

**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 THIRTY-FIFTH MEETING
June 5, 2009**

NACCAM Members present

Dr. Lori Alvord, Hanover, NH
Dr. Stephen Barnes, Birmingham, AL
Dr. Timothy Birdsall, Goodyear, AZ
Dr. Boyd Bowden, Columbus, OH
Dr. Gert Bronfort, Bloomington, MN
Dr. Lupo Carlota, Memphis, TN
Dr. Sheldon Cohen, Pittsburgh, PA
Dr. Fabio Cominelli, Cleveland, OH
Dr. Silvia Corvera, Worcester, MA
Dr. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Joan Fox, Cleveland, OH
Dr. Margery Gass, Cincinnati, OH
Dr. Ted Kaptchuk, Boston, MA
Dr. Shin Lin, Irvine, CA
Dr. Richard Niemtow, Clinton, MD
Dr. Bruce Redman, Ann Arbor, MI
Dr. Katherine Shear, New York, NY
Dr. Danny Shen, Seattle, WA
Dr. Herman Taylor, Jackson, MS
Dr. Xiaoming Tian, Bethesda, MD

NACCAM Members not present

Dr. Charles Johnson, Washington, DC
Dr. Raynard Kington, Bethesda, MD
Dr. Richard Niemtow, Clinton, MD

NIH Staff present

Maguerite Klein, ODS, OD, NIH
Isis Mikhail, OCCAM/NIH
Linda Southworth, NCI, NIH
Dan Xi, NCI, NIH

Members of the Public

Miles Brawn
Tyler Cymet

Steven Dentali
Anthony Dinit
Philip Eskew
Harry Gewanter
R. Hansen
Hape Kellman
Lydia Laskin
Lauren Musiol
Denise Napoli
Pratik Patel
Susan Eads Role

I. Closed Session

The first portion of the 35th 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 277 applications were assigned to NCCAM. Of these, 232 were reviewed by NCCAM, 45 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 155 applications and voted to concur with IRG on 2 applications, requesting \$ 36,916,513 in total costs.

II. Open Session—Call to Order

The open session of the NACCAM meeting convened at 11:28 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

Minutes from the Council meetings on February 6, 2009; April 7, 2009 (teleconference); and May 5, 2009 (teleconference) were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen noted that the next Council meeting will be held on September 11, 2009, and that there may be an interim teleconference meeting in August. He then explained procedures for public comment and introduced Dr. Josephine Briggs, Director of NCCAM.

III. Intramural Research Strategic Planning—Blue Ribbon Panel Report

Dr. Briggs noted that the Blue Ribbon Panel on Intramural Research Strategic Planning is the first stage in NCCAM's current 10-year strategic planning effort. A planning day for extramural research will take place on September 10, 2009 (the Thursday before the Council's next meeting). Dr. Briggs introduced Dr. Jack Killen, Deputy Director of NCCAM, who is overseeing NCCAM's strategic planning effort. Dr. Killen outlined the morning's presentation.

Intramural Research at NIH

Dr. Robert Nussenblatt, Acting Scientific and Clinical Director, NCCAM Intramural Research Program, presented an overview of intramural research at NIH. The NIH Intramural Research Program conducts distinctive, high-risk, high-impact laboratory, clinical, and population-based research and trains a diverse population of young researchers. A key program element is intellectual freedom, fostered by a predominantly retrospective review system. NIH provides extensive research resources. Its Clinical Center is the world's largest hospital dedicated entirely to research; about 1,400 studies are under way at any given time. New intramural initiatives focus on human immunology and disease, molecular/cellular imaging technology, and systems biology. Other areas of focus include translational research, bioengineering, obesity, and adult stem cell research. Training addresses principles of clinical research and pharmacology, and ethics/regulation of human subjects research.

Blue Ribbon Panel Report

Dr. Stephen Barnes, University of Alabama at Birmingham and a member of the Blue Ribbon Panel, summarized the panel's activities and key findings.

The panel's charge was to identify research areas that can best capitalize on NIH resources and contribute to the field of complementary and alternative medicine (CAM) research. Two areas were chosen: herbals and mind-body medicine, the most popular CAM modalities in the United States, as reported in the 2007 National Health Interview Survey (NHIS). The panel's report outlines potential research topics and benefits for each of the two areas and recommends that NCCAM concentrate on one of the areas. The report also recommends qualifications for an NCCAM Scientific Director and for individuals to lead research activities in the areas under consideration. Other recommendations relate to intramural research staffing, facilities, and training.

Discussion

Discussion topics included possible reasons for focusing on mind-body research; cost and staffing considerations; the importance of identifying the ultimate goal of NCCAM research and determining how to measure progress; and the need to address health disparities in research planning.

Council unanimously passed a motion to accept the panel's report.

IV. Report From the Director

Following a 45-minute break for lunch, Dr. Briggs reconvened the meeting at 1:15 p.m. and highlighted news from NIH and NCCAM.

NIH News

NIH is awaiting announcement of a new Director. Dr. Raynard Kington continues as Acting Director.

Dr. Briggs is a member of the congressionally mandated NIH Scientific Management Review Board (SMRB), created to address organizational issues. The SMRB held its

first meeting on April 27-28, 2009. Agenda items included the possible merger of the National Institute on Alcohol Abuse and Alcoholism with the National Institute on Drug Abuse, and Intramural Research Program structure and cost allocations.

NACCAM News

Dr. Briggs welcomed two new Council members: Katherine Shear, M.D., and Xiao Ming Tian, M.D., C.M.D., L.Ac.

NCCAM Staff Update

Dr. Briggs introduced two new staff members: Dr. Wendy Weber, Program Officer, Division of Extramural Research; and Dr. Catherine Meyers, Director, Office of Clinical and Regulatory Affairs.

Research Highlights and 2008 Publication Summary

Dr. Briggs highlighted several examples of recent NCCAM-funded research, including two studies published in the *Archives of Internal Medicine*: “Acupuncture-Like Treatments Improve Outcomes Compared to Standard Care for Low-Back Pain” and “Translating CAM Research Results Into Clinical Practice.”

A 2008 bibliography of scientific publications citing NCCAM support was distributed to Council members. There were 520 such publications, citing 283 grants. The publications are ranked by journal “impact factor.”

Budget Update

Dr. Briggs presented NCCAM budget information, including appropriations for fiscal year (FY) 2009, the President’s request for FY 2010, and American Recovery and Reinvestment Act (ARRA) operating allowances for FY 2009 and FY 2010. She called attention to the “mech table,” which compares NCCAM’s FY 2008 expenditures and FY 2009 budgeted amounts by category. The President’s request for FY 2010 is \$31 billion for NIH overall (an increase of 1.5 percent from FY 2009); NCCAM’s share is \$127.2 million. Dr. Briggs also listed major solicitations funded under ARRA.

Legislative Update

Dr. Briggs noted recent activities indicative of congressional awareness of NCCAM’s portfolio and mission. For example, at the Senate Committee on Health, Education, Labor, and Pensions hearings on integrative health, held February 23 and 26, 2009, several participants expressed enthusiasm for the concept.

NCCAM News

Recent activities involving NCCAM include the Institute of Medicine Summit on Integrative Medicine; the first Stephen E. Straus, M.D., Distinguished Lecture, by Dr. Sherwin Nuland; a 2-day meeting of the Centers of Excellence for Research on CAM; the Interagency Autism Coordinating Committee meetings; the NIH Workshop on Nonpharmacologic Management of Back Pain; and the Trans-NIH Pain Consortium, which focused on the genetics of pain susceptibility.

Outreach Update

Dr. Briggs and NCCAM staff attended the North American Research Conference on Complementary and Integrative Medicine. Dr. Briggs also visited the Penny George Institute on Health and Healing, North Texas Health Science Center, Howard University, and Stanford University. NCCAM conducted an outreach program with the American Bar Association.

Upcoming Events

Cost data from the 2007 NHIS will be released in summer 2009. An anniversary symposium, focusing on basic science elements of the NCCAM portfolio, will take place on December 8, 2009.

V. High-Dose Creatine for Huntington's Disease

Dr. Steven Hersch, Associate Professor of Neurology at Harvard Medical School and Director of the Massachusetts General Hospital Huntington's Disease Center, described the Center's research on creatine for Huntington's.

Huntington's is a genetic neurodegenerative disease that usually emerges in midlife. Its symptoms—incapacitating movement disorders, emotional disturbance, and cognitive decline—are caused by deterioration of the brain's basal ganglia and cortex. The biological mechanism is very complex. Creatine, a protein consumed in meat and available as a dietary supplement, interacts with a number of processes involved in Huntington's. Studies of its effects in animal models of Huntington's have been promising. The Center's human research on creatine began with dose determination studies, which found that people can tolerate doses as high as 30 to 40 grams. Laboratory results and brain scans showing the effects of high-dose creatine in 10 Huntington's patients were very encouraging; the effects on cortical thinning were especially dramatic.

In cooperation with the University of Rochester, the Center is now undertaking a Phase III clinical trial known as CREST-E (Creatine Safety, Tolerability, and Efficacy in Huntington's Disease) to study the long-term effects of creatine in a large sample of Huntington's patients. Funded by NCCAM, the randomized, double-blind, placebo-controlled study will recruit 650 patients at 50 sites worldwide and will test dosages ranging from 10 to 40 grams (individuals will take the highest dose they can tolerate) over a period of 36 months. The study's primary outcome measure will be change in total function capacity; it will also measure a number of biomarkers and other indicators. Enrollment begins in August 2009, and the study will be completed in 2014.

Portions of CREST-E are funded by the National Institute of Neurological Disorders and Stroke, which is also funding a separate clinical trial of creatine in people at risk of developing Huntington's.

Discussion

Discussion topics included dosage control challenges, early completion if efficacy clearly outweighs risk (researchers need to continue long enough to compile an adequate safety database), reasons for high doses, and recruitment issues.

VI. Back Pain Roundtable

The 2007 NHIS found that back pain is by far the main reason for CAM use. As part of its exploration of how to address related research issues, NCCAM organized the Workshop on Nonpharmacological Management of Back Pain, held May 27, 2009. Dr. Partap Khalsa, Program Officer, NCCAM Division of Extramural Research, presented an overview of the workshop, and Dr. Gert Bronfort, Northwestern Health Sciences University, co-chair of the workshop, highlighted salient points from the event.

The workshop was designed to identify gaps in the evidence base for back pain, and to explore the need for effectiveness research on nonpharmacological interventions. Participants included steering committee members from NCCAM, other NIH institutes and centers, and agencies outside of NIH, and 12 invited experts in the field. In addition, 141 people participated via the Internet.

One conclusion from the workshop is that back pain research is underfunded, given its burden on public health. Other conclusions concern the need for better translational tools, better understanding of underlying factors, and innovative clinical research paradigms. Recommendations include continued encouragement of investigator-initiated studies on back pain and continued participation in relevant funding opportunities.

Among the salient points to emerge from the workshop is the possibility that chronic back pain is not yet fully understood. Questions remain about its biology (possible research directions include how the brain processes chronic pain and the clinical biomechanics of spinal function), as well as the contextual factors involved. A number of promising therapies have been identified, but all have had only moderate effects, and none has emerged as a clear first-line treatment. More research is clearly needed, but it may be advisable to take a different approach. For example, what constitutes a successful outcome for interventions needs to be refined, and more qualitative assessments should be included in clinical trials.

Discussion

Discussion topics included the importance of bioengineering expertise in back pain research; the status of evidence on multimodality treatment; the importance of long-term studies (most research has used an acute pain model); and the complexity of back pain (in contrast to the simplistic approach of clinical research to date).

Dr. Briggs noted that NCCAM will continue to explore research directions and NIH teambuilding efforts for back pain. She identified four key needs: better biological tools

for categorizing patients; better natural history and epidemiology databases; more complex outcome measures; and input from sectors concerned with the economic and policy implications of back pain (e.g., employers and health care providers).

VII. Council Operating Procedures and Changes in Peer Review

Operating Procedures

Dr. Goldrosen reviewed the Council's operating procedures, focusing on the process for secondary review of grant applications in closed session. He discussed the handling of applications in two categories (with and without special concerns), decision options available to Council, administrative decisions and actions that follow Council review, the new expedited concurrence process approved by Council in April 2009, and handling of exceptional situations. Dr. Goldrosen noted that NCCAM reviews Council procedures periodically; the next review probably will address changes only.

A brief discussion followed, during which Dr. Goldrosen and Dr. Briggs clarified aspects of the procedures. Council unanimously passed a motion approving the operating procedures.

Peer Review

Dr. Goldrosen outlined recent and upcoming changes in the NIH peer review process, including:

- Changes through January 2009: phase-out of A2 applications, identification of applications from early-stage investigators
- Ongoing changes (May-June 2009): enhanced review criteria, new scoring system, structured critiques (including a new template for reviewers), clustering of applications from new investigators
- Future changes (beginning with January 2010 submissions): introduction of shorter application forms, alignment of application forms and review criteria.

Dr. Goldrosen noted that the new process focuses more on the significance of the research concept and less on the research approach. He explained the new scoring system in detail.

Dr. Goldrosen and Dr. Briggs addressed Council's questions on the new scoring system, and Dr. Briggs provided background information on the new system.

VIII. Public Comment Session and Closing

Dr. Briggs opened the floor for public comment. Dr. Harry Gewanter, representing the American Academy of Pediatrics' Section on Complementary and Integrative Medicine, reviewed the section's activities and distributed materials (including a CAM brochure for parents). Dr. Steven Dentali, American Herbal Products Association, commented on issues related to herbals research.

Dr. Goldrosen adjourned the meeting at 4:25 p.m.

We hereby certify that, to be 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
National Advisory Council for
Complementary and Alternative
Medicine