

**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-SEVENTH MEETING
September 11, 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. Stephen Ezeji-Okoye, Palo Alto, CA
Dr. Joan Fox, Cleveland, OH
Dr. Margery Gass, Mayfield Heights, OH
Dr. Ted Kaptchuk, Boston, MA
Dr. Shin Lin, Irvine, CA
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

*Teleconference

NACCAM Members not present

Dr. Francis Collins, Bethesda, MD
Dr. Silvia Corvera, Worcester, MA
Dr. Richard Niemtow, Clinton, MD
Ms. Kathleen Sebelius, Washington, DC

NIH Staff present

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

Members of the Public

Beth Clay

Tyler Cymet
Steven Dentali
Harry Gewanter
Lydia Laskin
Ben Rebeir
Susan Eads Role
Steven Qian
Eixi Wu

I. Open Session—Call to Order

The open session of the 37th meeting of the National Advisory Council for Complementary and Alternative Medicine (NACCAM) convened at 8:30 a.m. Dr. Martin Goldrosen, NACCAM Executive Secretary, called the meeting to order.

A moment of silence was observed, to commemorate the events of September 11, 2001.

Minutes from the Council meeting on June 5, 2009, and teleconference on August 18, 2009, were unanimously approved, with no votes against and no abstentions.

Dr. Goldrosen explained procedures for public comment and noted that the next Council meeting will be held on February 5, 2010. He then introduced Dr. Josephine Briggs, Director of NCCAM.

II. Report From the Director

Dr. Briggs thanked Council for their participation in the planning session held September 10, 2009. She then highlighted news from NIH and NCCAM.

NIH News

Dr. Francis S. Collins is the new NIH Director. Dr. Briggs commented on his professional accomplishments and noted his interest in CAM.

NACCAM News

Dr. Briggs acknowledged six departing Council members: Dr. Fabio Cominelli, Dr. Silvia Corvera, Dr. Joan Fox, Dr. Ted Kaptchuk, Dr. Bruce Redman, and Dr. Danny Shen.

Enhanced Peer Review and R01 Award Trends

The September 2009 Council marks the first round of grant application reviews with the new scoring system and summary statements. Dr. Briggs noted the availability of a modified application submission process for NIH advisory group members.

Dr. Briggs reviewed trends in NCCAM's R01 grant awards, which have increased from 7 in fiscal year (FY) 2006 to 26 in FY 2009. She noted the need to think about shaping priorities for NCCAM's investigator-initiated research portfolio.

NCCAM News

Staff Update

Eric Gallagher is NCCAM's new Chief Information Officer.

NCCAM is currently recruiting for three positions: Director, Division of Extramural Research; Scientific Director and Senior Investigator, Intramural Research Program; and Director, Office of Policy, Planning, and Evaluation.

2007 NHIS CAM Cost Data

CAM cost information from the 2007 National Health Interview Survey was recently released. Dr. Briggs highlighted some of the key findings, noting that the results are in line with data from other sources that used different methodologies.

Research Highlights

Dr. Briggs commented on four examples of recently published research sponsored by NCCAM. The research topics were effects of cranberry juice on pharmacokinetics of antibiotics for urinary tract infections, concomitant use of prescription drugs and dietary supplements among older adults, red yeast rice for cholesterol control in statin-intolerant patients, and effects of chromium picolinate on metabolic syndrome features in obese adults.

Budget and Legislative Update

Dr. Briggs presented NCCAM budget information for FY 2010, including appropriations bills from the U.S. House of Representatives (\$129.9 million) and U.S. Senate (\$127.5 million). The House bill represents an increase of 3.6 percent, and the Senate bill an increase of 1.7 percent over FY 2009. She also summarized NCCAM's American Recovery and Reinvestment Act allocation (\$34.4 million) and FY 2009 commitments (\$16.9 million).

Dr. Briggs noted congressional activity related to health care reform. Issues of particular relevance for NCCAM include comparative effectiveness and wellness/prevention.

Recent Conferences

NCCAM participated in an international symposium on evaluating clinical trial methodologies, held June 25-28, 2009; and a conference on soy protein and isoflavone research, held July 28-29, 2009.

Outreach Update

During the summer, Dr. Briggs spoke at the Center for Mind-Body Medicine. NCCAM exhibited at conferences of the Endocrine Society, American Academy of Nurse Practitioners, Association of American Indian Physicians, National Medical Association, and American Psychological Association.

Upcoming Events

NCCAM will hold a wellness workshop September 25, 2009; participants will focus on defining the concept of wellness. NCCAM's 10th anniversary research symposium will be held December 8, 2009.

III. Back Pain Research: Past History, Pitfalls, and Possibilities

Dr. Richard Deyo, Kaiser Permanente Professor of Evidence-Based Family Medicine, Oregon Health and Science University, spoke about back pain research. Dr. Deyo focused on clinical research issues.

There has been a history of ineffective treatment “fads” for back pain. Treatment utilization and costs have increased rapidly, but without corresponding declines in reported functional limitations and number of work disability claims related to back pain. It is unclear whether much meaningful progress has been made.

Pitfalls that have impeded true progress include exaggerated reports of treatment success from “experts” and the popular media; misleading outcomes from clinical trials (e.g., apparent treatment-related improvements that actually reflect factors such as placebo, a patient’s favorable natural history, or the statistical phenomenon of regression to the mean); and methodological challenges in randomized clinical trials (RCTs), especially for nondrug interventions. Another pitfall is that statistically significant results from trials often are not clinically important; for example, if an expensive treatment reduces a patient’s pain level but the patient remains inactive and continues to take opioids for pain, can the treatment be considered “successful”?

Some possibilities for facilitating research progress relate to measuring treatment success. Examples include moving to more meaningful outcome measures; acknowledging that change in pain may not be the only criterion of success; reporting the percentage of subjects who achieve a specified benchmark of improvement, not just the average change in pain or functioning; and building consensus on what constitutes treatment “success.”

Other possibilities relate to designing and prioritizing studies. Examples include emphasizing pragmatic trials that ask whether a therapy usually works in real-world settings; trying innovative randomization designs (e.g., cluster randomization) that may make it more feasible to do RCTs; considering new contexts for CAM trials, such as how CAM use relates to other health care practices (e.g., whether people substitute CAM for other care); and exploring uses for observational studies and existing data sets.

Places to “shine more light” in back pain research include the pathophysiology and natural history of back pain; relevance of a chronic pain model, as opposed to an acute pain model; and the role of “nonspecific” factors, such as patient expectations and preferences, in determining trial outcomes.

Discussion

Discussion topics included the question of when acute back pain becomes chronic pain, and potential topics for research on the natural history of back pain.

The morning portion of the open session ended at 10 a.m.

IV. Closed Session

A total of 527 applications were assigned to NCCAM. Of these, 239 were reviewed by NCCAM, 288 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 193 applications, requesting \$ 65,980,962 in total costs.

This portion of the 37th meeting of 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).

V. Reconvened Open Session

Dr. Briggs reconvened the open session at 1 p.m.

VI. Acknowledgment of Retiring Council Members

Dr. Briggs presented certificates of appreciation to departing Council members. She also acknowledged honors recently received by two Council members: The Foundation for Chiropractic Education and Research named Dr. Gert Bronfort the 2009 Researcher of the Year, and the American Association of Naturopathic Physicians named Dr. Tim Birdsall the 2009 Physician of the Year.

VII. Update on Centers of Excellence for Research on CAM (CERC) Program

Dr. Barbara Sorkin, Program Officer, NCCAM Division of Extramural Research, presented an assessment of NCCAM's signature P01 initiative, the Centers of Excellence for Research on CAM (CERC) program, and recommendations for reissuing the CERC initiative. Dr. Sorkin began with some caveats about assessing CERC: it is relatively young (6 years), has made only 15 awards (7 within the last 2 years), and accounts for just over 15 percent of NCCAM's total research budget. She also noted that publications are not the only metric for assessing the success of the program.

The P01 share of NCCAM's research budget has increased over the years and is among the highest at NIH. NCCAM's annual cost limit for individual P01s is lower than the NIH average and has not been adjusted for inflation. P01 success rates (percent of applications funded) and publication productivity have also generally increased, and correspond to overall NIH trends. Although the program has focused on mechanistic studies, it has addressed a wide range of research questions and a variety of CAM modalities and diseases/conditions. The CERC program uniquely supports a multidisciplinary, multipronged research approach; serves as a platform for CAM research collaborations; and increases visibility of rigorous CAM research.

Recommendations for reissuing the CERC initiative include continued emphasis on multidisciplinary research; stronger focus on NCCAM priority research areas (one or more targeted priorities each year, with CAM for pain as the initial priority); and emphasis on areas with the greatest potential for having an impact on practice. It is

recommended that the CERC share of NCCAM's overall research budget hold constant, but with inflation adjustments to the maximum annual direct costs allowed.

Discussion

Council members commented on the CERC program, including the importance of synergy (multiple investigators thinking about related issues), the question of how to define "multidisciplinary," and the benefit of involving investigators who are not funded individually.

Council unanimously passed a motion to approve the concept for reissuing the CERC initiative.

VIII. Update on Product Integrity Working Group (PIWG)

Dr. Craig Hopp, Program Officer, NCCAM Division of Extramural Research, presented an overview of NCCAM's product integrity process and suggestions for revising the process.

Dr. Hopp traced the history of the product integrity process and summarized features of the interim policy and guidance (information for applicants) and the current Product Integrity Working Group (PIWG) review process. The majority (63 percent) of products evaluated are botanicals. To date, the PIWG has evaluated 250 applications in 12 Council rounds; in 2008, 90 percent of applicants achieved a "satisfactory" designation within 2 months. Applicants have been receptive to the process. However, the process places a burden on principal investigators (PIs), PIWG members, and NCCAM staff. Suggestions for refining the process include conducting more evaluations in-house at NCCAM, consulting with specialty experts as needed, increasing one-on-one dialog with PIs, shortening the time to a "satisfactory" designation, and making the process more analogous to other programmatic evaluations.

Product integrity policy and guidance issues include variability in the amount of product information applicants provide, PI/supplier inability to answer questions about products, as well as PI unawareness of potential issues with botanicals and unconditional trust in supplier-provided information. Suggestions for addressing these issues include placing page limits on information submitted, clarifying product categories (complex vs. refined products), emphasizing the need for independent analysis, and stratifying requirements based on a product's intended use (in vitro, animal, or human study). In addition to product complexity and intended use considerations, requirements for clinical studies will depend on the project's IND (investigational new drug) status with the U.S. Food and Drug Administration.

The proposed changes are intended to increase the efficiency of product approval without sacrificing quality. They also are intended to make PIs aware of product issues earlier in the process.

Discussion

Discussion topics included the possibility of using existing data to guide applicants, the challenges of determining an appropriate level of intensity for product testing, the potential for overburdening PIs, how NCCAM might help PIs find laboratories to analyze

products, and the possibility that suppliers will do a better job of standardizing products in light of integrity program requirements for inclusion in clinical trials.

IX. Public Comment Session and Closing

Dr. Tyler Cymet, American Association of Colleges of Osteopathic Medicine, noted the importance of a common language for talking about CAM and mentioned the association's glossary of osteopathic terminology. Dr. Harry Gewanter, representing the American Academy of Pediatrics' Section on Complementary and Integrative Medicine, updated Council on the section's activities. Ms. Beth Clay commented on the concept of "health freedom" and a number of other issues related to health care and CAM. Dr. Steven Dentali, American Herbal Products Association, noted that the product integrity process should not become simply a checklist for PIs but rather should encourage them to consult with experts for assistance in providing the required information.

Dr. Briggs adjourned the meeting at 2:20.

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
National Advisory Council for
Complementary and Alternative
Medicine