

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NCCAM TRANS-AGENCY CAM COORDINATING COMMITTEE
MINUTES OF MEETING
MAY 20, 1999**

The NCCAM Trans-Agency CAM Coordinating Committee convened its first meeting on May 20, 1999, at the National Institutes of Health campus in Bethesda, Maryland. Dr. William Harlan presided as the Acting Director, NCCAM.

NCCAM COORDINATING COMMITTEE MEMBERS PRESENT

Dr. William Harlan, NIH, Chairman
Mr. Michael Bacon, OPAT/CSAT
Ms. Joy Boyer, NHGRI
Dr. Norman Braveman, NIDC
Ms. Michele Chang, CDC
Dr. Rebecca Costello, ODS/OD
Dr. Mary A. Cummings, AHCPR
Dr. Ralph Helmsen, NEI
Dr. Carole Hudgings, NINR
Dr. Joseph Kaczmarczyk, HRSA
Dr. Jacjitsing Khalsa, NIDA
Dr. Barry Lebowitz, NIMH
Dr. Michael Lin, NHLBI
Dr. Michael Ken May, NIDDK
Dr. Michael McClure, NIEHS
Dr. Richard Nahin, NCCAM
Dr. Jean Paddock, CSR
Dr. Sharee Pepper, NLM
Dr. Theresa San Agustin, ED (NIDRR)
Dr. Brian Schuster, DoD
Dr. Susan Serrate-Sztejn, NIAMS
Ms. Barbara Sina, FIC
Dr. Paula Skedsvold, OBSSR
Dr. Kermit Smith, IHS
Dr. Scott Somers, NIGMS
Dr. Robert Temple, FDA
Mr. Vincent Thomas, NIAID
Dr. Alan Trachtenberg, SAMHSA
Dr. Harold Varmus, NIH
Ms. Judith Whalen, NICHD
Dr. Jeffrey White, NCI
Mr. Patrick Williams, NCCAM

OTHERS PRESENT

Mr. Louis Biondi, NCCAM Clearinghouse
Dr. Geoffrey Cheung, NCCAM
Ms. Linda Cramer, NCCAM Clearinghouse
Mr. Doug Hussey, NCCAM

Call To Order

The first meeting of the NCCAM Trans-Agency Complementary and Alternative Medicine (CAM) Coordinating Committee was called to order at 2:00 pm by Dr. Harlan.

I. Opening Remarks - Dr. William Harlan, Office of the NIH Director

Dr. William Harlan, chair of the NCCAM Trans-Agency CAM Coordinating Committee, welcomed all the participants to the meeting. He said that last years' IC coordinating meetings were productive and that participants provided significant input into the former Office of Alternative Medicine's efforts to collaborate on both research projects and information transfer. As a result, a number of collaborative projects are taking place between NCCAM and the various Institutes and Centers at NIH. He described the legislative mandate that elevated the former Office of Alternative Medicine to the National Center of Complementary and Alternative Medicine last fall. The requirement for the Director of NIH and the Director of NCCAM to designate a representative from each Institute and Center to serve as full time liaisons with NCCAM to facilitate appropriate coordination and scientific input for CAM research was the basis for the expanded committee that is meeting today. Dr. Harlan thanked Dr. Cheung for his impressive work as Deputy Director and for helping coordinate this group. He also thanked Mr. Doug Hussey for his time and efforts in arranging this meeting.

Dr. Harlan said this meeting was designed to promote discussion about the various research programs in process and the mechanisms and approaches used. Participants were asked to consider how the programs discussed might be relevant to their organization's needs and to share their ideas on how future collaboration might benefit both organizations. The scientific expertise and fiscal resources provided by the other Centers and Institutes has greatly benefitted NCCAM. At this time, participants introduced themselves.

II Current NCCAM Research Programs - Dr. Richard Nahin, Extramural Program Officer, NCCAM

Dr. Nahin discussed some of the current and future research programs within NCCAM. He summarized the differences and provided examples of the three types of programs: (1) development grants, (2) Phase III trials, and (3) Center grants. The developmental program addresses methodological and design issues for clinical research on CAM. Applications are identified through program announcements as well as through investigator-initiated applications

(R21). Phase III trials are either awarded through contract RFPs or RFAs. The Centers program has two types of awards. U24s are exploratory projects designed to establish an infrastructure for conducting CAM research at academic institutions around the country. By contrast, P50s fund specific clinical and basic research projects within the Centers and core facilities that support Center research.

Dr. Nahin discussed relative NCCAM funding by program areas, by content, and by funding mechanism for FY 1998 and FY 1999 (estimated). For FY 1998, the Centers program consumed 46 percent of the total NCCAM budget, and only a slight decrease is projected for 1999 (44 percent). Significant funding for this program is required to generate pilot data, to train investigators (an integral requirement), and to manage public awareness programs. Another significant aspect of the NCCAM research budget is that 53.5 percent of funding is allotted to NCCAM-initiated projects (RFAs and RFPs). This is not surprising, he said, since rapid budget growth in the last few years has made it difficult to use funding for investigator-initiated grants. Initiatives are focused on funding quality research within a given fiscal year. However, funding for NCCAM-initiated projects should decrease once the budget becomes stable. Following NCCAM's mission to identify and validate CAM, about two thirds (67 percent) of the total NCCAM budget was allocated to clinical research in both FY 1998 and 1999. Congressional initiatives to legitimize alternative medicine for public uses through clinical research are a major factor driving these numbers. However, basic research is expected to increase in the future as the budget increases and as conventional scientists become more interested in looking at the mechanisms of action of CAM. Although no current initiatives are planned in basic research, P50 centers are required to include mechanistic studies in their portfolio.

A sampling of multicenter Phase III trials include (1) hypericum for depression in collaboration with National Institutes of Mental Health (RFP), (2) acupuncture for osteoarthritis in collaboration with NIAMS (RFA), (3) ginkgo biloba for dementia in collaboration with NIA (RFA under review), and (4) glucosamine/chondroitin for osteoarthritis in collaboration with NIAMS (RFP under review). A sampling of single-site Phase III trials includes (1) shark cartilage for cancer in collaboration with NCI (CTEP), (2) "Gonzales Regimen" for cancer in collaboration with NCI (CTEP), (3) acupuncture in the treatment of depression (RPG), (4) melatonin for sleep disorders in Parkinson's Disease in collaboration with NINR (RPG), (5) nonpharmacologic analgesia for invasive procedures (RPG), (6) chiropractic manipulation for chronic pelvic pain (Center), (7) osteopathic manipulation for spastic cerebral palsy (Center), and (8) Hawthorn to treat heart failure.

The entire portfolio of basic (mechanistic) studies consists of (1) neurobiology of acupuncture analgesia (RPG), (2) neurophysiological consequences of lumbar facet movement (RPG), (3) ginseng pharmacology and cytokine stimulation (Center), (4) in vitro evaluation of antioxidants with standard anticancer drugs (Center), and (5) in vitro studies of static magnetic fields on cancer cell growth (Center). The following six are priority projects under consideration for future NCCAM initiatives: (1) investigations of echinacea efficacy in the treatment of otitis media in children, (2) saw palmetto and benign prostatic hyperplasia, (3) massage therapy for low birth weight infants, (4) milk thistle for liver disease, (5) garlic for cardiovascular disease and cancer, and (6) training and career development for investigators (actively being pursued). Currently,

training and career development initiatives are limited to cofunding training slots on existing T32s or occasionally for a National Research Service Award fellow. Program announcements are being circulated for Ks, Ts, and Fs but the response hasn't been significant. In the future, set-asides may be an alternative route toward meeting this objective.

In the discussion session that followed, Dr. Harlan said that the disproportionate amount of funding for RFAs was in large part attributable to the fact that the former OAM did not have direct authority to fund research grants nor did it have appropriate peer review panels in place. Dr. Nahin said that since the transition of OAM to Center status, NCCAM has its own study sections; three reviews will take place this summer, one for investigator-initiated and training grants, one for the center RFA, and the other for a ginkgo biloba RFA. Most of the investigator-initiated R01 type applications will still be sent to the Center for Scientific Review (CSR) and appropriate ad hoc reviewers will be identified if necessary. R21 grants are being reviewed by NCCAM because they require more knowledge about alternative medicine. One participant inquired whether the referral guidelines had been approved. Dr. Nahin said the guidelines are at CSR; comments have been received only from three Institutes and some conflicts must be resolved. The guidelines will not be finalized until it becomes more clear how well they are working.

In response to a question about how the size and focus of the Center has changed. Dr. Nahin said that all Centers except for the chiropractor center are disease specific (cancer, asthma, arthritis, etc.), designed to yield a cohort of investigators with common knowledge to integrate clinical and basic research toward a common goal. He said the number of applicants for the new centers has been highly satisfactory; 39 P50s were submitted. The ginkgo biloba trial, however, is much more specialized and not expected to attract nearly as many applicants.

Dr. Nahin attributed much of the temporary problem with obtaining appropriate training to the fact that mentors are required and there is a short supply of them as well as academic scientists studying alternative medicine. As more and more conventional scientists enter the field and receive funding from the other Institutes, the pool of mentors is expected to expand.

In response to the question of whether there is currently any alternative medicine research looking at substance abuse, Dr. Nahin described two projects: addiction research (P50) at the University of Minnesota and a few NCCAM-sponsored NIDA basic science projects.

Dr. Nahin and Dr. Cheung stressed that NCCAM exercises flexibility in how cofunding decisions are made by looking on a case-by-case basis at the ways in which the proposed research ties into what the NCCAM is doing. There are several opportunities for conventional research to introduce a CAM component or arm. The concept of adding arms to projects is relatively new and it must be planned for in the early stages of a project. Participants were encouraged to provide input and identify opportunities for adding arms to trials and for ways of utilizing the existing resources and networks more efficiently and cost-effectively.

Other discussion points revolved around the need to promote better dialogue between Eastern and Western medicine and the challenges of sustaining growth and commitment bases in vastly

fluctuating, unpredictable cycles of expansion/contraction. With regard to the first point, Dr. Cheung noted that NCCAM has established liaisons with many countries around the world, and Dr. Harlan said that NCCAM is the designated evaluation and coordinating center for traditional medicine for WHO. With regard to the second point, Dr. Harlan said it was imperative to invest and emphasize training opportunities and to ensure that training leads research rather than the other way around. Ts, Fs, and K training funding are available. Ts are particularly needed and co-funding for all training awards is possible.

III. Models for Collaboration - Dr. William Harlan

Dr. Harlan introduced the next part of the program, which was designed to show approaches for collecting information, collaboration, and using various mechanisms and resources. As he introduced Dr. Jeffrey White, he said that a close relationship has been forged between NCCAM and the Office of Cancer Complementary and Alternative Medicine at the National Cancer Institute.

IV Activities of OCCAM, NCI - Dr. Jeffrey White, Director of Office of Cancer Complementary and Alternative Medicine, NCI

Dr. White reviewed key aspects of NCI's CAM history. He said that grant support represents a large proportion of the NCI's CAM portfolio and that much of NCI's CAM research focuses on large NCI-sponsored clinical trials. He said that NCI's collaborative efforts with OAM may be helping to shed previous public misconceptions that NCI was trying to debunk the effectiveness of CAM research. A major study with the University of Texas-Houston CAM Cancer Center generated significant information about CAM cancer treatments and started many pilot projects in this area. Last October, the NCI created a new office, OCCAM, which was designed to focus all of its activities on CAM. The office had four main responsibilities: (1) to serve as the NCI liaison to the National Center for Complementary and Alternative Medicine (identify common projects with NCCAM), (2) to coordinate NCI's existing CAM projects, (3) to develop NCI's CAM agenda (i.e., to develop a proactive approach), and (4) to serve as an interface to the public, CAM community, and oncology community regarding CAM cancer research.

Some of NCI's CAM cancer projects include the following: (1) Phase III clinical trial of oral shark cartilage in patients with cancer (in protocol review phase), (2) evaluation of intensive pancreatic proteolytic enzyme therapy with ancillary nutritional support in the treatment of inoperable pancreatic adenocarcinoma, (3) University of Texas Center for Alternative Medicine Research, and (4) an NIH RFA for the Center for Complementary and Alternative Medicine Research. Dr. White said the Cancer Advisory Panel on Complementary and Alternative Medicine (CAPCAM) developed between NCI and NCCAM was designed to promote productive communication between the interests of practitioners of conventional and alternative medicine groups. CAPCAM is comprised of 15 members that include a variety of different types of oncologists, an oncology nurse, statistician, and patient representative, and it will become a chartered body in July 1999. Best case series will be presented to CAPCAM, a process instituted at NCI in 1991, to evaluate a certain number of case reports of patients treated with an alternative approach. In 1998, the program was modified to include an independent review by the

CAPCAM. There will be opportunities in July 1999 for organizations to participate in the best case series process. In terms of published cancer research at NCI, 3,198 total studies exist; of these, 68 randomized clinical trials have involved CAM (but there actually may be more clinical trials, since some studies may be mislabeled). In closing, Dr. White said that NCI will co-sponsor a conference on integrating CAM therapies into comprehensive cancer care on June 11 through June 13, 1999.

In the discussion session that followed, Dr. Harlan mentioned that NCI has been using a purifying process for screening natural products and finding the active ingredient and introducing it into clinical trials (e.g., taxol). Dr. White added that research is underway involving a number of products that relate to cancer prevention such as green tea. Natural products as he defined them, he said, are believed to fall under the category of research called CAM-related, not CAM. Dr. Harlan said that best case series research is done similarly at other organizations such as CDC under the name of field investigations. Dr. White said he had limited experience with that process and that he believes it to be laborious although it may generate some useful information. Ms. Michele Chang, CDC, said the Centers for Disease Control does need health services research training to link practitioners in the local community with the scientific and medical community. She said more discourse is needed on how to define common terms and build better relationships between regulatory agencies and the organizations they are evaluating. In response to a question about the future of field investigations within NCCAM, Dr. Harlan said different models are being explored. One in particular is with CDC and involves collecting information, structuring the data, and determining what difference it made in the treatment (not randomized, but purely observational). Dr. White said this model answers the question based on practitioner data but the information yielded cannot be generalizable to entire populations. In response to a question about whether international research studies are expected to become part of the alternative medicine program, Dr. White mentioned one best case study that will reviewed in July from India. Dr. Cheung also mentioned that collaborative efforts for a CAM best case series study is also being pursued with a German physician.

V. Remarks - Dr. Harold Varmus, Director, NIH

Dr. Varmus said that the elevation of OAM to NCCAM and increases in funding underscore the need for greater interagency collaboration among the Institutes at NIH and other agencies. He expressed his appreciation to Dr. Harlan for accepting the position of Acting Director of NCCAM and mentioned that the search for a permanent NCCAM Director is well underway. He said it is unknown what NCCAM funding levels will be for next year. However, for the funding that does become available, NCCAM must ensure it best utilizes the various contributions that all organizations can bring to this effort. He emphasized the need to pursue research that enables the research community to test most promising treatments for the worst types of problems and to pinpoint "what works" and "what's safe" rather than spending significant effort on philosophies, dogmas, and anecdotes. In response to a question about prospects for intramural alternative medicine research, Dr. Varmus said this type of research will be done within the context of the intramural program that currently exists and that funding for training is available.

VI Activities of AHCPR - Dr. Mary A. Cummings, Agency for Healthcare Policy and Research

Dr. Cummings first presented a history of AHCPR's work with CAM. She said most of the agency's extramurally funded research in alternative medicine has taken place at the Center for Outcomes and Effectiveness Research. The agency's interest in CAM began in the early 1990s, and two other centers within AHCPR are employing CAM research. They are the Center for Cost and Financing Studies and the Center for Practice and Technology Assessment. (Participants received a fax prior to this meeting which describes research taking place at these centers.)

Much of the CAM research at AHCPR has focused on chiropractic medicine, then and now. The first study was a randomized controlled trial that compared the effectiveness and costs of patients using chiropractors and physical therapy versus patients following treatment prescribed in an educational booklet. This study drew significant publicity, and a congressional mandate requested that investigators spend \$300,000 to further investigate how to integrate chiropractic and medical education. AHCPR then funded a study to compare medical education versus chiropractic education at three medical schools across the country and prepared a report. AHCPR also funded a study at University of North Carolina to look at back pain outcomes and efficiency of care in urban versus rural settings. The study compared treatments by orthopedic surgeons, chiropractors, and primary care physicians. Outcomes were the same across these groups, but costs varied. Another funded study at UNC involved teaching primary care physicians to use a few simple spinal manipulations to treat back pain. The outcome of that study was that primary care physicians were comfortable doing this procedure themselves as well as referring patients to chiropractors.

A current study with Group Health in Seattle, Washington, is looking at alternative therapies for back pain. The primary objective is to compare Chinese acupuncture and therapeutic massage for chronic low back pain versus using a booklet and a videotape about self-management. This study is still in progress. AHCPR is cofunding a national alternative medicine ambulatory care survey. The goal is to provide comprehensive descriptions of alternative providers, the numbers and types of patients served, types of problems encountered, methods used for diagnosis and treatment, and the amount of time spent with patients. AHCPR is also funding the state of Washington part of the study (with acupuncturists, massage therapists, and naturopaths), which is patterned after the national alternative medicine ambulatory care survey. AHCPR is cofunding with NCCAM two acupuncture pilot studies just underway: one evaluates the efficacy of acupuncture for back pain; the other looks at treatment of depression during pregnancy.

A few years ago, AHCPR cofunded a conference with OAM to assess how insurance companies make coverage decisions for CAM. The findings were that decisionmakers had very little data sources to guide these decisions. In response to this finding, AHCPR worked with OAM on a methods conference to develop strategies that address the common challenges for assessing the evidence of effectiveness (What works for whom? And at what costs?) of all CAM interventions. The plan is to hold a conference that will bring together experienced methodologists with alternative medicine methodologists to discuss how to develop new methodologies. A second conference will bring alternative providers with these two groups of methodologists.

One of the largest surveys completed, the medical expenditure panel study with AHCPR, NCHS, and other organizations looks at national expenditures of health care use, sources of payment, and insurance coverage for the US civilian, noninstitutionalized. Supplemental data were collected on alternative care in the 1996 panel and will be collected again in the future. The types of alternative care covered included acupuncture, nutritional advice, massage therapy, herbal remedies, biofeedback, meditation, homeopathy, spiritual healing, prayer, hypnosis, traditional medicine, Chinese, Ayurvedic, etc. This survey excluded chiropractors.

There are also evidence-based reports and technology assessments. In 1997, AHCPR established 12 evidence-based practice centers to develop evidence reports and technology assessments of clinical topics that are common, expensive, and/or significant to Medicare or Medicaid. AHCPR is working with University of Texas to do two evidence-based reports: one on garlic and the other on milk thistle.

Dr. Harlan said that NCCAM is working with AHCPR to develop centers dedicated to doing evidence-based practice reviews in CAM, providing the requisite expertise in CAM as well as the methodology for properly handling the data. In the future, it is hoped that more guidelines will be developed, making it possible to evaluate the evidence before embarking on the next step of research. One participant inquired how the AHCPR surveys would capture ethnic and culturally diverse populations. Dr. Harlan said that the Surveillance, Epidemiology and End Results (SEER) database deliberately selected states that represented cultural diversity. SAMHSA is specifically looking at culturally sensitive healing practices.

VII. Discussion: Opportunities for Collaboration - Dr. William Harlan

Dr. Harlan recapped the various types of possible collaboration models, including: (1) joint funding, including add-on supplements to explore CAM approaches, (2) working across many institutes that have extraordinary resources and access to networks of investigators and cohorts, and (3) other contract and grant programs in which organizations can add their expertise. In addition, he said NCCAM would like to collaborate with other Institutes on responding to information requests on CAM therapy. NCCAM would like input regarding how it can build its database so that other organizations can effectively use it as well. The goal is to bring the best expertise together to provide accurate and up-to-date information to the public as well as to develop common sources for reference material. The development of a public clearinghouse and database were mandated within OAM and NCCAM. NCCAM and Office of Dietary Supplements have each developed the database, with citations, and there are opportunities for collaboration there as well.

VIII. Role of the NCCAM Clearinghouse - Ms. Linda Cramer, Project Director, NCCAM Clearinghouse

Ms. Linda Cramer provided an overview of the NCCAM clearinghouse and requested ideas for collaboration and cooperation. The clearinghouse mission was prescribed by Public Law 105-277, to “facilitate and enhance, through the effective dissemination of information, knowledge, and understanding of alternative medical treatment, diagnostic, and prevention practices by

health professionals, patients, industry, and the public.” The clearinghouse began operating in October 1996 to provide a gateway to balanced information about CAM modalities, practices, and related research. Ms. Cramer enumerated several major areas of clearinghouse activity. These areas include but are not limited to (1) providing high quality responses to requests for information (customized for the particular query and audience); (2) recruiting and maintaining a cadre of experienced clearinghouse staff and providing ongoing training about CAM, information, and customer services, and (3) building a complementary and alternative medicine subfile of the Combined Health Information Database (CHID); (4) actively networking with other NIH-funded research and information dissemination programs and with other Government health information clearinghouses to identify publications and services that contribute to CAM for the NCCAM clearinghouse constituency, and (5) conveying back to NCCAM the types of information in which the public expresses interest. She said more outreach will be conducted in the future. She discussed the clearinghouse audience, which is mostly comprised of the general public (57%)—people with an interest in CAM who haven’t volunteered details about the reason for their interest; patients, families, or friends, (20%)—people who request information regarding a specific health condition, and conventional health professionals, (11%)—requestors who practice conventional medicine, and the remaining 12%—media, students and researchers, and others. Clearinghouse services include but are not limited to a toll-free telephone information line, fax on demand service, publications and quarterly newsletter, referrals to CAM information available from other federal agencies, online database of the CHID, and exhibits at meetings, health fairs, and conferences. In closing, Ms. Cramer said comments on the CHID subfile would be greatly appreciated.

Dr. Cheung and Dr. Harlan asked participants to consider having the NCCAM clearinghouse serve as a bridge to their agency with respect to disseminating information within their particular mandates. All participants will receive the newsletter and the monthly clippings of CAM articles. Dr. Cummings noted that chiropractic guidelines (evidence based) are available on the AHCPR national guideline clearinghouse, providing opportunities for referrals. One participant inquired whether there is an organized way for participants to interact with the various Institute and Center clearinghouses. Dr. Cheung said he would like to work with the NIDA and Alcohol Abuse clearinghouse, adding a CAM piece. Ms. Michelle Chang, CDC, said she would like to work with NCCAM to develop a CAM-specific clearinghouse as well as videoconferencing to exchange information related to CAM methodologies for established public health practice. Dr. Ralph Helmsen discussed the rise and score program (SO6) at the National Eye Institute, which provides an opportunity for confunding in the areas of botanicals. Dr. Cheung said that they would consider partnering on this type of research and that an IC Rep first would screen the information. Dr. Cheung also mentioned that SBIR funding is available and asked Institutes and Centers with SBIR or STTR Phase I or II CAM components to forward information.

IX Closing Remarks - Dr. William Harlan

Dr. Harlan thanked the participants for their participation in a lively, engaging meeting. He encouraged them to contact NCCAM staff and to keep the lines of communication open in pursuing a wide range of opportunities for collaboration. The meeting was adjourned at 4:20 pm.