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Featured Scientific Meetings

Ayurvedic Medicine Formulations from India Reviewed for Cancer Treatment

A panel of researchers and clinicians was convened by the National Cancer Institute's (NCI) Office of Cancer Complementary and Alternative Medicine (OCCAM) on June 30, 2010 to discuss cases of cancer patients in India treated with metal-based Ayurvedic treatment (MBAT) formulations.



Vaidya Balendu Prakash, an Ayurvedic practitioner, presents his clinical findings to NCI

The meeting provided an opportunity for NCI staff and outside experts to review and discuss some of the case reports which Vaidya Balendu Prakash, an Ayurvedic practitioner from Mumbai, India had submitted via the NCI Best Case Series (BCS) program. Director of OCCAM's Case Review and Intramural Science Program (CRISP), Dr. Farah Zia, noted, "The NCI BCS program offers CAM practitioners expert assistance in identifying and compiling persuasive case studies as well as the opportunity to have their data evaluated by NCI. The goal of the program is to make a determination about whether or not NCI-initiated research is warranted."

Mr. Prakash provided background on his practice of Rasa-Chikista, a branch of the ancient Indian Ayurvedic medicine system, which uses compounds made of various combinations of native plants, animal products, and metals (mercury, gold, silver, copper, iron, tin, lead, and zinc). The ayurvedic compounds are created through a "tedious method of preparation" of grinding, heating and combining the various compounds that can take 2-3 years to complete for each batch, he noted.

Mr. Prakash learned about the preparation and use of ayurvedic medicines from his father, an Ayurvedic physician who used one of the compounds to treat cancer for the first time in 1973 in a 38-year-old man with pancreatic cancer. The patient, who was considered terminally ill, had noticeably improved after six months treatment, and he remains alive today, Mr. Prakash reported. Despite this success, his father was unable to consistently replicate the results with other cancer patients, which Mr. Prakash later understood was probably due to batch variations in the ayurvedic formulation process.

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After the death of his father, Mr. Prakash decided to prepare the same ayurvedic medicines while documenting the process and has used these preparations on many cancer patients. He presented findings from case studies of 14 patients with different leukemias and solid tumors treated with ayurvedic compounds. The typical treatment lasts 5-7 years, Mr. Prakash noted. He reported uniformly positive responses and long-term survival for most of the patients.

Dr. Irina Maric, a pathologist at the National Institutes of Health (NIH) Clinical Center, reviewed cytology slides from a few of Mr. Prakash's case studies, that include patients who were treated by him in the late 1990s. "The slides are about 13-years-old now, and there is marked degradation of the material in the slides and very poor preservation," she said, making

confirmation of the patients' diagnoses very difficult. Mr. Prakash apologized and noted he usually was unable to get good quality slides and pathology reports from the hospitals his patients had attended before, during, and after ayurvedic treatment.

Dr. David Newman, director of NCI's Natural Products Branch, questioned Mr. Prakash about the controls and standardization used in the ayurvedic formulation process. Dr. Newman also asked if Mr. Prakash conducted chemical analyses of the individual batches of the ayurvedic compounds to help identify what specific chemicals may be causing the responses in the cancer patients. Mr. Prakash said he has taken steps to achieve standardization of the batches, monitoring and controlling the temperatures used in melting and combining the various ingredients, including the metals used in creating the ayurvedic medicines. However,

he acknowledged that he has not done chemical analyses of his ayurvedic compounds but that he is currently in discussions with a center in India to do so.

The remainder of the discussion explored Mr. Prakash's past attempts and future plans to participate in collaborative clinical research projects and the kind of information that would be necessary to complete the NCI Best Case Series review. OCCAM's director, Dr. Jeffrey White promised to follow up with Mr. Prakash to request additional data and case studies of more recent patients and to make suggestions for next steps in NCI's evaluation of the ayurvedic compounds. Such investigations fit with the Institute's CAM research goals to study novel therapeutics in the pharmacopoeia of traditional medical systems around the world, Dr. White said. 🙌



NCI staff discuss Mr. Prakash's cases in a lively roundtable discussion.



A Conversation with:

George A. Komatsoulis, Ph.D.
Deputy Director
NCI Cancer Biomedical Informatics Grid (caBIG®)

Dr. George Komatsoulis

What is caBIG® and what is your role in this NCI program?

NCI's Cancer Biomedical Informatics Grid® (caBIG®) (<https://cabig.nci.nih.gov/>) enables the implementation of molecular medicine by creating a world wide web of cancer research; a virtual network of interconnected data, individuals, and organizations that redefines how research is conducted, care is provided, and patients/participants interact with the biomedical research enterprise. The caBIG program brings cancer researchers together by supporting communities, providing access to content and enabling connectivity. caBIG® is a federation; data is managed by the organizations that generate it with the caBIG® interoperability infrastructure (called caGrid) enabling data sharing to authorized individuals both within and between organizations.

We build caBIG® tools to support the needs of cancer researchers. These needs were identified through a series of outreach activities in the cancer research community that began in 2003. We continue to engage the community through a series of “workspaces” - groups that meet regularly by teleconference

and face-to-face to discuss needs in particular research domains. There are four of these “domain” workspaces: Integrative Cancer Research, Tissue Banks and Pathology Tools, Clinical Trials Management Systems and in vivo Imaging. In addition we have what are known as “cross cutting” and “strategic” workspaces that deal with semantics, interoperability infrastructure, training and data sharing and intellectual capital.

To date, we have built 78 tools to support various areas of research including microarray management and analysis, proteomics, nanotechnology, storage, annotation and analysis of images, and biobanking software. We've also made investments in the area of clinical trials software by developing a Clinical Trials Management Suite that includes a patient registration module, an adverse event module, a laboratory integration hub and a study calendar. All of these tools are designed to be interoperable using caBIG® infrastructure.

The director of caBIG® is Kenneth Buetow, Ph.D., who is also director of the NCI Center for Bioinformatics and Information Technology (CBIIT). I support Dr. Buetow as the Deputy Director of CBIIT. In this role, I have fairly broad management

responsibilities over the caBIG® program and represent it in a variety of settings.

Do you think cancer research on complementary and alternative medicine (CAM) is different than conventional medicine research and does it have different data sharing needs?

I don't think that CAM research is fundamentally different than conventional medical research. All of the caBIG tools are as applicable to CAM investigations, and I believe that CAM researchers have the same needs to integrate information or collaborate with others.

The difference between CAM and more conventional researchers is that a big part of caBIG® is usage of data standards, controlled biomedical terminologies and data elements to describe the data you're collecting. For the more conventional clinical trials, we have many standards, data elements and terminologies already available to support research in those areas.

One of the things we hope to do in working with CAM partners is to help them devise the standards and terminologies that are needed in CAM

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research. For example, we are in the process of registering the questions from the Ayurveda extension to our registration module; once there, they are available to other trials.

With that said, many of the assessments that are going to be done in a CAM clinical trial are ultimately going to be the same as for conventional treatments. The same laboratory values, outcomes measures, and patient demographic data are going to need to be collected. Where we're catching up in is in the area of getting good descriptors for the CAM treatment regimens and getting the CAM compounds appropriately characterized. Ultimately, after the first CAM trial is done using caBIG® tools, the next CAM study will be able to use the content from the first trial.

We're looking to engage the CAM community so that what we build and create for caBIG® is usable and accessible to them as much as it is for conventional cancer research. For any CAM researchers who have questions about caBIG®, we're happy to sit down and talk to them about the capabilities that we can create, so they can make a decision as to whether or not caBIG® technology is something that is useful for them and their work.

Could you provide an example of some CAM research studies using caBIG® tools?

A private company in India, BioMantra, that supports research from the Department of AYUSH (Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopath) of the Indian Ministry of Health and Family Welfare, has taken some caBIG® technologies and adapted them

to support research into traditional Ayurvedic medicine. They used the caBIG® Clinical Trials Suite and found that when they register patients into these trials, there was some additional information they wanted to have in the caBIG® patient registration module. They therefore took the module and extended it to support a set of questions that support the kinds of information you would want on a patient treated with Ayurvedic medicine.

This modified caBIG® system is now being offered to participant institutions in India for use as they perform clinical trials. It is quite exciting because we have wanted researchers to take caBIG® technology, modify it for their own specific purposes – in this case for CAM trials – and then move forward to provide those capabilities to their research communities. Further, this is another step toward assessing traditional products and practices in a manner consistent with the standards used to assess standard medical practice.

We're hoping to see other groups take our technology and where it makes

sense, turn it into a commercial or non-commercial product supports specialized communities. Because the caBIG® tools start out as free, open source software, these groups can develop tools that they can more easily offer free, or at a reduced price.

Have you received specific requests and inquiries about caBIG® from CAM researchers?

In addition to the projects in India I mentioned, we have some early phase discussions going on with some groups in China, and we're also working with OCCAM right now to identify opportunities for use of caBIG® technologies for CAM research projects. Frankly, one of the reasons we've been having discussions with the CAM community is because we think that caBIG® tools have a particular value for CAM research. CAM researchers may not have the same level of funding as industry-sponsored studies and because caBIG® software is free, it represents an opportunity for researchers to gain access to a world-class, production-grade clinical trial and genomics research infrastructure. 🐼

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<http://cancer.gov/cam>

NIH Advocates Use of Plain Language for Research Grant Applications

The NIH Office of Extramural Research (OER) is asking current and future research grantees to use “plain” professional language in titles, abstracts, and statements of public health relevance in their NIH grant applications. “It is vital that the NIH makes information about the scientific projects we fund available to the public and Congress in a way that clearly relays the value and potential impact of the research on public health,” OER stated.

Tips for writing in a plain language style include:

1. Remember that the audience reading the title, abstract, and public health relevance statements may not be scientists.
2. Avoid scientific jargon or technical writing.

3. Communicate the bigger picture. State what you are proposing, why it is important, and explain the potential impact on public health.

Additional information about plain language grant submissions is found at http://grants.nih.gov/grants/plain_language.htm.

NCI Surveying Integrative Medicine Programs in the US

OCCAM and NCI’s Office of Communications and Education (OCE) are conducting a brief but comprehensive survey and inventory of integrative medicine programs offered by NCI Cancer Centers and other academic institution-based health centers in the United States.

“There are current knowledge gaps in the literature, on the Internet, and within and among health centers in the US regarding research, clinical, and outreach/communications programs in cancer complementary and alternative medicine,” noted CDR (U.S. Public Health Service) Colleen Lee, M.S.,

CRNP, AOCN®, nurse consultant with OCCAM. To address those gaps, NCI will survey and interview integrative medicine staff from among the 66 NCI-designated Cancer Centers and the US members of the 46 institutions in the Consortium of Academic Health Centers for Integrative Medicine (CAHCIM).

The NCI survey will inventory the research, clinical practices, and educational programs in integrative medicine offered at the health centers. In the research area, OCCAM staff intend to use the information gained in this project to expand their

awareness of the key experts within those institutions and the extent to which they are collaborating with clinical CAM resources. “We believe there is probably some research overlap, and the institutions can benefit from knowing one another’s work, and maybe save some time and funding and advance science a little more quickly,” said CDR Lee. OCCAM will also develop an interactive map of integrative medicine centers in the US which will allow researchers, practitioners, and educators to easily find additional information about the institutions.

SEER and OCCAM Explore a Potential New Collaboration

The use of complementary and alternative medicine by cancer patients is widespread and growing. Recent studies have estimated that between 30%-70% of cancer patients use one or more therapies that fall under the CAM umbrella, and this number will likely continue to increase. To date, the studies estimating CAM use among cancer patients in the United States have come from individual institutions, or have aggregated many such smaller

Surveillance Epidemiology and End Results

providing information on cancer statistics to help reduce the burden of this disease on the U.S. population

reports. Currently, no national cancer registry collects detailed data on CAM for use by the research community.

This data gap may soon be addressed. Recently, OCCAM and NCI’s Surveillance, Epidemiology and End

Results (SEER) (<http://seer.cancer.gov/>) program have begun a discussion on the feasibility of expanding SEER’s data collection on CAM use. The 17 current SEER-participating cancer registries cover approximately 28% of

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Following the 2010 meeting of the National Cancer Registrars Association, representatives from OCCAM and SEER proposed new categories for data collection on CAM use in the United States. This proposal is being considered by several technical and policy review groups responsible for setting standards for cancer registry data systems in the U.S.

PROPOSED NEW CATEGORY	INCLUDES ONE OR MORE OF THE FOLLOWING
No CAM given	It is known that the patient did not receive CAM
CAM, NOS	It is known the patient used some type of complementary or alternative medicine, unknown what type
Alternative medical systems	<ul style="list-style-type: none"> • Traditional Chinese medicine • Homeopathy • Acupuncture • Ayurvedic medicine
Nutritional therapeutics	<ul style="list-style-type: none"> • Diet modification: e.g. vegetarianism • Specific foods, nutrients, non-nutrients • Bioactive food components • Examples: vitamins, antioxidants, soy phytoestrogens, CoQ10, etc.
Pharmacological and biologically-based therapies	<ul style="list-style-type: none"> • Off-label use of prescription drugs not traditionally used as cancer therapies, hormones, vaccines, and other biological interventions • Examples: low dose Naltrexone, Melatonin, antineoplastins, Laetrile, etc. • Complex natural products • Botanicals: herbs and herbal extracts, mistletoe • Extracts from marine animals, i.e., shark cartilage
Exercise therapies	<ul style="list-style-type: none"> • Aerobics • Isometrics • T'ai Chi • Yoga
Manipulative and body-based therapies	<ul style="list-style-type: none"> • Therapeutic massage • Osteopathy • Chiropractic • Reflexology
Energy therapies	<ul style="list-style-type: none"> • Electromagnetic-based therapies such as pulse fields and magnetic fields • Biofield therapies such as Reiki, Qi gong • Therapeutic touch
Mind-body interventions	<ul style="list-style-type: none"> • Meditation • Hypnosis • Art therapy • Biofeedback • Imagery • Relaxation therapy • Support groups • Music therapy • Cognitive-behavioral therapy • Aromatherapy
Spiritual therapies	<ul style="list-style-type: none"> • Intercessory prayer • Spiritual healing
Unknown if CAM was given	It is unknown if CAM was given

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the U.S. population, providing a rich data resource for researchers studying all aspects of cancer incidence and treatment.

“Access to better CAM data in SEER would be of great significance for CAM research, because SEER provides access to such a large database of the American population,” said Isis Mikhail, M.D., M.P.H., Dr.P.H., director of OCCAM’s Extramural Research Program, who is leading the OCCAM side of the discussion. “CAM use is becoming more and more prevalent among cancer patients and CAM research is growing, so it would be beneficial to have more specific information about what kinds of CAM patients are using,” she added.

In April 2010, Dr. Mikhail and Ms. Antoinette Percy-Laurry from SEER presented the concept of a potential OCCAM-SEER collaboration at the annual meeting of the National Cancer Registrars Association (NCRA). Over 300 registrars from all over the United States attended the session. “The registrars are seeing a lot of CAM use, and it’s something that appears to be of growing interest,” Dr. Mikhail recounted.

Currently, SEER collects all CAM use data under a single code in the ‘Other Therapy’ category. This single code provides no specific information other than the fact that a treatment potentially classified as CAM was used. Following the NCRA meeting, Dr. Mikhail and Ms. Percy-Laurry proposed a set of new codes that could better represent the diverse types of CAM used by cancer patients. (See sidebar at left) The proposal is being considered by several technical and policy review groups responsible for setting standards for cancer registry data systems in the United States.

CAM data collection could potentially pose a special challenge for SEER, which is very much dependent on medical records, primarily from hospitals, explained SEER Director Brenda K. Edwards, Ph.D. Physicians do not always ask patients about CAM use and patients often do not think to volunteer that information or may choose to not do so, for fear that a doctor might tell them to stop using CAM treatments.

“There are many domains of CAM, and some aren’t that likely to be recorded in a medical record,” said Dr. Edwards. “If we can’t find it in a medical record we can’t collect the information through routine operations. And if we can’t collect the data we don’t know if it’s something that didn’t happen or if it did happen

and just didn’t get included in the medical chart. We need to get a better handle on what is recorded versus what is actually happening” in terms of CAM use.

Such an understanding would require a pilot project in one or two SEER registries, which could potentially happen in 2012. A pilot project would begin with officially defining the elements to be collected and vetting them with other national registry groups.

“Once the data to be collected has been defined, we like to gather some background information on how easy or hard it is for a registrar to collect this data,” explained Dr. Edwards. “Basically, we would be asking what would you collect, how would you do

it, and if can you find it.”

Some well-established CAM interventions that are often offered within cancer centers – such as nutritional interventions, exercise therapy, massage, and acupuncture – may be easier than others to capture, she said. But even those items will challenge registrars, since it may not always be clear whether patients began use of these therapies after a cancer diagnosis, or if they had already integrated them into their lifestyle.

“These issues aren’t insurmountable, but it’s a big effort to create a new data element that’s collected with integrity,” said Dr. Edwards. “We want to collect data that are meaningful, and have confidence in the quality of the data,” she concluded. 🌊

Funding Opportunities

Funding Available for Research Focused on Symptom Interactions in Cancer and Immune Disorders

Over the past ten years, symptom research has been an area of interest to the cancer research community, with a particular focus on the inter-relationship between various common cancer symptoms. Researchers have begun to consider the interactions of symptoms as a cluster instead of just focusing on individual symptoms, for example, pain depression, and fatigue. To better understand the mechanisms of symptom interaction and further the symptom cluster concept, more research is needed.

In March 2008, the National Cancer Institute, National Institute of Nursing Research, National Institute on Aging, and National Center for Complementary and Alternative Medicine released Program Announcement (PA) PA-08-121 titled “Symptom Interactions in Cancer and Immune Disorders (R01)”. This PA seeks research that will work towards identifying and assessing interactions among two or more related co-occurring symptoms and “characterize mechanisms and

pathways underlying the symptom interaction”. It also encourages research that can more closely define and categorize a symptom cluster. Both observational and intervention research is encouraged.

To learn more about this PA, please visit: <http://grants.nih.gov/grants/guidel-pa-files/PA-08-121.html>. 🌊

Biology of Manual Therapies (R01) studied at NIH

The National Cancer Institute and the National Center for Complementary and Alternative Medicine are committed to funding large projects that study manual therapies such as spinal manipulation, mobilization and massage therapy. The funding opportunity announcement (FOA) titled PA-10-209: Biology of Manual

Therapies, originally released on May 27, 2010 solicits research applications exploring the basic science and mechanisms of action underlying the biomechanical, immunological, endocrinological and/or neurophysiological consequences of manual therapies.

Manual therapies focus on a host of techniques that target structures and systems of the body such as bones and joints, muscles, connective tissues, and the neurological systems. The belief that reducing abnormal stresses and improving alignment of the skeleton

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and its associated soft tissues will elicit the body's natural ability to heal is a driving force in these therapies.

Examples of appropriate investigations for this FOA include, but are not limited to:

1. Imaging studies of the central nervous system response to manual therapies using relevant technologies (e.g., fMRI, PET, SPECT, EEG, etc.) with the goal of

elucidating mechanisms that result in modulation of chronic pain;

2. Development of validated biomarkers for back pain that would be used in subsequent clinical studies of manual therapies;
3. Measurement of physiological changes that may result from manual therapies, with emphasis on the nervous system (and especially the central nervous system), immune system, endocrine system, and interactions thereof.

More examples and information are available on the program announcement web page at: <http://grants.nih.gov/grants/guide/pa-files/PA-10-209.html>.

You may also contact Dr. Isis Mikhail, Director of the Extramural Research Program, in the Office of Cancer Complementary and Alternative Medicine at NCI for more information or guidance when applying for this announcement. Dr. Mikhail can be reached at: mikhail@mail.nih.gov.

The Role of Microbial Metabolites in Cancer Prevention and Etiology (U01)

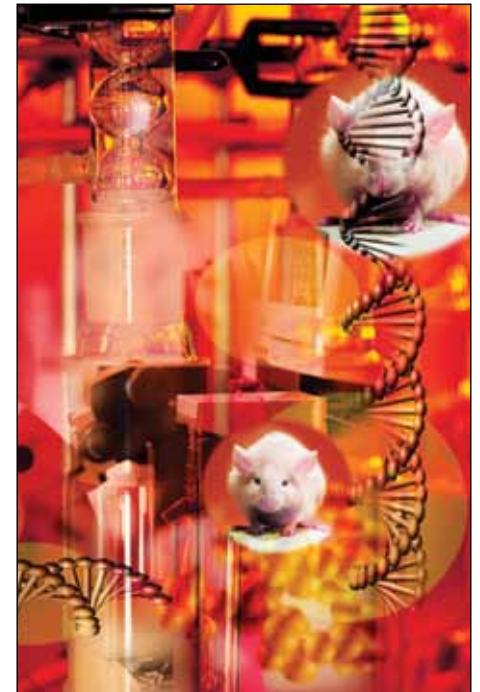
This FOA utilizes the U01 cooperative agreement mechanism and encourages research to better understand the role of dietary components in cancer etiology, prevention, and cancer health disparities to identify who might benefit from specific dietary recommendations and who might be placed at risk.

Program Announcement (PA) number PAR-10-208 titled the "The Role of Microbial Metabolites in Cancer Prevention and Etiology (U01)" was initially released on May 27, 2010 by the NCI and the National Center for Complementary and Alternative Medicine (NCCAM). This announcement encourages the submission of grant applications that characterize the effects of microbially generated metabolites of dietary components on host cell biology to understand the molecular mechanisms of action that affect host cell proliferative/apoptotic responses, cytokine production, inflammatory and immunomodulatory effects. Human intervention studies that identify inter-individual variability among various racial and ethnic groups in the production of bacterial metabolites will help determine their efficacy in cancer prevention. One of the goals of this PA is to facilitate interdisciplinary

collaborations among scientists engaged in nutrition, cancer prevention, cancer cell biology research, and cancer disparities research with those conducting studies with gut microorganisms. All applications must include multiple principle investigators with different areas of expertise such as microbiology, nutrition, cancer biology, analytical chemistry, or genetics.

Specific research areas of interest include, but are not limited to, the following areas:

- Examining metabolites of polyphenols generated by gut bacteria and determine their role in inflammation and colorectal cancer.
- Utilizing mouse models of human cancer with either a human flora or germ free for evaluating the role of soy constituents/metabolites on key cancer related processes.
- Examining urolithin production in humans as a function of ellagic acid intake on activities and expression of cytochrome P450 and phase II enzymes in human buccal cells and esophageal tissue.



- Evaluating the role of dietary animal fat on the population of sulfur-reducing bacteria and their production of genotoxic metabolic products such as hydrogen sulfide.

For more information about this program announcement visit the web page at <http://grants.nih.gov/grants/guide/pa-files/PAR-10-208.html> and/or contact Cindy Davis, Ph.D. at davisci@mail.nih.gov.

New Policy Requires Grant Applications to be Complete Upon Initial Submission

In a policy that became effective for grant applications submitted for the September 25, 2010 receipt date, certain types of late grant application materials will no longer be accepted. The new NIH policy encourages applicants to submit completed grant applications that are ready for review in order to expedite and provide uniformity in the review process.

However, NIH understands that unforeseen circumstances may still

require late submission of certain materials to ensure an informed evaluation of the application. Post-submission material exceptions, which must be received 30 days prior to the initial peer review, include:

- Revised budget page(s) (e.g., change in budget request due to new funding or institutional acquisition)
- Biographical sketches (e.g., change in senior/key personnel due to the loss of an investigator)
- Letters of support or collaboration resulting from a change in senior/key personnel due to the loss of an investigator
- Adjustments resulting from natural disasters (e.g., loss of an animal colony)
- Adjustments resulting from change of institution (e.g., PI moved to another university)
- News of an article accepted for publication

A few other exceptions are outlined in the notice, which can be viewed on NIH's Office of Extramural Research's web site: <http://grants.nih.gov/grants/guide/notice-files/not-od-10-091.html>.



My NCBI Tool replaces eRA Commons for Bibliography Management

NIH strives to streamline the process of information management and sharing. With 27 Institutes and Centers any attempt to integrate processes and procedures is integral in advancing science from both the perspective of the laboratory and the library. The Electronic Research Administration (eRA) Commons systems provide information technology solutions to support the grants administration process from electronic grant submission, processing, review, and bibliography management. eRA Commons allows research program directors and

principal investigators to use the publications page of their personal profiles as a library for publications resulting from their funded grants. However, the current eRA system for bibliographic management was not meeting the needs of the NIH community. Because of this, the NIH has partnered with the the National Center for Biotechnology Information (NCBI) to link NCBI's personal online bibliography management tool "MyNCBI" [<http://www.ncbi.nlm.nih.gov/sites/myncbi/>] with the current eRA Commons personal research profile bibliography Management system.

The NCBI system is a more efficient and accurate way to manage professional bibliographies and ensure compliance with the NIH Public Access Policy, available here: <http://publicaccess.nih.gov/>. The change, effective July 23, 2010, required users to use the NCBI "My Bibliography" tool. This tool helps maintain a list of authored works, such as journal articles and manuscripts accepted for publication. For more information on the integration and how to better use NIH eRA and NCBI information organizing tools, visit the redesigned eRA web site at <http://era.nih.gov/>.

Career Development Awards Recipients Get Advice on Managing Their Grants

Selecting and applying for a NIH Career Development Grant award, or K award, as they are known, is a high honor, as well as an intense commitment. Questions can arise on how to select the correct award, how to submit applications and how to maintain the integrity of one's work while advancing a career in a way that is beneficial to both the grantee and NIH.

Dr. Henry Khachaturian, Director of Policy and Liaison Activities, Division of Loan Repayment, discusses using Career Development Awards to achieve independence in a new podcast available from the Office of Extramural Research.



The podcast is available on the OER web site: http://grants.nih.gov/podcasts/All_About_Grants/index.htm. [titled

Using Career Development Awards to Achieve Independence (June 21, 2010)]

Research Highlights

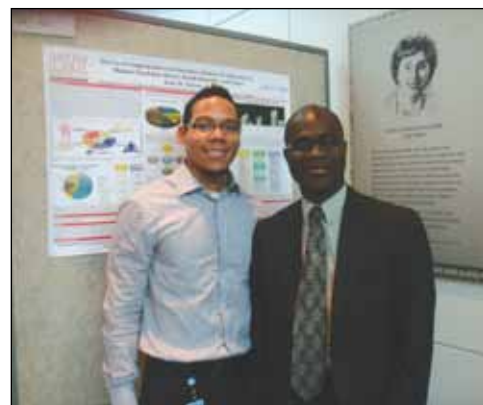
OCCAM Fellows Present CAM Data and Original Research at Research Poster Festival

OCCAM hosted two Cancer Research Training Award fellows in the summer of 2010, each with distinct skill sets and personalities, and each of whom contributed to the science of CAM in very different ways. Jeans Santana, a recent 2010 graduate from Boston College with a degree in Sociology and a concentration in PreMed worked with Drs. Farah Zia and Oluwadamilola Olaku in the Case Review and Intramural Science Program (CRISP). Jeans' personal research, along with working closely on case reviews for the CRISP program, focused on Hispanics and CAM use. Yichao Mark graduated from Boston University with a B.S. in Biology in 2010. He worked in Dr. Francesco Mariconla's laboratory in the Department of Transfusion Medicine on research related to PHY906, a herbal Chinese medicine preparation used in cancer treatment.

Each presented at the NIH Summer Research Program Poster Day on August 5, 2010 at the Natcher

Conference Center on the main NIH campus in Bethesda, MD. Mr. Santana's poster was titled: "The Use of Complementary and Alternative Medicine (CAM) in the U.S. Hispanic Population: History, Health Disparities and Cancer." The objective of this research was to summarize current literature on the use of CAM for the management of cancer within the Hispanic population in the US and how it is related to health disparities. Mr. Mark presented on microRNA profiling of colorectal tumor tissues from rats treated with PHY906 in conjunction with CPT11 (Irinotecan, a chemotherapeutic agent). Each of these posters attracted significant attention from the viewers and provided the fellows with valuable career experience.

For more information about the research presented in this article please contact OCCAM at ncioccam1-r@mail.nih.gov



OCCAM CRTA fellow Jeans Santana and Oluwadamilola Olaku, M.D., M.P.H., MRCOG, Case Review and Intramural Science Program coordinator



OCCAM CRTA fellow Yichao Mark awaits questions on his poster

Study Indicates Ginkgo Biloba Does Not Reduce the Risk of Cancer

Reprinted from NCCAM Research Spotlight

<http://nccam.nih.gov/research/results/spotlight/072010.htm?nav=spl>

A new analysis of data from the Ginkgo Evaluation of Memory (GEM) study suggests that the herbal dietary supplement Ginkgo biloba does not reduce the risk of most cancer types in older adults. Previous research suggested ginkgo might have anti-cancer properties, and this study investigated that possibility in the largest randomized, placebo-controlled trial of ginkgo to date. The findings were published in the journal *Pharmacoepidemiology and Drug Safety*.

The parent study, supported in part by NCCAM, involved 3,069 participants at least 75 years old who were randomly assigned to take 120 mg of a carefully standardized ginkgo product or a placebo twice daily for 6 years. Using hospital admission and discharge



records, the researchers observed 310 cancer hospitalizations among the participants—148 in the placebo group and 162 in the ginkgo group.

The rate of cancer overall was similar between the two groups; however, compared with the placebo group, breast and colon cancers were increased

among participants receiving ginkgo, while prostate cancer was reduced. Although these results were statistically significant, the researchers noted that the study's small number of cancer cases should be taken into account when interpreting their findings for ginkgo and specific kinds of cancer. In addition, the scientists also point out that their research does not rule out the possibility that use of ginkgo starting at a younger age, or with a longer follow-up period might decrease cancer occurrence.

Previous results of the GEM study showed that ginkgo had no effect on dementia and that it did not prevent heart attack, stroke, or death, but may reduce the risk of developing peripheral arterial disease. 🐼

Reference: Biggs ML, Sorkin BC, Nahin RL, et al. Ginkgo biloba and risk of cancer: secondary analysis of the Ginkgo Evaluation of Memory (GEM) Study. *Pharmacoepidemiology and Drug Safety*. 2010;19(7):694–698.

Vitamin D Studied to Treat Advanced Prostate Cancer

The link between vitamin D and cancer risk remains a priority research topic. Researchers are working to address the unanswered questions that surround this connection.

People primarily generate the vitamin D3 hormone (the biologically-active form) when their skin is exposed to ultraviolet B radiation from the sun, explained Candace S. Johnson, Ph.D., deputy director and the Wallace Family Chair in Translational Research at the Roswell Park Cancer Institute in Buffalo, New York. Dietary vitamin D – found in eggs, fish and fortified dairy and cereal products – is usually inadequate, so that people who live

further from the equator or spend less time outdoors have higher rates of vitamin D deficiency, she added.

Dr. Johnson and her colleague Roswell Park CEO Donald “Skip” Trump, M.D., have been pioneering ways to explore the vitamin D link to cancer risk, particularly in prostate cancer. In an earlier phase II trial*, more than 30 percent of men had their prostate-specific antigen (PSA) levels reduced by at least half, after taking a form of vitamin D (1,25 dihydroxycholecalciferol) known as calcitriol. The vitamin D compound was given along with dexamethasone (one of the synthetic hormones known



as glucocorticoids), which appeared to improve the impact of the drug. This impact may be due to increasing the amount of vitamin D receptor (VDR) that is expressed on most of the body's cells, including cancer cells.

continued on next page

* Trump DL, Potter DM, Muindi J, Brufsky A, Johnson CS. Phase II trial of high-dose, intermittent calcitriol (1,25 dihydroxyvitamin D3) and dexamethasone in androgen-independent prostate cancer. *Cancer*, May 15, 2006;106(10):2136-42.

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In her current NCI-funded research**, Dr. Johnson and her colleagues are looking at men previously diagnosed with castration-resistant prostate cancer whose disease has usually spread (metastasized) and is growing without restraint. “Many of them have persistent bone pain and are feeling pretty lousy,” she noted. Most of these patients were originally treated with radiation or surgery, and now hormonal therapy is no longer effective.

“Many of the men in our earlier trial felt better and had less bone pain after treatment with combination of calcitriol and dexamethasone,” explained Dr. Johnson. “We need to know more about what is happening at the molecular level, so that we can determine how much calcitriol we can give safely and the best way to administer it.” In some people, it turns

out that blood levels of vitamin D do not simply rise when you give higher doses of calcitriol. “I think that the dosing schedule may be a crucial part of the vitamin D puzzle,” she said. Early results suggest the best strategy might be to give very large doses for one or a few days, followed by 4 or more days off.

But a larger problem is keeping cancer patients from developing hypercalcemia, Dr. Johnson cautioned. This condition arises when the calcium blood levels get too high and can sometimes lead to digestive and kidney problems; muscle and bone pain; and even psychological issues such as apathy, irritability, and depression. Dexamethasone may decrease calcium absorption by reducing the amount of VDR in the intestinal mucosa, where calcium enters the bloodstream, while at the same time increasing VDR in the tumor, she explained.

So far, the greater amount of calcitriol that’s given, the greater the impact on the cancer and its symptoms, Dr. Johnson added. However, within minutes of calcitriol entering the bloodstream, the *cyp24* gene is activated and starts a process that breaks down calcitriol. Dr. Johnson and her colleagues are now looking to add a third drug, ketoconazole, to the combination, with the idea that ketoconazole will turn off induction of *cyp24* and thereby increase the amount of calcitriol actually getting to the prostate tumors.

“We’re looking at the whole sequence of events from every angle,” Dr. Johnson said. If their current phase II trial provides good information about dosing and effectiveness of calcitriol in combination with the two drugs, it may eventually lead to another treatment option in prostate and other solid tumors, she added. 🌐

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CAM Information

NCI CAM Fact Sheets Page Views Statistics-Fiscal Year 2009

NCI offers evidence-based, easily understandable facts on a variety of topics for the public. There are ten cancer and CAM fact sheets available at <http://www.cancer.gov/cancertopics/factsheet>. Each month NCI records the number of page views for these fact sheets. At the end of the Fiscal Year (FY), the monthly numbers are added up to calculate total page views for the year for each fact sheet and for all ten. The chart to the right lists the statistics for the fact sheet page views for FY 2009. The sheets are available for download free of charge to the public and are an integral part of cancer education at NCI. To download the fact sheets visit: <http://www.cancer.gov/cancertopics/factsheet>. 🌐

FACT SHEET TITLE	TOTAL VIEWS
Antioxidants and Cancer Prevention: Fact Sheet	71,513
Calcium and Cancer Prevention: Strengths and Limits of the Evidence	3,622
Garlic and Cancer Prevention: Questions and Answers	14,732
Physical Activity and Cancer: Fact Sheet	9,166
Questions and Answers About Beta Carotene Chemoprevention Trials	2,736
Red Wine and Cancer Prevention: Fact Sheet	18,769
Selenium and Vitamin E Cancer Prevention Trial (SELECT): Questions and Answers	1,885
Tea and Cancer Prevention: Fact Sheet	11,853
Vitamin D and Cancer Prevention: Strengths and Limits of the Evidence (New)	81
Complementary and Alternative Medicine in Cancer Treatment: Questions and Answers	24,353
ALL	158,710

New Fact Sheet on the Status of Credentialing CAM Providers

While most consumers may be familiar with professional licensing and credentialing for conventional medicine (e.g. Medical doctors, nurses), credentialing for CAM providers is not as well understood. The National Center for Complementary and Alternative

Medicine (NCCAM) has created a new fact sheet on the status of credentialing CAM providers in the United States to help consumers understand CAM education, training, regulation, and licensing. The fact sheet provides an overview of each of these areas as well as specific information about state

licensure for a few selected types of CAM providers. View this fact sheet on NCCAM's web site:

<http://nccam.nih.gov/health/decisions/credentialing.htm>.

NCCAM Clinical Digest: A New Monthly E-Newsletter About CAM

NCCAM published their first issue of *NCCAM Clinical Digest* in October, offering readers a new monthly e-newsletter containing evidence-based information on CAM. The Digest will

offer clinical guidelines, scientific literature searches, summaries of NCCAM-funded research, and fact sheets for patients. The first issue focused on cancer and CAM. To read the first issue

and subscribe to the *NCCAM Clinical Digest*, visit:

<http://nccam.nih.gov/health/providers/digest/cancer.htm>.

NCI Launches Cancer CAM Portal Web Site on Cancer.gov

NCI has made it easier for individuals to find the latest evidence-based information on cancer CAM research and programs with the recent launch of a "portal" web site on NCI's Cancer.gov. The web site is designed to be user-friendly and organizes and consolidates links to information about CAM on Cancer.gov, including information from OCCAM's web site, NCI's PDQ database, the NCI Cancer Bulletin newsletter, and the NIH National Center for Complementary and Alternative Medicine (NCCAM).

The site, which was developed in consultation with OCCAM, is found at <http://www.cancer.gov/cancertopics/cam>. The home page includes a video introduction by OCCAM Director Dr. Jeffrey White about the use of CAM in cancer. The web site organizes cancer CAM information into five sections: *Alternative Medical Systems*, *Mind-Body Methods*, *Nutritional Methods*, *Pharmacologic and Biologic Treatments*, and *CAM News and Resources*.

For example, under the Alternative Medical Systems section, users can find brief descriptions and links to the latest information about acupuncture, Ayurvedic medicine (India), homeopathy, naturopathy, and Traditional Chinese Medicine. Each CAM section also includes links to the OCCAM and NCCAM home pages. NCI web editors will be continually updating the CAM site as new information and articles become available.

The screenshot shows the National Cancer Institute website. At the top, there is a red header with the NCI logo and the text "National Cancer Institute U.S. National Institutes of Health | www.cancer.gov". Below the header is a navigation menu with links for "NCI Home", "Cancer Topics", "Clinical Trials", "Cancer Statistics", "Research & Funding", "News", and "About NCI". The main content area is titled "Complementary and Alternative Medicine" and features a video player. The video is titled "Lifelines: Complementary and..." and shows Dr. Jeffrey D. White, OCCAM Director, explaining the use of complementary and alternative medicine in cancer. To the left of the video is a "Quick Links" section with links to "Director's Page", "Dictionary of Cancer Terms", "NCI Drug Dictionary", "Funding Opportunities", "NCI Publications", "Advisory Boards and Groups", "Science Serving People", and "Español". Below the video is a "What Is Complementary and Alternative Medicine (CAM)?" section with text explaining CAM and a link to "Overview of CAM Approaches".

NCI on Facebook; Another Way to Learn About CAM

Now you can connect with NCI on Facebook to receive the latest news, research updates, videos, and stories on a host of cancer topics. NCI launched its official Facebook page in July as another way to connect with and disseminate information to the public. NCI is no stranger to new media, already having a presence on Twitter and YouTube.

With over a thousand people already signed on as “fans” of the page, NCI hopes to engage its Facebook community and solicit feedback while also allowing users to share personal stories. The page will also serve as a place to learn more about different cancer topics like complementary and alternative medicine (CAM). CAM has already been featured on the

page, directing fans to many resources available on the topic.

Visit NCI’s Facebook page and become a fan at <http://www.facebook.com/cancer.gov>.

Acupuncture and Persistent Hiccups in Patients With Cancer

Acupuncture may be a viable treatment for persistent hiccups in patients with cancer according to new case series research from the NIH Clinical Center and the NCI’s Center for Cancer Research. In the published article titled: “Acupuncture treatment for persistent hiccups in patients with

cancer” sixteen male study subjects with cancer and persistent hiccups were treated with one to three acupuncture sessions over a one to seven day period. Thirteen patients experienced complete remission, and the remaining three experienced decreased hiccup severity. This form of CAM treatment may

prove beneficial to those suffering from recurrent, persistent hiccups and wishing to alleviate discomfort. For more information please refer to the original study at <http://www.ncbi.nlm.nih.gov/pubmed/20575702>.

Traditional Chinese Medicine Reduces Chemotherapy Induced Side Effects

NCI-supported research from Yale University has studied the effects of an ancient four-herb Chinese Medicine formula called PHY906. PHY906 is derived from a Chinese canonical medicine which originated 1800 years ago for the treatment of different gastrointestinal symptoms including diarrhea, nausea and vomiting.

Researchers and clinicians are constantly searching for ways to reduce the side effects of chemotherapy and this research attempts to use PHY906 as an adjuvant to chemotherapy drugs (Irinotecan, 5-fluorouracil and leucovorin) for treating colon or rectal carcinoma. Results for the murine (mouse) model study showed that

PHY906 decreased animal weight loss caused by irinotecan, promoted intestinal recovery from damage caused by irinotecan and several other outcomes. For further details please refer to the published article in Science Translational Medicine: <http://www.ncbi.nlm.nih.gov/pubmed/20720216>.

Meetings

American Public Health Association Annual Meeting & Exposition

Over 13,000 public health professionals attended the 138th American Public Health Association (APHA) Annual Meeting & Exposition from November 6-10, 2010 in Denver, Colorado. More than 1,000 scientific sessions, 700 booths, and over 4,000 scientific papers detailed the latest public health challenges. The theme of this year’s meeting focused on the link between social justice and public health and featured Dr. Cornel West and Dr. Bill Jenkins as the keynote speakers.

Complementary and alternative medicine was a topic of interest to many meeting attendees, with two days of CAM-related sessions held by APHA’s special primary interest group *Alternative and Complementary Health Practices*. Anne Doherty-Gilman, Associate Director of the Zakim Center for Integrative Therapies, Dana-Farber Cancer Institute and Program Chair for the Alternative and Complementary Health Practices group was very pleased with the quality of the CAM-related sessions. “This year’s *Alternative and Complementary*

Health Practices’ sessions included an impressive array of innovative public health initiatives and scientifically rigorous studies that offered important guidance to those of us working in this field. It was truly inspiring to see the breadth of high quality work being done to advance the evidence base for these therapies and to promote access to wellness and whole person care,” said Doherty-Gilman. Highlights included a session on CAM for Cancer and Chronic Diseases and a special session that Dr. Isis Mikhail, M.D., M.P.H., Dr.P.H., OCCAM’s Extramural

Research Program director and Dr. Wendy Weber, N.D., Ph.D., M.P.H. from NCCAM led on NIH grants applicable for the public health field.

Dr. Mikhail was also impressed with this year's meeting. "There is a growing interest in CAM research at APHA. It's evident not only through the CAM-related conference sessions, but also through the attendees I talked to about

cancer CAM research and the research abstracts presented during the poster sessions." Dr. Mikhail also participated in NCI's "Meet the Expert" session at the NCI expo booth. As one of 19 NCI experts she was able to connect with many researchers interested in funding opportunities at NCI.

NCI had a large presence at APHA, connecting with health professionals

about NCI programs, products, and services. This year the NCI expo booth won first place for a non-profit, island exhibit booth. Improved IT services at the booth allowed meeting attendees to order NCI publications and have them shipped directly to their offices. NCI also had a big screen TV showcasing NCI web sites and a seating area for presentations of interest to meeting attendees. 🐼

OCCAM Staff Attends Leading Integrative Oncology Conference

The Society for Integrative Oncology hosted its Seventh International Conference at the New York Academy of Medicine in New York City, New York, November 11-13, 2010. The Society for Integrative Oncology (SIO) is a non-profit organization of research professionals and practitioners dedicated to studying and facilitating cancer treatment and the recovery process through the use of integrated complementary treatment options. SIO's conference draws attendees from around the world because of its important lectures, scientific sessions and tight focus on the field of integrative oncology. The title of this year's conference, "Integrative Oncology: Informing the Debate in Practice, Research and Public Policy", placed an especially important focus on public policy in this time of health care reform and change.

OCCAM's Communications and Outreach Program exhibited at the conference and handed out research grant information and patient education materials to attendees as well as discussed aspects of OCCAM's research portfolio. Information about funding opportunities in integrative

oncology was of great importance to those that visited the booth.

Dr. Isis Mikhail, M.D., M.P.H., Dr.P.H., director of the Extramural Research Program(ERP) at OCCAM sat on a panel titled: "Career Development Workshop for CAM Practitioners and Students." Dr. Mikhail noted, "This workshop was received very positively by the audience that included a group of physicians, junior research investigators, practitioners, post-doctoral fellows, among others. The panel included speakers from NIH (NCCAM, NCI, National Institute of Nursing Research), cancer research organizations (American Cancer Society and American Institute for Cancer Research), and academia; and addressed different areas of interest and prospects for career development. A number of attendees used this opportunity to communicate with the speakers who made themselves available for additional inquiries after the end of the session."

Dr Dan Xi, Ph.D., program officer at OCCAM also took part in a panel titled: "Whole Systems Workshop"

in which she presented a talk titled: "Traditional Chinese Medicine, Systems Biology and Systems Medicine". She stated that the topics of the workshop were extremely relevant to Cancer CAM research because: "many CAM interventions use personalized whole systems approaches to patient care. This provided the platform for research methodology discussion, information exchange, and education."

Conference chair Heather Greenlee, N.D., Ph.D. wrote that this year's conference goals included addressing the challenges facing integrative oncology in the era of healthcare reform, indentifying gaps in integrative oncology comparative effectiveness research and issues related to reimbursement for services. Three days of scientific sessions covered various aspects of integrative oncology from emerging research in vitamin D supplementation, energy balance in cancer survivorship and patient advocacy. Information about the conference and the Society for Integrative Oncology are available at the Society's web site at <http://www.integrativeonc.org/>. 🐼

Sign-up for OCCAM's Listserv

Stay up-to-date on the latest cancer CAM news at NCI with OCCAM's listserv, *OCCAM Announcements*. As a listserv subscriber, you will receive a monthly email about upcoming workshops and lectures, new funding opportunities, publications, and other resources. To subscribe, simply visit OCCAM's web site: http://www.cancer.gov/cam/news_listserv.html.

Featured Scientific Meetings

Date	Meeting	Location	OCCAM Staff Attending
October 8-9, 2010	Vitamin C and Cancer Symposium	Wichita, KS	Dr. Oluwadamilola Olaku
October 10-14, 2010	Symposium of Integrative Medicine Professionals the Land of Enchantment	Albuquerque, NM	Dr. Oluwadamilola Olaku
October 24-27, 2010	2010 International Cancer Education Conference - 20th Annual CPEN Meeting	San Diego, CA	Elizabeth Austin
November 6-10, 2010	American Public Health Association Annual Meeting & Exposition*	Denver, CO	Dr. Isis Mikhail
November 13-14, 2010	Society for Integrative Oncology**	New York City, NY	Miriam Al Keliddar Elizabeth Austin Dr. Libin Jia Dr. Isis Mikhail Dr. Dan Xi

*Dr. Isis Mikhail will be at the NCI booth (Booth #1220) for a Meet-the-Expert session on Monday, Nov. 8, 11:00 am.

**Indicates that an OCCAM staff member will be at the NCI or OCCAM exhibit booth.

To obtain a copy of this newsletter or for inquiries on cancer and CAM, please contact
1-800-4-CANCER (1-800-422-6237).



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