. If yoga is found to be more effective, the team will look for physical, psychological, and hormonal changes that may explain its effectiveness.

New LBP clinical guidelines. The American Pain Society and American College of Physicians (APS/ACP) sponsored a multidisciplinary panel representing more than 15 specialties and organizations to review the research literature on LBP treatment and recommend new clinical guidelines. The guidelines will be published October 2, 2007, in *Annals of Internal Medicine*. Dr. Cherkin focused on CAM-related findings for persistent LBP.

Based on their assessment of treatment effect and quality of evidence, the panel recommended eight nonpharmacologic therapies clinicians should consider adding when patients with chronic or subacute LBP do not improve with medication, education, and self-care: progressive relaxation, exercise therapy, cognitive-behavioral therapy, acupuncture, massage, spinal manipulation therapy, yoga, and intensive interdisciplinary rehabilitation. The panel found insufficient evidence to recommend any specific treatment as first-line therapy. They also found that patient expectations of benefit should be considered, as they appear to influence outcomes.

Summary. Dr. Cherkin noted unifying elements in his presentations. Fair-to-good evidence now exists that popular CAM therapies have a moderate effect on chronic back pain. Of the eight therapies the APS/ACP guidelines recommend, four are CAM—this represents an enormous change from the past. Growing evidence suggests that patients' beliefs and expectations affect outcomes, a finding that should help guide future care and research, both CAM and allopathic.

Discussion

Council discussed issues related to acupuncture research, such as the rationale for including simulated acupuncture in the SPINE Trial, the potential role of acupressure in LBP research, and the lack of research on patients with failed back syndrome. They also commented on methodological issues related to research on massage therapy.

VIII. NCCAM Symposium: Physiology of the Lumbar Spine and Spinal Manipulation

Neurophysiologic Research Approach

Dr. Khalsa introduced Dr. Joel Pickar, Professor, Palmer Center for Chiropractic Research, Palmer College of Chiropractic, in Davenport, Iowa. Dr. Pickar described research on the neurophysiology of the lumbar spine and related effects of spinal manipulation.

Many people seek chiropractic care for LBP. To date, research on spinal manipulation for LBP has been promising but limited. Most LBP is of unknown origin and unspecified pathophysiology. Understanding the physiology of the spine will help us understand pathophysiological processes. This research focuses on neuromuscular control of the spine, which is a critical aspect of spinal physiology.

Researchers developed an experimental animal model for studying neurophysiological and biomechanical interactions in the lumbar spine. They measured the sensitivity of lumbar muscle spindles, which provide neural information, to changes in intervertebral position. The researchers found that these spindles are more sensitive than those in limbs, perhaps because of the spine's requirement for stability. They also found that spinal manipulation appears to take advantage of an inherent signaling property of muscle spindles. Its therapeutic effects may arise from the high-frequency discharge it evokes in these spindles; it may also activate a novel set of sensory receptors. However, the relationship between muscle spindle activation and the therapeutic effects of spinal manipulation remains unknown.

Dr. Pickar also summarized future directions for spinal manipulation research at the Palmer Center. He noted the Center's vision for a "translational science center" that will bring research findings to bear on clinical practice.

Discussion

Dr. Pickar discussed the relevance of the animal (cat) model to humans, why changes in paraspinal muscle activity might cause back pain relief, and the effect of sensory input (such as using a mirror image to relieve phantom pain) and sensory awareness (such as using a toothpick to simulate acupuncture) on proprioceptors and pain.

IX. Public Comment Session

There were no public comments.

Dr. Killen and Dr. Kirschstein thanked Council and the speakers for their participation.

Dr. Killen adjourned the meeting at 4 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

Ruth L. Kirschstein, M.D.
Chairperson
National Advisory Council for
Complementary and Alternative
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