

**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-SECOND MEETING
February 6, 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
*Ms. Wanda Burch, Fultonville, NY
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. Randy Gollub, Charlestown, MA
Dr. Ted Kaptchuk, Boston, MA
Dr. Shin Lin, Irvine, CA
*Dr. Martha Menard, Charlottesville, VA
Dr. Richard Niemtzw, 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

*Ad hoc members

NACCAM Members not present

Dr. Charles Johnson, Washington, DC
Dr. Raynard Kington, Bethesda, MD

NIH Staff present

Guillermo Arreaza NIDDK,NIH
Paul Coates, ODS, OD, NIH
Maguerite Klein, ODS, OD, NIH
Isis Mikhail, OCCAM/NIH
Toni Scarpa, CSR,NIH
Linda Southworth, NCI, NIH
Christine Swanson, ODS, OD, NIH
Dan Xi, NCI, NIH

Members of the Public

Charles Christianson
Tyler Cymet
Steven Dentali
Harry Gewanter
Diane Gioia-Bargunetti
Rick Hansen
Aviad Haramati
Quinton Johnson
Leslie Kole
Lydia Laskin
Josanne McBride
Georgia Perdue
Herb Simmers
Carmen Tamayo-Arreza
Haidi Zhanghang

I. Closed Session

The first portion of the 32nd 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 238 applications were assigned to NCCAM. Of these, 178 were reviewed by NCCAM, 60 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 142 applications requesting \$ 34,234,392 in total costs.

II. Open Session—Call to Order

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

Minutes from the Council meeting on September 12, 2008, were unanimously approved, with no votes against and no abstentions. NCCAM's human subject enrollment report for 2007-2008, certifying compliance with congressionally mandated population inclusion guidelines, was also unanimously approved.

Dr. Goldrosen noted that the next Council meeting will be held on June 5, 2009. He then explained procedures for public comment and introduced Dr. Josephine Briggs, Director of NCCAM.

III. Report From the Director

Dr. Briggs outlined the agenda for the meeting and highlighted news from NIH and NCCAM.

NIH News

With the departure of Dr. Elias Zerhouni, Dr. Raynard Kington is serving as Acting Director of NIH. Dr. Lawrence Tabak is Acting Deputy Director and Dr. Sally Rockey is Acting Director of the NIH Office of Extramural Research. Dr. Lana Skirboll is now acting head of the Division of Program Coordination, Planning, and Strategic Initiatives. Dr. Linda S. Birnbaum has been appointed Director of the National Institute of Environmental Health Sciences. The first data release from the new Research, Condition, and Disease Categorization (RCDC) automated grant-coding system took place on January 15, resulting in some substantial changes in research categorization. The amount of funding allocated to CAM changes somewhat under RCDC. Yancy Bodenstein represents NCCAM in this process.

NACCAM News

Dr. Briggs welcomed new Council member Dr. Xiaoming Tian. She also acknowledged four ad hoc Council members—Ms. Wanda Burch, Dr. Randy L. Gollub, Dr. Martha Menard, and Dr. Katherine Shear.

NCCAM Organizational Update

Dr. Briggs welcomed two new program officers, Dr. Craig Hopp and Dr. John Glowa, and noted that Dr. Lawrence Friedman, a contractor, is helping to review clinical studies. She also noted the departure of Dr. Catherine Stoney, program officer, who has joined the National Heart, Lung, and Blood Institute; Dr. Patrick Mansky, intramural cancer researcher, who is entering private practice; and Dr.

Jeanette Hosseini, scientific review officer, who has joined the National Institute of Nursing Research.

Dr. Dale Birkle Dreer has been appointed chief of the NCCAM Office of Scientific Review.

Budget Update

Dr. Briggs summarized the status of the NIH and NCCAM budgets for fiscal year (FY) 2009, including the President's requests, continuing resolutions, House and Senate allowances, and likely appropriations. The expected appropriation for NCCAM is \$125.4 million, an increase of 3.2 percent from FY 2008.

Dr. Briggs also discussed possible scenarios for the NIH portion of economic stimulus bills before Congress. One possibility is a challenge grant program, which would provide 2-year grants for innovative projects to meet major scientific needs. NCCAM has proposed several research areas for such grants; if the program is approved, it would begin immediately. Another possibility is funding for comparative effectiveness research—e.g., studies to compare a CAM modality with standard care.

Research Highlights

Dr. Briggs cited three major NCCAM-supported studies reported in late 2008: GAIT II (glucosamine/chondroitin for osteoarthritis), SELECT (selenium for prostate cancer prevention), and GEM (ginkgo for dementia prevention). In briefly describing GAIT II results and complications (controls experienced less joint deterioration than predicted), she noted the need for more sensitive translational tools in future studies.

Dr. Briggs also cited a recent Cochrane review of acupuncture for tension-type headaches, as well as three articles on management of low-back pain that illustrate the hierarchy of scientific evidence. She noted NCCAM's role in driving CAM research to a point where rigorous systematic reviews are possible.

Current Events

NCCAM's 10th anniversary is being observed during 2009 with banners on the NIH campus; a special section in the February issue of *MedlinePlus Magazine*; an address by Dr. Sherwin B. Nuland, on March 10 to inaugurate the Stephen E. Straus, M.D., Distinguished Lecture Series; and a scientific symposium on December 10.

New components on integrative medicine and spiritual health/healing were added to NCCAM's online continuing medical education series. A CAM tutorial was added to the seniorhealth.gov Web site.

Two research solicitations were published: Partnerships for CAM Clinical Translational Research and Translational Tools for Clinical Studies of CAM Interventions (focusing on mind-body, meditative, and manual therapies).

The Trans-Agency CAM Coordinating Committee met to discuss research directions, focusing on pain management. An AHRQ report on CAM for back pain was published. A 1-day workshop on management of back pain is being planned. The Blue Ribbon Panel on the NCCAM Intramural Research Program will meet in February and March. On April 2-3, representatives from NCCAM's Centers of Excellence for Research on CAM will meet to present scientific findings.

Dr. Briggs briefed Congresswoman Tammy Baldwin's staff on NCCAM. Dr. Briggs addressed the Advisory Council to the NIH Director, providing an update of NCCAM's research and plans. She also continued her "listening tour" with visits to several organizations. The 2007 National Health Interview Survey data were released, generating significant media interest and documenting public interests that can inform directions at NCCAM.

IV. Center for Scientific Review: Peer Review

Dr. Antonio Scarpa, Director of NIH's Center for Scientific Review (CSR), presented an overview of CSR's peer review activity, analyzed outcomes for NCCAM grant applications, and outlined efforts to enhance peer review processes.

In relation to other NIH institutes and centers, NCCAM has a much higher proportion of new (A0) applications, which tend not to score as well as other applications and have a low resubmission rate for failed applications.

Drivers for change at CSR include trends in NIH and CSR budgets, the number of applications submitted, and reviewer loads (applications per reviewer). CSR has achieved cost savings by reducing the number of reviewers and increasing the use of electronic review platforms, among other measures. CSR's efforts to improve peer review have focused on reorganizing to better reflect the needs of science, recruiting excellent scientific staff and reviewers, improving study section alignment and performance, shortening the review cycle, and advancing additional review platforms.

NIH's recent peer review enhancement initiative has four priorities: engaging the best reviewers, improving the quality and transparency of reviews, ensuring balanced and fair reviews across scientific fields and career stages, and continually assessing the peer review process. Changes include a new process for reviewing highly transformative ("revolutionary") research; efforts to fund the best research earlier and make the review process less burdensome (e.g., introducing more flexible deadlines and abolishing A2 applications); and improvements in applications and scoring.

Discussion

Discussion topics included the need for a more compact peer review process, metrics for evaluating changes in the process, factors behind NCCAM's low resubmission rates, gradual improvements in NCCAM's A0 success rate, and efforts to cluster NCCAM applications within fewer CSR study sections.

V. NCCAM: Ten Years

Following a 1-hour break for lunch, Dr. Briggs reconvened the meeting at 1 p.m. and introduced Dr. David Eisenberg of Harvard Medical School, where he is the Bernard Osher Associate Professor of Medicine, Director of the Osher Institute, and Director of the Division for Research and Education in Complementary and Integrative Medical Therapies. In a presentation that marked the beginning of NCCAM's 10th anniversary celebration, Dr. Eisenberg reflected on NCCAM's past, present, and future.

Dr. Eisenberg traced the history of how CAM is perceived and defined, and summarized elements of integrative and comprehensive care models. He observed that the study of CAM therapies provides opportunities for both incremental and "disruptive" innovation, as well as ongoing refinement of comprehensive medical care.

Dr. Eisenberg identified historical milestones for CAM and NCCAM. He advised Council to look at NCCAM's achievements relative to its most recent strategic plan, and offered his own assessment. In discussing shifts in NCCAM's research emphasis, he highlighted the importance of focusing on mechanisms. Dr. Eisenberg then reflected on lessons learned and questions raised relative to four aspects of CAM research: surveys of public use, botanicals research, placebo research, and clinical studies. He noted the need for survey data on CAM expenditures; emphasized the importance of reproducibility and quality assurance in botanicals research; identified key questions for placebo research; and suggested some directions for clinical studies (e.g., taking into consideration how people actually use CAM, and investigating the cost-effectiveness of multidisciplinary team approaches).

In closing, Dr. Eisenberg offered a wide range of strategic considerations for NCCAM as it enters its next 10 years, including the importance of building bridges with other disciplines and CAM's potential role in prevention, lifestyle, and self-care.

Discussion

Dr. Briggs and Council members thanked Dr. Eisenberg for his presentation. Council, staff, and guests then observed NCCAM's anniversary with a birthday cake.

VI. Ginkgo Evaluation of Memory (GEM) Study

Dr. Jeffrey Williamson of Wake Forest University gave an overview of results from the GEM study. At Wake Forest, Dr. Williamson is professor of internal medicine, head of the section on Gerontology and Geriatric Medicine, Director of the Roena B. Kulynych Center for Memory and Cognition, and clinical director of the J. Paul Sticht Center on Aging. He is the principal investigator of the GEM Clinical Coordinating Center.

GEM was a randomized, double-blind, multicenter clinical trial that looked at the effects of ginkgo on the occurrence of Alzheimer's disease in people age 75 or older who have normal memory or very mild cognitive impairment. The first prevention trial with cognition as the primary outcome, GEM had more than 3,000 participants, who were assessed every 6 months for cognitive and other outcomes; the median follow-up period was 6.5 years. The study's main conclusion was that ginkgo taken at 120 mg twice a day was not effective in preventing Alzheimer's disease or other dementia. Ginkgo also did not reduce the risk of heart disease, stroke, or death. It did not increase risk of bleeding or other adverse events.

GEM demonstrated the feasibility of involving a large number of elderly volunteers in prevention trials. GEM met its recruitment goals very quickly, and participant compliance was excellent. Important elements of the study design included the use of proxies (spouses or other individuals to assist participants as needed) and home visits. Data from GEM may help to answer other important questions about aging, and may hold clues that will help to identify people at risk of developing Alzheimer's disease. Additional analyses are in progress.

Discussion

Discussion topics included the value of "negative" findings (learning that something does not work is important and has an impact on sales and usage), rationale for studying ginkgo for claudication, response to criticisms about dosage choice, and why few ethnic minorities participated in GEM.

VII. R21 Update

Dr. Goldrosen, Director of NCCAM's Division of Extramural Activities, presented an overview of R21 grants at NIH and NCCAM. Dr. Joseph Campbell, with NCCAM's Office of Policy, Planning, and Evaluation, presented results from analyses of NCCAM's R21 portfolio.

At NIH, R21 grants are intended to encourage development of research in specific program areas. They are restricted in level of support and in time, are not renewable, and do not require preliminary data. Compared with other ICs, NCCAM's research portfolio has been heavily skewed toward R21s, in part because the exploratory nature of R21s dovetailed with the state of CAM research. Whereas the NIH-wide R21 program emphasizes innovation, NCCAM's R21 program has focused on generating data to justify future studies. NCCAM is currently weighing the pros and cons of R21s in an effort to determine the right balance for its research portfolio. Among concerns about R21s are their relatively low success rate and progression to R01 funding and their appropriateness for current programmatic needs.

Analysis of NCCAM clinical and basic R21 grants during 2004-2005 found that basic grants were more likely than clinical grants to be followed by subsequent research grants and to be acknowledged in publications. Analysis of R21 clinical grant activity for 2003-2004 found that more than 55 percent of projects achieved at least 75 percent of their specific aims, more than 70 percent met at least 75 percent of their accrual targets, about 40 percent resulted in at least one publication, and about 30 percent of the R21 investigators went on to obtain another, related grant.

Discussion

Dr. Briggs led Council in a discussion of issues in evaluating NCCAM's R21 portfolio. One suggestion was to modify the program's original approach by allocating some funds for innovation and some for targeted areas of research. Another was to define trajectories for developing NCCAM intervention research. Dr. Briggs summarized lessons learned to date, noting how difficult it is to evaluate funding mechanisms. She also noted plans to evaluate the Centers of Excellence program, and commented on NCCAM's current focus on the role of CAM modalities in pain management.

VIII. Looking Forward

Dr. Briggs discussed ways in which NCCAM is working to move its research program forward. Staff members in the Division of Extramural Activities are increasingly developing expertise focused on specific interventions. This approach is reflected in the Division's reorganization into two branches: natural products (encompassing interventions based on biochemistry mechanisms), headed by Dr. Carol Pontzer; and manual therapies and mind-body medicine (interventions based on neuroscience mechanisms), with Dr. Richard Nahin serving as acting branch chief.

Dr. Briggs also reviewed NCCAM's four-part paradigm for thinking about research in terms of the kinds of questions addressed—basic science, translational research, efficacy studies, and effectiveness research—pointing out that the specific questions for mind-body interventions differ somewhat from those for natural products interventions. She also noted the challenge of ensuring scientific rigor in trials that must capture the complexities of CAM use in the real world.

IX. Strategic Plan 2010

Dr. Jack Killen, NCCAM Deputy Director, outlined the guiding principles and process for developing NCCAM's next strategic plan. The goal is to produce a strategic, high-level, long-range vision that provides guideposts for future scientific direction and a useful, dynamic framework for priority-setting. The process and the plan will be driven by science and data and will reflect the progress made to date. The plan will be grounded in NCCAM's mission and will reflect collaborations and partnerships across NIH and the field. Under the aegis of Council, planning will move forward in three phases. The process will be transparent and open, will seek input from NCCAM's diverse stakeholder community, and will maximize use of communication technologies. The target date for completion is June 2010.

Discussion

The possibility of developing a preliminary assessment of the past 5 years of NCCAM research as a framework for discussions with stakeholders was raised. Dr. Briggs noted that the plan will be organized around types of activities rather than CAM domains. She commented that NCCAM should work to make its research portfolio more transparent and to communicate its achievements in terms of developing an evidence base, not just results of individual studies.

X. Public Comment Session and Closing

Dr. Briggs opened the floor for public comment. Ms. Diane Bargonetti, a naturopath and melanoma survivor, shared her personal experiences in dealing with her illness. Dr. Quinton Johnson of the South African Herbal Science and Medicine Institute, University of the Western Cape, encouraged NCCAM to continue support for research on phytotherapies used by HIV/AIDS patients. Mr. Herb Simmens, a cancer survivor, requested information about the clinical trial on the Gonzalez regimen. Dr. Harry Gewanter, representing the American Academy of Pediatrics' Section on Complementary, Holistic, and Integrative Medicine, reviewed the section's activities. Dr. Tyler Cymet, American Association of Colleges of Osteopathic Medicine, noted the need for common terminology on musculoskeletal conditions.

Dr. Goldrosen adjourned the meeting at 4:30 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
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Medicine