The National Cancer Institute's (NCI) Office of Cancer Complementary and Alternative Medicine (OCCAM) hosted an ambitious conference titled 'Traditional Chinese Medicine and Cancer Research: Fostering Collaborations; Advancing the Science,' held April 10 through 12 at the National Institutes of Health (NIH) campus. This endeavor took six months of planning and was prompted by multiple meetings with the China Academy of Chinese Medical Sciences (CACMS), a national center for TCM research, teaching, and health care in China.

Almost 200 scientists and physicians attended the conference, including more than 40 who traveled from China to participate. While the conference included posters and presentations like a standard biomedical gathering, its main purpose was to serve as an incubator for establishing new collaborative relationships between Chinese and Western scientists interested in researching Traditional Chinese Medicine (TCM) for cancer prevention, treatment, and palliation. “This meeting is about getting to know each other,” said Dr. Jeffrey D. White, Director of OCCAM, on the first day of the conference. “Hopefully, we have structured it in a way to allow people to meet each other and learn from each other, and we want to encourage that as much as possible.” A primary goal of the meeting was to provide an opportunity for NCI intramural researchers to explore specific topics that could be the subject of collaborations with Chinese investigators.

The last several decades have seen an explosion of interest in all types of complementary and alternative medicine (CAM), within both the public and the biomedical research community. TCM is unusual among modalities that fall within what is considered CAM in the West in that it is a complete medical system developed over thousands of years, encompassing physiology, pathology, and prevention and diagnosis of disease.
As Dr. Yong Ming Li from Warren Hospital, New Jersey, explained to the audience, TCM and Western medicine view the body differently. While Western medicine has traditionally used dissection to obtain knowledge of the inner workings of the body, TCM has used observation of how the body reacts to treatments to elucidate organ function. In the realm of cancer therapy, Western medicine has one target—the cancer—while TCM is also concerned with restoring energy balance, called qi, within the body.

Dr. Lorenzo Cohen from MD Anderson Cancer Center, whose research group has an ongoing, NCI-sponsored collaborative agreement with Fudan University in Shanghai, China, described his understanding of the principal of qi on the third day of the conference: “TCM examines the human being as an ecosystem in which polarities constantly interact in flowing regular cycles. The methods employed in the practice of TCM are intended to treat perceived or suspected blockages or imbalances, either excesses or insufficiencies, and to restore balance, energy flow, and vitality.”

Many aspects of TCM, such as anti-cancer herbal therapies and acupuncture, are being studied by oncologists in both China and the West. The main challenge facing researchers is how to apply modern scientific methodology to the evaluation of TCM therapies, which are traditionally highly individualized for each new patient. Two subjects that arose over and over during the three days of the conference were the vital need to understand the molecular mechanisms behind the observed efficacy of any TCM treatment and the need for product authentication and quality control.

“I would argue that it is foolish to go right to large clinical trials without reproducible product,” stated Dr. David Eisenberg, Associate Professor of Medicine at Harvard Medical School, closing the first day of the conference. “Furthermore, and this is perhaps the most important point, clinical trials alone will be insufficient. Preclinical, mechanistic studies alone will be insufficient. We absolutely...need both to authoritatively research TCM or any herbal preparation.”

Participants discussed the challenges faced in international collaborations during the second day of the conference, which provided open breakout sessions on topics ranging from human-subjects and animal-use issues to the integration of TCM and Western cancer research. On the third day of the conference, a panel of researchers from the United States, Europe, and China related their experiences with successful—and unsuccessful—collaborations in TCM: what worked and what needed work.

“I don’t believe there should be Chinese medicine or Western medicine...medicine is medicine,” said Dr. Yung-Chi “Tommy” Cheng from Yale University, who closed the conference with a talk on translational research in TCM. The conference participants agreed, as they made plans to explore new applications of TCM to cancer therapy together. “I think that this conference has achieved its expected goal,” stated Dr. Liu Baoyan, Vice President of the CACMS. “We have built a bridge for future cooperation on TCM studies between scientists in the U.S. and China.”
Please say a little about the scope of your responsibilities as Deputy Director of the NCI and how complementary and alternative medicine (CAM) fits into those duties.

I lead the trans-NCI strategic scientific planning and prioritization process. My portfolio includes 13 offices, centers, and divisions with a focus on cancer prevention, cancer control, international cancer control, and health services research. My principle efforts are focused on applying systems thinking to increase the impact that NCI has on the quality, cost, and reimbursement of cancer care, as well as the reduction of cancer health disparities. One office to which I provide strategic leadership is OCCAM. OCCAM functions as a coordinating office for the Institute’s research and information activities regarding CAM, so its work supports the efforts of programs throughout NCI’s intramural and extramural components.

Through my exposure to OCCAM’s programs and projects, I have found that CAM research and information issues are relevant in some way to most, if not all, of the 8 strategic objectives that we have elaborated for the Institute in The NCI Strategic Plan for Leading the Nation. Given my focus on cancer care delivery, I have taken particular notice that a significant percentage of the grants in NCI’s CAM research portfolio relate to our objective to improve the quality of cancer care, however, an even larger percentage of grants are relevant to NCI’s strategic objective to accelerate progress in cancer prevention. Many of these details are being prepared for public dissemination in the first NCI’s CAM Annual Report: Fiscal Year 2005.

Recently, you’ve been invited to speak at two international CAM meetings: Non-Conventional Treatments for Cancer Patients held by the AIMaC, the Italian equivalent to the Cancer Information Service, and the Traditional Chinese Medicine and Cancer Research: Fostering Collaborations; Advancing the Science. What do you see as potential collaborations that can be accomplished through dialogue with international partnerships?

From my participation at those meetings, it was apparent to me that CAM is an international phenomenon. Issues related to CAM vary from country to country, but there are common connecting elements. For example, there is a universal need to generate an evidence-base for clinical practice through rigorous cancer CAM research. We should not work in silos but share our resources and advancements through international partnerships.

Another similarity amongst countries is the necessity for high quality information products on CAM therapies for cancer geared for the general population. As a result of this particular need, Thinking About Complementary and Alternative Medicine, a booklet jointly produced by NCI and the National Center for Complementary and Alternative Medicine that gives an overview of the various cancer CAM therapies...
and how to find credible CAM information resources, has been translated into Italian and French.

International connections and collaborations are important as they give us an opportunity to learn from the experience of others.

Are there specific ways in which NCI can make a meaningful impact on the field of cancer CAM? What can NCI do to further research in the field of CAM?

The National Cancer Institute has a mandate and responsibility to support the development of scientific knowledge that improves the care of cancer patients. Since many cancer patients, estimated to be as high as 80%, use CAM resources, NCI will continue to fund research into CAM practices in cancer patients. In addition to maintaining a research portfolio in cancer CAM, OCCAM will continue to work with other programs within NCI, such as the Cancer Centers Branch and the Community Oncology and Prevention and Trials research group, and collaborate with other NIH Institutes and Centers to support cancer CAM research. We also have an important role to play in educating health care practitioners and consumers about the evolving research in the field of CAM and cancer.

NCI to Publish First Annual Report on CAM and Cancer Research

Led by the efforts of OCCAM, NCI plans to release in fall 2006 the first in a series of annual reports regarding the agency’s cancer CAM activities. This publication, NCI’s CAM Annual Report: Fiscal Year 2005, will be a collection of the successes, large and small, of the cancer CAM communication, training, and research projects that NCI has sponsored between October 1, 2004 and September 30, 2005, as well as results announced in that period from previously funded projects.

The report will present research highlights from NCI’s comprehensive grant portfolio organized by the strategic areas as defined in The NCI Strategic Plan for Leading the Nation, cancer CAM information products, meetings and workshops, and a reference list of peer-reviewed literature that resulted from NCI grant awards. The report also will provide a closer look at the definitions of CAM as well as a break-down of NCI’s CAM research portfolio by CAM category.

“This annual progress report on NCI’s CAM research and programs was commissioned to communicate the breadth and depth of the projects contained in NCI’s CAM portfolio, to share the commitment of the research community that I witness every day, and to convey the sense of hope that progress brings,” noted Mark Clanton, M.D., NCI Deputy Director and Deputy Director for Cancer Care Delivery Systems.

Project summaries featured in the “CAM Annual Report” will include:

- The Women’s Healthy Eating and Living (WHEL) Study Testing High Vegetable Diet for Breast Cancer Recurrence
- Milk Thistle and Prostate Cancer: Moving from Bench to Bedside
- New PDQ CAM Summaries Developed for Patients and Health Professionals

“I am encouraged and excited about what NCI has accomplished in advancing the development of evidence-based CAM and what each of those achievements means for the future,” Clanton said. “I commend the work of our NCI scientists and the many extramural researchers who we support through our various programs.”

The announcement of the publication of NCI’s CAM Annual Report will be made on the OCCAM Web site, and it will be available online at

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Investing in Cancer CAM Research: An Analysis of NCI's CAM Portfolio

After each fiscal year comes to a close, OCCAM takes an in-depth look at NCI’s CAM research expenditures. This yearly analysis is an exercise which reveals an estimated total amount of funding that goes to cancer CAM research projects (both intramural and extramural research) and breakdowns according to the type of research (prevention, treatment, side effect/symptom management, and epidemiology), CAM category, and cancer type.

Analysis of the NCI’s fiscal year 2005 (FY 05) CAM portfolio of projects shows that the agency has funded over 400 research projects which include an assortment of intramural and extramural research) and breakdowns according to the type of research (prevention, treatment, side effect/symptom management, and epidemiology), CAM category, and cancer type. One example of information gained from the portfolio analysis is the breakdown of cancer CAM research by approach. The accompanying pie-chart shows the distribution of the NCI’s CAM research projects by: prevention, treatment, symptom/side-effect management, and epidemiology. (See pie-chart). In FY 05, 67% of cancer CAM-related research funds were spent on various cancer prevention efforts, while treatment, symptom/side-effect management, and epidemiology received 17%, 11%, and 5%, respectively.

Examination of NCI’s CAM portfolio is an important step in helping to identify research gaps in the field of cancer CAM and to encourage dialogue about the potential direction of future research. A detailed analysis of NCI’s CAM portfolio will be available in the publication *NCI CAM Annual Report: Fiscal Year 2005*, see previous article for more information.

Can't wait another 6 months for the next newsletter to get your CAM news...

OCCAM has created a new way for you to keep up-to-date with NCI’s activities regarding CAM. You can subscribe to receive OCCAM Announcements, timely e-mail updates about meetings and other events, new information products, funding announcements, and more.

Re-Issuance of Program Announcement “Developmental Projects in Complementary Approaches to Cancer Care” (PA-06-400)

In an ongoing effort to help promote dialogue and collaboration between CAM practitioners and conventional cancer researchers, as well as promote research focusing on complementary approaches in cancer, program announcement (PA-06-400) “Developmental Projects in Complementary Approaches to Cancer Care” has been re-issued for a second time.

Originally released in December 2001, this program announcement soliciting grant applications was generated by OCCAM and the National Center for Complementary and Alternative Medicine to encourage and support the development of basic and clinical complementary cancer research. The support for exploratory/developmental projects through these R21 grants is intended to provide the basis for more extended research projects by establishing the methodological feasibility, strengthening the scientific rationale for these projects, and allowing the collection of data. This announcement is also intended to attract the entry of promising investigators into research of these topics.

Examples of applicable complementary approaches include, but are not limited to nutritional approaches, natural products, mind-body approaches, energy therapies, herbal medicines, and interventions based on medical systems such as Traditional Chinese Medicine or Ayurvedic medicine.

For additional information including topics of programmatic interest and contact information for inquiries, please view the complete announcement at http://grants.nih.gov/grants/guide/pa-files/PA-06-400.html.

Looking for Non-NIH Funding? OCCAM Builds Cancer CAM Research Funding Database

One of the biggest obstacles associated with the field of cancer CAM research is in finding funding. Although there exists a recognized process for applying for federal funds, there is a plethora of non-federal funding sources that are not as easy to locate or identify. The difficulty in finding non-federal funding can then, in turn, be a barrier to obtaining federal funding for foundational or exploratory research. Non-federal funding is often needed to back preliminary research that aids in providing proof of concept required to acquire larger-scale grants from NIH.

To assist cancer CAM researchers in identifying potential funding sources for their proposed projects, OCCAM has developed a directory of non-federal funding sources, which will eventually be converted into a database called the Cancer CAM Research Funding Database. Both the directory and database will contain contact information, organizational characteristics, an overview of the organizations funding programs/processes, and the particular CAM funding interests of a growing number of foundations, advocacy groups, non-federal government organizations, and private sector organizations.

To be included in this new funding resource, organizations must meet two criteria:

- Open Grant Application Process- accepts investigator submitted grant applications
- Interest in cancer and/or CAM research- accepts grant applications for cancer CAM research

“When we ask researchers what we can do to help them, grant funding is always at the top of the list. Often, even fairly small

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amounts of funds can allow a researcher to get critical data which can improve the quality and competitiveness of an application to NIH. Investigators of large, research-intense institutions may have access to information about a range of funding sources, but for smaller centers, this information may not be as easy to come by. This database will provide unique information for researchers looking to have their cancer CAM research financially supported.” Dr. Jeffrey D. White, OCCAM Director said of the new database.

The Cancer CAM Research Funding Database will replace the directory upon completion of design and construction. To access this temporary directory, please visit the OCCAM Web site at http://www.cancer.gov/cam/research_funding.html.

Save the Date: Grant Writing Workshop on November 8, 2006

Mark your calendars for November 8, 2006, when OCCAM leads an upcoming workshop Strategies for Success: How to Write a Grant in Cancer CAM. This technical assistance workshop will be offered as a preconference activity during the 3rd International Conference of the Society for Integrative Oncology (SIO). Held at the John B. Hynes Veterans Convention Center in Boston, Massachusetts, this one day workshop is intended for researchers with an interest in cancer CAM and will address many of the issues raised by review committees.

Specifically, the workshop will focus on the challenges unique to preparing applications in cancer CAM topics and will present some of the potential solutions for applicants. In addition to a mock review session, the agenda will also include presentations from NIH program staff interested in supporting research in cancer CAM. The workshop will be helpful for those preparing grant proposals to the NCI as well as other peer-review funders providing support for scientific cancer CAM research.

Dr. Hongjie Zhang, a previous workshop participant from the University of Illinois at Chicago, says, ”The workshop gave me a clear picture of what OCCAM [NCI] is looking for and what I should do when writing a proposal. The mock grant review let me know how my submitted proposal would be evaluated. Great workshop.”

For more information about the workshop or SIO’s 3rd International Conference, please visit http://www.integrativeonc.org/index.php.

Enhanced Version of Cancer Research Portfolio Released

More information about cancer and CAM research projects and contracts, clinical trials, funding opportunities, and research tools are now available to you than ever before through the enhanced Cancer Research Portfolio.
Updates to this resource, including several new features to the database, were launched this past spring. In addition to NCI-supported projects, cancer-related projects funded by the National Institute on Allergy and Infectious Diseases, National Institute of Child Health and Human Development, National Institute of Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse are now also searchable. Other recent improvements integrated into the database include the ability to find projects supported by a specific funding opportunity, access to the International Cancer Research Portfolio, and clearly defined limitations to database search results.

On the OCCAM Web site, results of pre-canned searches of the Cancer Research Portfolio supply you with CAM projects as they apply to prevention, treatment, and the supportive care of patients and survivors. To view this information, please visit http://www.cancer.gov/cam/research_portfolio.html.

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Research Highlights

Natural Compounds Studied for Prevention of Colon Cancer

Limited information exists on the cellular mechanisms by which natural compounds may inhibit disease processes, including cancer. The lack of clear information presents a barrier for moving natural compounds into chemopreventive clinical trials.

Chinthalapally Rao, Ph.D., professor of Hematology and Oncology at the University of Oklahoma Health Sciences Center, is leading a study to understand the mechanisms of action of curcumin, found in the spice turmeric, and phenylethyl-3-methylcaffeate (PEMC), a compound found in honey-bee hives. Both products have been used in folk medicine to treat various diseases for thousands of years and have been shown to inhibit colon tumor formation in laboratory animal models.

Preliminary studies showed that these two compounds inhibit the metabolism of arachidonic acid (AA), a substrate of cyclooxygenase (COX) and lipoxygenase (LOX) - enzymes that produce tumor-promoting substances. Tumeric and PEMC also block the formation of adenocarcinomas in the colons of rats that are caused by azoxymethane (AOM), a known colon carcinogen.

In their NCI-funded investigation, the researchers used rat models to examine the effects of curcumin and PEMC on the expression and activity of enzymes known to be involved in different stages of AOM-induced colon carcinogenesis. The investigators found that curcumin and PEMC suppressed colon tumor growth, and PEMC also exerted an anti-angiogenic effect on colon tumors by preventing the formation of new blood vessels to feed the tumors.

Neither curcumin nor PEMC showed any toxicity or unwanted side effects in the animal models used in the studies. Human studies will be required however to determine if curcumin and PEMC inhibit colon tumor growth without the side effects seen with synthetic COX-2 inhibitors, such as celecoxib.

Recent Phase I clinical trial studies have shown that administration of curcumin at 3.6 grams per day produced no side effects and significantly decreased levels of a...
COX-2 metabolite in humans. Currently, Rao and colleagues are considering a Phase II clinical trial to test the effectiveness of curcumin as a preventive agent in individuals at high risk for colorectal cancer.

**Study Examines Impact of Lifestyle Changes on Breast Cancer Outcomes**

For nearly three decades, breast cancer survivors have led a grassroots movement to involve patients more in their care and treatment. The result has empowered many women not only to survive their cancer, but to emerge with a greater sense of purpose, closer ties with other patients and women, and perhaps a different diet and lifestyle.

“However, there is little information on whether these changes actually impact their prognosis,” says Lawrence H. Kushi, Sc.D., associate research director at Kaiser Permanente in Oakland, California. “We wanted to do a large study that followed women from the time they are diagnosed, and examine whether their lifestyles may influence their cancer outcomes - including their risk of recurrence and survival rates. As far as we know, this will be the largest prospective cohort study ever conducted in breast cancer survivorship to look carefully at lifestyle changes and diet.”

The study is called “Pathways: A Study of Breast Cancer Survivorship”, and Kushi and his colleagues, starting in January 2006, will enroll more than 5,000 women soon after their initial diagnosis. Study participants are welcomed with a credo: “There are many ways to live with breast cancer. Each woman will make her own choices and walk her own path.” Nonetheless, *Pathways* participants will be exposed to information about diet, dietary supplements, herbal remedies, exercise, social networks, and other CAM interventions commonly used among breast cancer patients.

Researchers interview all women who join the study to develop baseline information on the use of CAM therapies, food intake, quality of life, and other lifestyle factors. “Pathways isn't an intervention study per se, so we're not asking study participants to make specific changes,” says Kushi. “But we know that many women in these circumstances do change their diet, may seek CAM treatments, and otherwise respond individually to the challenge of breast cancer. The study is designed to tell us whether the changes women do choose to make may have a bearing on their prognosis.”

For example, “We will be comparing women who consume relatively high amounts of fat compared to those who consume relatively low amounts of fat during the study time period,” Kushi adds.

The investigators are also collecting DNA from blood and tumor samples, and will be able to analyze specific genes for variants or damage, as well as those expressed in the tumor microenvironment. This should yield associations between certain genes and progression, as well as how certain genes may influence the effectiveness of conventional treatments, or modify the effect of lifestyle factors.
New and Improved CAM and Cancer Clinical Trials Tables

Searching for cancer CAM clinical trials in the National Cancer Institute (NCI) PDQ® database just got a little bit easier. With over 4,000 trials listed in the database and approximately 160 of them active cancer CAM clinical trials, it can be challenging to find those one or two particular CAM clinical trials of interest. A newly designed CAM clinical trials search table has recently been added the OCCAM Web site. While similar to the search function on the NCI Web site, this new search table places you one mouse click away from direct access to the entire list of cancer CAM clinical trials, including clinical trials that have already closed.

The new clinical trials search table allows you to view active CAM clinical trials by either cancer type or an associated symptom. There are currently approximately fifteen cancer types listed as active CAM clinical trials, examples include:
- Bladder Cancer
- Head and Neck Cancer
- Lung Cancer
- Prostate Cancer

There are six common symptoms for active CAM clinical trials, which include:
- Anorexia
- Hot Flashes
- Fatigue
- Nausea
- Pain
- Oral Complications

For the complete list of CAM clinical trials by cancer type and to access the CAM clinical trials table, please visit the OCCAM Web site at http://www.cancer.gov/cam/clinicaltrials_list.html.

OCCAM Brochures Available

OCCAM’s newly redesigned general office brochure and the NCI Best Case Series Program brochure are now available.

The OCCAM brochure aims to introduce OCCAM’s role as a coordinating office within NCI and its three distinct programs.

The purpose of the NCI Best Case Series Program brochure is to provide practitioners who treat cancer patients with alternative therapies information on how to submit data for NCI review. This publication includes an overview of the submission process, criteria for optimal cases, and answers to the most frequently asked questions.

Copies of the brochures can be requested by calling the Cancer Information Service at 1-800-4-CANCER.
Join Us at the OCCAM Monthly Lecture Series

OCCAM invites you to attend the OCCAM Monthly Lecture Series, in which notable researchers present their work in CAM and cancer. These lectures occur every second Wednesday of the month and are open to the public. As examples, previous lecture topics have included traditional medicine as prevention of colon cancer, herbal medicine for chemoprevention of lung cancer, and ascorbic acid in cancer treatment.

Dr. Jin-Rong 'Joseph' Zhou of Beth Israel Deaconess Medical Center will be presenting in September. The title of Dr. Zhou’s talk will be “Soy Phytochemicals and Tamoxifen Combinations on Breast Cancer Progressions.” Subsequent topics and speakers as well as archived videocasts of several past lectures will be posted on the OCCAM Web site at http://www.cancer.gov/cam/news/monthly-lecture-series.html.

A Cancer CAM Primer for Oncology Nurses

The Oncology Nursing Society (ONS) sponsored its first all-day session on cancer CAM at its 31st Annual Congress in Boston, Massachusetts in May 2006. Presenters Georgia Decker, ONS President, and Commander (CDR) Colleen O. Lee, Practice Assessment Program Coordinator from OCCAM, developed the session in response to ONS members' requests for comprehensive national programming. They were joined in the afternoon by a third presenter Marion Bergan Irwin, a licensed acupuncturist from Albany, New York. The content was tailored to nurses whose practices span from community, hospital, to research-based facilities involving the care of cancer patients within acute, chronic, and supportive care settings.

The Cancer CAM Primer for Oncology Nurses was split into morning and afternoon workshops. The morning educational workshop included topics such as the historical role of CAM and care of the whole person; complexities surrounding certification, reimbursement, ethics, and legal

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considerations in the delivery of CAM therapies by nurses and non-nurses; current evidence-based use of conventional and CAM modalities for symptom management; and the potential impact of herbs and supplements with cytotoxic agents. Demonstrations and hands-on learning about acupuncture; various herbs, vitamins, and biologics and how to read supplement labels; and searching CAM information databases comprised the three afternoon workshops.

As a result of the success of this year’s CAM Primer, a cancer CAM supplement will be submitted to the Society’s two peer-reviewed journals *The Oncology Nursing Forum* and *The Clinical Journal of Oncology Nursing*. In addition, a pocket guide highlighting the evidence-based conventional and CAM interventions for the symptoms discussed in the Primer session will be published. “If all goes well, our proposal to repeat the CAM Primer at the 2007 Congress will be accepted. We plan to offer an advanced tier to the session that will provide more experiential sessions,” said CDR Colleen Lee.

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### Featured Scientific Meetings

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<td>November 4-8, 2006</td>
<td>American Public Health Association 134th Annual Meeting &amp; Exposition</td>
<td>Boston, MA</td>
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<td>November 9-11, 2006</td>
<td>Society for Integrative Oncology Third International Conference</td>
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To obtain a copy of this newsletter or for inquiries on cancer and CAM, please contact 1-800-4-CANCER (1-800-422-6237).