

# CCEB Newsletter



*Complementary and alternative medicine (CAM), generally and at Penn, is briefly introduced in our feature article this quarter.*

A Quarterly Newsletter

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## The Integration of Complementary and Alternative Medicine into Research and Clinical Practice

*Mary Lou Galantino, PhD (Professor of Physical Therapy, The Richard Stockton College of New Jersey, Pomona, NJ, and Adjunct Scholar in the CCEB) and Jun Mao, MD (Resident Fellow, Clinical Instructor, Dept. of Family Medicine and Community Health, University of Pennsylvania)*

Complementary and alternative medicine (CAM) has been defined by the National Center for Complementary and Alternative Medicine (NCCAM) as “a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.”<sup>1</sup>

NCCAM has classified CAM therapies into five distinct areas: alternative medical systems, mind–body interventions, biologically based therapies, manipulative and body-based methods, and energy therapies (Table 1).<sup>1</sup> Eisenberg et al. found a substantial increase in the use of CAM among the US public in the early to mid 1990s<sup>2,3</sup>; however, the trend has leveled off in recent years.<sup>4</sup> It is estimated that 36% of US adults use CAM on an annual basis. Because of consumer interest, leading academic institutions are increasingly incorporating CAM into medical education, clinical practice, and research.<sup>5–8</sup> The CCEB is among the first to receive funding to train CAM practitioners to conduct rigorous clinical research.

Out-of-pocket expenditures of over 34 billion dollars per year in

the US are testimony to a widely held consumer belief that CAM therapies confer benefits for general health as well as for specific diseases. More importantly, many individuals turn to CAM when conventional medical therapies do not adequately address their illness.<sup>9</sup> Despite favorable public opinion, very little scientific evidence exists for the health and economic implications of CAM therapies.<sup>10</sup> The popularity of CAM has brought into keen awareness clinical issues such as the lack of knowledge and concern about interactions among dietary and herbal supplements, prescribed medications, and diseases. These clinical issues underscore the need for a coordinated approach to integrating knowledge about CAM therapies into the teaching of conventional medicine.<sup>11</sup> The

*(Continued on page 5)*



# Faculty Profile:

## *Thomas Ten Have, PhD, works to adapt treatments to the patient context*



Thomas Ten Have, PhD,  
Professor of Biostatistics in  
the CCEB

The eldest son of missionaries, Thomas Ten Have was raised in Korea, Malaysia, and Nepal before his family left missionary work and moved to Grand Rapids, MI when Tom was 12 years old. After concentrating on art during high school, Tom focused on accounting and algebra in junior college prior to entering the undergraduate business program at the University of Michigan in Ann Arbor. Of the entire business curriculum, he found himself most interested in data analysis and management. A serendipitous perusal of a pamphlet on statistics found in the university counseling office prompted Tom to change the course of his undergraduate career.

He began his research career as a research assistant at the University of Michigan Department of Biostatistics in 1980. In 1981, he received a BA in statistics with distinction. Tom perpetuated his familial tradition of earning a master's in public health (though in a discipline not typical of his family) when he received his MPH in biostatistics at the University of Michigan the following year. He stayed in Ann Arbor, analyzing craniofacial and orthodontic data for about six years while also working at a mental health community center before embarking on doctoral studies. He earned the University of Michigan's Regents Fellowship from 1989 to 1990 and the Rackham Graduate School Predoctoral Fellowship from 1990-1991. In 1991, Tom received a PhD in biostatistics, staying on at the University of Michigan to work as a research associate in the Department of Pathology, in the School of Medicine, and in the Department of Oral Biology, in the School of Dentistry. In addition, Dr. Ten Have served as a computer consultant in the university's Statistical Research Laboratory. He served as a visiting associate professor at the University of Michigan Department of Biostatistics from 1991-92.

In 1992, Dr. Ten Have became an Associate Professor in the Center for Biostatistics and Epidemiology at the Pennsylvania State University College of Medicine. During the ensuing five years, he conducted research in categorical data analysis, random effects models, and informative drop-out approaches. During this time, he authored papers that were published in peer-reviewed journals such as *Applied Statistics*, *Statistics in Medicine* and *Biometrics*. In 1995, he was awarded the March of Dime's Basil O' Connor Starter Research Award followed by an NCI First Award.

In 1997, Dr. Ten Have joined the University of Pennsylvania's CCEB as an Associate Professor in the Division of Biostatistics, becoming a full professor with tenure in 2001. As evidenced by the psychiatric and mental health research that he conducts and on which he collaborates, Dr. Ten Have is committed to enhancing the range and quality of treatments for mental health disorders and improving treatment adherence on the part of patients and providers. He has recently completed, as principal investigator, an R01 NIH grant for a study titled "Mixed Effects Models for Discrete Data with Non-Compliance." This project extended current statistical methodologies for estimating causal treatment effects under non-ignorable treatment non-compliance in psychiatric randomized trials to modeling clustered discrete responses with mixed effects logistic models. Dr. Ten Have is also collaborating on an R01 NIH-supported trial titled "Managed Problem Solving: An HIV Adherence Trial." This is a randomized clinical trial of problem solving-derived interventions to improve HIV treatment adherence. In addition, he is a co-investigator for the Advanced Center for Intervention Services Research for Depression in the Aged, sponsored by the National Institutes of Mental Health, and is currently collaborating on a P20 NIH study titled "Cognitive Therapy for the Prevention of Suicide," which is being led by Dr. Aaron Beck, the "father of cognitive therapy." In short, the overarching emphasis of Dr. Ten Have's investigative focus is translational research, specifically incorporating feedback from the community and medical providers to render more robust treatments. Consequently, Dr. Ten Have is interested in not only whether a medication is efficacious, but on how best to get the drug to work in realistic conditions. His methodologies can be applied, for example, to the proposed once/daily treatment for AIDS, which has been driven by patient input. In fact, Dr. Ten Have is collaborating with the Robert Gross, MD, MSCE, Assistant Professor of Medicine, Infectious Diseases Division, on research into AIDS treatment. In addition, he is collaborating on asthma treatment research with Andrea Apter, MD, MA, MSc, Associate Professor of Medicine, Allergy and Immunology Division. In adapting treatments to the patient context, Dr. Ten Have notes that behavioral theories on changing treatment non-adherence are often not sensitive to culture and economic disparity.

In addition to his research and teaching responsibilities, Dr. Ten Have serves as a member of the American Statistical Association, the Institute of Mathematical Statistics, The International Biometrics Society, the Society for Epidemiological Research, and the American Public Health Association. In 1999, he was named a Fellow of the American Statistical Association. Currently, he is a charter member of an NIMH study section and an NIMH DSMB. He is also an associate editor for *Biometrics*.

# Faculty Profile:

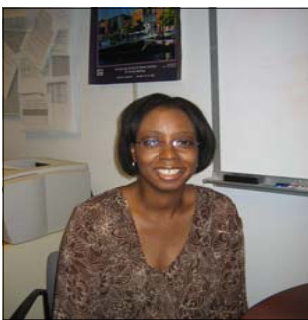
*Charnita M. Zeigler-Johnson, PhD, focuses on the molecular epidemiology of prostate cancer, particularly among African American men*

Charnita M. Zeigler-Johnson, PhD, a new Research Assistant Professor of Epidemiology in the Department of Biostatistics and Epidemiology in the CCEB, has been at Penn since 1999 focusing on molecular epidemiology. Seven years earlier, she earned a BS in psychobiology at Albright College in Reading, Pennsylvania. She had begun her undergraduate career with the intention of following a pre-med track, but halfway through college, decided on research, particularly in neuroscience. Under Dr. Judy Cameron at the University of Pittsburgh, Charnita studied the GnRH response to short-term fasting in rhesus monkeys.

Having decided to pursue a research career pertaining to human beings and enthusiastic about a multidisciplinary approach to furthering her education, Charnita enrolled at the Graduate School of Public Health at the University of Pittsburgh, where she received an MPH in 1997. She was awarded Best Master's Thesis of the Year from the Omicron Chapter of the Delta Omega National Honor Society. In 1998, she received a PhD in epidemiology from the University of Pittsburgh. Her research focused on the association between hysterectomy status and cardiovascular disease in African American women.

Dr. Zeigler-Johnson arrived at the CCEB in 1999 to pursue molecular epidemiology research as a post-doctoral fellow. As part of her fellowship, she worked as project manager for Dr. Timothy Rebbeck's "Molecular Epidemiology of Prostate

Cancer Study." She was involved in the recruitment, data collection, data entry, data analysis, and training of employees for this study. Her interest in health disparities prompted her to ensure that more African Americans were recruited for the study. Dr. Zeigler-Johnson became an Instructor of Epidemiology in the Department of Biostatistics and Epidemiology in 2005 and was named a Research Assistant Professor of Epidemiology earlier this year. Her primary research focus remains the molecular epidemiology of prostate cancer, with a focus on why African American men are at greater risk for disease as well as poor disease outcomes. Dr. Zeigler-Johnson strives toward a holistic, multidisciplinary approach to understanding prostate health, incorporating characteristics such as the neighborhood environment, nutrition, and body mass index. She currently has an NCI Career Development Award for a project entitled "Prostate Cancer and Genes of the One-Carbon Cycle."



Charnita M. Zeigler-Johnson, PhD,  
Research Assistant Professor of  
Epidemiology in the CCEB

Some of her research has included consideration of the clinical characteristics of prostate cancer in American men, black and white, and in men from Senegal. In fact, Dr. Zeigler-Johnson and several Penn colleagues are collaborating with

Senegalese urologists and researchers in order to understand prostate cancer occurrence and progression in West Africa, with the hope that this work will also enhance understanding of risk factors in African American men. Contacts have also been made in Ghana, and it is hoped that the study will expand to Cameroon as well as Kenya in the near future. In 2004, Dr. Zeigler-Johnson was invited to lecture at Hospital General de Grand Yoff in Dakar, Senegal, where her lecture was titled, "Testosterone Metabolizing Genes and Prostate Cancer."

Dr. Zeigler-Johnson's work has earned her the NCI CURE Minority Supplement Award, University of Pennsylvania, from 2001-2004 and the National Center on Minority Health and Health Disparities Scholar award, 2003-2006. Dr. Zeigler-Johnson has been the principal author of peer-reviewed articles published in *Cancer Research*, the *Clinical Journal of Oncology Nursing*, *Human Heredity*, *Pigment Cell Research*, and *Stroke*. She has also contributed to articles published in journals such as the *American Journal of Human Genetics*, *Cancer Epidemiology*, *Biomarkers and Prevention*, *Circulation*, *CVD Prevention*, the *International Journal of Cancer*, and *Urology*.

Dr. Zeigler-Johnson is also active in the African American community, specifically working on projects that provide health education. She was on the planning committee for the American Heart Association for African American women in  
*(Continued on page 4)*

## From the Director:



**Brian L. Strom, MD, MPH**

Welcome to this issue of the Center for Clinical Epidemiology and Biostatistics (CCEB) Newsletter, which serves as a forum for us to keep you informed of activities within the CCEB. Each issue highlights a few members of our faculty, some of the services we provide to those external to the CCEB, and current activities and events likely to be of interest. Feature articles occasionally are included also.

In this issue of the newsletter, we include articles on two members of our faculty: Tom Ten Have and Charnita Zeigler-Johnson. Tom is a senior member of our biostatistics faculty. His methodologic research interests include categorical data analysis, random effects models, informative dropout, treatment non-adherence, and designs and statistical analyses for complex adaptive treatment regimens. The majority of his collaborative work focuses on treatment adherence and mental health disorders. Charnita is a new member of our epidemiology faculty, having recently completed a post-doctoral fellowship at Penn. Charnita's primary research interests are in health disparities, molecular epidemiology, and prostate health.

Our feature article for this issue is written by two former trainees in our Master of Science in Clinical Epidemiology (MSCE) degree program: Mary Lou Galantino and Jun Mao. Both are actively involved in research in complementary and alternative medicine (CAM). In this article, Mary Lou and Jun advocate strongly for the critical examination of the safety, efficacy, and effectiveness of CAM therapies.

Another article in this issue briefly describes our MSCE degree program. The application deadline for enrollment in 2007-08 is January 15, 2007. Please read this article and, if interested, contact Shanta Layton (215-573-2382) for information about the application process and fellowship opportunities.

I also would like to take this opportunity to remind you to regularly check our new website for announcements and other newsworthy events (<http://www.cceb.upenn.edu/>), find potential faculty collaborators (<http://www.cceb.med.upenn.edu/faculty/>), review the research services available to you (<http://www.cceb.med.upenn.edu/services/>), and examine our education training program opportunities, either for yourself or for others (<http://www.cceb.upenn.edu/education/>).

Enjoy!

*(Zeigler-Johnson, continued from page 3)*

Pittsburgh in 1997. She was a coordinator and presenter for the National Association of Negro Business and Professional Women in Philadelphia Prostate Cancer Workshop in 2000. In addition, from 2001 to 2003, Dr. Zeigler-Johnson helped plan a local event with 50 Hoops, a national organization that promotes awareness about prostate cancer in the African American community. In 2004, she was on the Community Advisory Participatory Panel affiliated with the Center for Population Health and Health Disparities.

At Simpson-Fletcher United Methodist Church, where her husband, Rev. Robert L. Johnson, is pastor, Dr. Zeigler-Johnson reaches out to

the West Philadelphia community in various ways. She leads several organizations serving children and teens and recently developed a self-empowerment workshop series for 13- to 18-year-old African American girls. This fall's workshop involves the girls in discussions and activities related to improving self-esteem. Next year's workshop for young women will focus on nutrition and exercise, featuring guest lecturers and cooking demonstrations. This workshop will be co-sponsored by the American Cancer Society.

In addition to staying busy in the community, Dr. Zeigler-Johnson is the mother of two children, ages 4 and 5.

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interest among CAM practitioners and traditional medical researchers, along with increased funding allocations by the NIH and other foundations, has increased scientific inquiry into the mechanism, safety, efficacy, and effectiveness of CAM.

Clinical epidemiology and biostatistics have played important roles in the evaluation of human diseases and conventional therapeutics; therefore, the appropriate use of these established methods becomes critical in examining the safety, efficacy, and effectiveness of CAM. While specific research methodologies have been refined over the years to study pharmaceuticals, these methods may need additional modifications and re-tuning for CAM research because of the unique characteristics of many CAM interventions. For example, and not unlike psychiatric interventions, the mind-body interaction is a major component of

some CAM therapies; however, this often-labeled "placebo effect" is what most pharmaceutical clinical trials control for from the study design perspective. A lack of understanding of the mind-body interaction may undermine the value of many conventional interventions for health promotion and disease management in addition to CAM therapies. It is likely that methodologically rigorous CAM research may help expose some of the weaknesses of existing study methodologies and lead to new ways of examining the efficacy and effectiveness of both conventional and CAM therapies.

There is a diverse representation of CAM research among the current projects led by CCEB faculty and MSCE students. Dr. Nana Smith is currently conducting a single-dose, Simon's optimal 2-stage phase II clinical trial to study the safety and efficacy of oral curcuminoids (an herb) in patients with chronic psoriasis

vulgaris. Dr. Rebecca Greenberg is conducting a randomized placebo-controlled clinical trial to determine the efficacy of acupuncture for promotion of timely delivery in pregnant women. Dr. Pat LaRiccia is evaluating the effect of OPC factor (a food supplement) on age-related decline in energy among healthy individuals in a randomized trial. Dr. Joyce Frye is assessing reasons for home versus practitioner-guided use of homeopathic medicines. Jane Buckle, RN, is using SPECT functional brain imaging techniques to determine the effects of a manual therapy technique, in collaboration with the Nuclear Medicine Division of the Department of Radiology and Dr. Andy Newberg. Dr. Newberg has conducted a number of functional brain imaging studies using both SPECT and PET scans to evaluate the changes in brain function related to several CAM modalities, including meditation, prayer, and acupuncture.

Dr. Jun Mao, a recent MSCE graduate, has focused on evaluating

### **Table 1. Major Types of Complementary and Alternative Medicines**

#### **Alternative medical systems**

Built on a specific system of theory and practice. Examples include homeopathic medicine, naturopathic medicine, traditional Chinese medicine (TCM), Ayurveda, and Kambo (Japanese traditional herbal medicine).

#### **Mind-body interventions**

Enhance the mind's capacity to affect bodily function and symptoms. Examples include inducing the relaxation response, support groups, and cognitive-behavioral therapy. Other CAM therapies in the mind-body realm include yoga, meditation, prayer, mental healing, and art/music or dance therapy.

#### **Biologically based therapies**

Use a substance found in nature, including foods, vitamins, and herbs. Dietary supple-

ments and herbal products are included in biologically based therapies.

#### **Manipulative and body-based methods**

Involve manipulation or movement of body parts. Included in this category are chiropractic, physical therapy and osteopathic manipulations and massage.

#### **Energy therapies**

There are two distinct groups: *biofield therapies*, which include Qi Gong, Reiki, and therapeutic touch; and *bioelectromagnetic-based therapies*, which include pulsed fields, magnetic fields, or alternating- or direct-current fields.

*Adapted from National Center for Complementary and Alternative Medicine. Available at: nccam.nih.gov. Accessed June, 2006.*

the implications of CAM for symptom management in cancer. He used the 2002 NHIS database to determine the prevalence of CAM and prayer for health use among the US cancer survivors. He found that the cancer survivors used more CAM than the general population but the use was similar to individuals with other chronic symptomatic illnesses. His study helped provide a meaningful context for understanding the previous findings generated from selected clinical populations and suggests that symptom control may be an important factor motivating cancer survivors to use CAM.<sup>12</sup> In addition, Dr. Mao is conducting a phase I clinical trial to determine the feasibility of using acupuncture for managing hot flashes among prostate cancer patients who are on androgen deprivation therapies.

Dr. Mary Lou Galantino completed her post-doctoral work with an article published in 2005 in *Stress and Health Journal* (Comparison of Psychological and Physiological Measures of Stress in Health Care Professionals during an Eight-Week Mindfulness Meditation Program: Mindfulness in Practice). Dr. Galantino, along with Dr. Geigle (another CAM fellow), presented results of a survey investigating CAM inclusion in physical therapy curricula at the yearly CAM and Rehabilitation Conferences. With Dr. Philippe Szapary, in the Department of Medicine, Dr. Galantino is collaborating on an NIH-funded project to investigate the cardiovascular effects of Iyengar yoga versus enhanced usual care in patients with high-normal to Stage I hypertension. In addition, Dr. Galantino is currently investigating the effect of yoga on quality of life and cognition for women with breast cancer.

Dr. John Farrar, now the director of the MSCE program and mentor to many CAM fellows, including those mentioned above, is conducting ongoing research in the areas of acupuncture for knee osteoarthritis (including imaging techniques) and efficacy of acupuncture for fatigue in radiation therapy. He is also testing the effect of craniosacral therapy and periodic acceleration on patients with fibromyalgia. Drs. Farrar and Newberg have received funding to explore changes in functional brain imaging with arthritis pain and acupuncture. In conjunction with Dr. Galantino, they are also investigating a subset of patients to explore the neurological mechanisms of yoga for patients with hypertension. Drs. Farrar and Newberg have also conducted a pilot study of the SPECT scanning of patients who develop pain after undergoing third molar extractions and receive treatment with non-steroidal anti-

inflammatory drugs.

CAM fellows and faculty meet on a monthly basis to discuss various research projects through our health system. These are sponsored by Dr. Alfred Fishman in the Office of Program Development in the School of Medicine. This close collaboration among researchers, physicians, and CAM practitioners provided by a multidisciplinary environment at the CCEB will result in advancement in both the methods and knowledge in this area.

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## Faculty News and Notes

Several CCEB faculty have appeared in the news in recent months. A brief summary dating from June follows in alphabetical order.

**J**oel M. Gelfand, MD, MSCE, Assistant Professor of Dermatology and Epidemiology, University of Pennsylvania SOM, Associate Scholar, Clinical Epidemiology Unit of the Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania, was quoted in the July 19<sup>th</sup> edition of *The Washington Post* in the article “Smartest Are Most Often Dumb About Sunburns regarding his recent report on sunburns (<http://www.washingtonpost.com/wp-dyn/content/article/2006/07/18/AR2006071801303.html>) regarding a report by his team that appeared online on July 16<sup>th</sup> and is currently in press (Brown TT, Quain RD, Troxel AB, Gelfand JM. The epidemiology of sunburn in the U.S. population in 2003. *J Am Acad Dermatol*, in press). Dr. Gelfand was also interviewed by local CBS affiliate channel 3 on July 19<sup>th</sup> on the same topic.

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The July 12<sup>th</sup> issue of the *American Journal of Managed Care* includes the editorial “Defending computerized physician order entry from its supporters” by **Ross Koppel, PhD**, Professor of Sociology and Affiliate Member of the Center for Clinical Epidemiology and Biostatistics at the University of Pennsylvania SOM. The article (<http://www.ajmc.com/Article.cfm?Menu=1&ID=3159>) is a follow-up to a paper published last year, and cited below, on computerized physician order entry (CPOE) and refers to another article published in the July 12<sup>th</sup> issue. See the UPENN Communications Department press release by Karen Kreeger for additional information ([http://www.eurekalert.org/pub\\_releases/2006-07/uops-dtl071306.php](http://www.eurekalert.org/pub_releases/2006-07/uops-dtl071306.php)).

In an August 7<sup>th</sup> article in *modernhealthcare.com* entitled, “The Limits of Technology: Far from a panacea, IT is merely a tool for solving problems,” Dr. Koppel was cited for his study conducted in 2005 (**Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL**. Role of computerized physician order entry systems in facilitating medication errors. *JAMA*. 2005 Mar 9;293(10):1197-203) that identified 22 situations in which a CPOE system increased the probability of medication errors occurring (<http://www.modernhealthcare.com/storyPreview.cms?articleId=40947&archive=N>).

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**Timothy Rebbeck, PhD**, Professor of Epidemiology, University of Pennsylvania SOM, Senior Scholar, Clinical Epidemiology Unit of the Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania was recently quoted in three articles. In the first, Dr. Rebbeck is quoted and featured in the June 25<sup>th</sup> issue of *Oncology Times*. His research focusing on prostate and colorectal cancers was discussed during a news conference and highlighted at the American Association for Cancer Research 97<sup>th</sup> Annual Meeting in Washington, DC in April (<http://www.oncotimes.com/pt/pt-core/template-journal/oncotimes/media/RTuma-AACR-MolecularSignatures-OT-June252006.pdf>).

In the second, headlined “Risk of Ovarian Cancer Remains in Women Who Have Ovaries Removed: Study,” which appeared on July 11<sup>th</sup> in the Canadian Broadcast Corporation online news (CBCNews), Dr. Rebbeck noted that oophorectomies reduce the risk of breast cancer among women with the BRCA1 or BRCA1 genetic mutations by 50% (<http://www.cbc.ca/cp/health/060711/x071134.html>).

Dr. Rebbeck’s editorial “Inherited Genetic Markers and Cancer Outcomes: Personalized Medicine in the Postgenome Era,” which appeared in the May 1 edition of the *Journal of Clinical Oncology* (Rebbeck TR. Inherited genetic markers and cancer outcomes: personalized medicine in the postgenome era. *J Clin Oncol*. 2006 May 1;24(13):1972-4) was cited by Reuters Health in the article “Polymorphisms May Influence Survival in Prostate Cancer,” which appeared on the *cancerpage.com* on July 13<sup>th</sup> (<http://www.cancerpage.com/news/article.asp?id=9812>).

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**Brian Strom, MD, MPH**, Director of the CCEB, Associate Vice Dean, Penn SOM, was interviewed and quoted in the article “Sanofi, Drugmakers Fail on Promise to Study Medicines’ Effects,” which appeared online in *Bloomberg.com* on June 12<sup>th</sup>. Dr. Strom is given the final word in this report on post-approval monitoring by the FDA of the safety of drugs already on the market (<http://www.bloomberg.com/apps/news?pid=10000085&sid=a.9xSzcrZbLs&refer=Europe>).

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## CCEB's Clinical Research Services: Formal Training in Clinical Research

*The CCEB serves as an interdisciplinary resource for clinical research throughout the School of Medicine. It offers a range of services and training programs, primarily for faculty, residents, and fellows within the University of Pennsylvania Health System, but also for clinicians and scientists in other schools at Penn and throughout the Delaware Valley. These programs and services are identified and described as a regular feature of this newsletter. The program highlighted for this newsletter is the Master of Science in Clinical Epidemiology (MSCE) degree program.*

**T**he MSCE degree program is geared toward health professionals interested in pursuing careers in clinical research. Admissions requirements reflect the emphasis on integrating epidemiology and clinical practice. Individuals admitted into the program must have an advanced degree in medicine, nursing, veterinary medicine, dental medicine, or pharmacy, or comparable experience in another health-related field.

The MSCE degree program provides comprehensive clinical research training. The curriculum is designed to give trainees appropriate methodologic tools to be used in the conduct of high quality research in their areas of interest. The curriculum is complemented with strong mentoring, offered in a highly productive, supportive, and team-oriented research environment. The pace of the program is quite rapid, taking advantage of the trainees' previous experience, maturity, and independence. The objectives of this clinical research training program are to: 1) produce a cadre of skilled investigators trained to conduct formal epidemiologic studies and prepared for academic research careers, and 2) produce national leaders in academic medical and health services research.

The MSCE degree program is designed to be completed in two to three years of full-time study. Generally, the first year is devoted to course work and the development of a research project proposal. During the second year, trainees complete elective course requirements and work on their research projects. It usually takes at least one year to complete the research project and write the thesis.

MSCE students enroll in one of six tracks: Epidemiology, Health Services Research, Human Genetics, Bioethics, Clinical Trials, or Community Oriented Research. Each track represents a specific concentration, has different elective requirements, and is directed by a faculty member with expertise in the track's area of focus.

Each trainee works closely with a primary mentor and other members of their mentoring team, including a biostatistician and an expert in the trainee's primary area of interest, to develop a program tailored to his/her individual interests. A series of core courses cover epidemiologic, statistical, and social science research methodology. A set of elec-

tives on topics of special interest are tailored to one's track and research interests. Trainees receive instruction in research ethics; regulatory affairs; and federal regulations, privacy rights of patients, and the handling of Protected Health Information (HIPAA). Seminars devoted to current topics in research and critical review of the medical and epidemiological literature are also part of the curriculum.

The formal courses serve as the framework for the training program's major component – developing and completing a closely mentored, but independently conducted research project, which is designed to lay the groundwork for a line of research that will continue into the trainee's career as a clinical researcher. Trainees are expected to develop, implement, and analyze a research project and summarize the results in a publishable manuscript. The research project provides hands-on experience in formulating one or more research questions; searching the medical literature; translating research questions into an appropriate research design; assessing study feasibility; writing a detailed study protocol; designing data collection instruments; conducting field work; performing data analysis; and preparing a manuscript for publication.

The following skills are mastered by those who complete the MSCE degree program: 1) knowledge of the core types of research design, including randomized clinical trials, cohort and case-control studies, surveys and quasi-experimental studies; 2) detailed and in-depth facility with one of the design methodologies listed above; 3) knowledge of the concepts of health measurement and assessment as applied to epidemiologic studies; 4) ability to critically appraise the medical literature; 5) ability to use and interpret various statistical programs for analyzing a data set; and 6) ability to design, implement and analyze a research project.

Approximately 35 to 40 trainees enroll in the MSCE program annually. Trainees are distributed among multiple health professional specialties. The vast majority of trainees are physicians, but entering classes also generally include a small number of combined MD/MSCE students, veterinarians, and pharmacists, and occasional nurses and physical therapists. The majority of trainees enter the program while completing clinical fellowships at Penn. Upon completion

*(Continued on page 10)*

Dr. Strom was also cited in the foodconsumer.org website article entitled “The Science of Soy: What Do We Really Know?” by Julia R. Barrett. The article, which appeared online on June 26<sup>th</sup> ([http://www.foodconsumer.org/777/8/The\\_Science\\_of\\_Soy\\_What\\_Do\\_We\\_Really\\_Know\\_.s.html](http://www.foodconsumer.org/777/8/The_Science_of_Soy_What_Do_We_Really_Know_.s.html)) reviews the evolving use, benefits, and health effects of soy products. Dr. Strom led one of the few human studies involving soy, which was published in 2001 (Strom BL, Schinnar R, Ziegler EE, Barnhart KT, Sammel MD, Macones GA, Stallings VA, Drulis JM, Nelson SE, Hanson SA. Exposure to soy-based formula in infancy and endocrinological and reproductive outcomes in young adulthood. *JAMA*. 2001 Aug 15;286 (7):807-14) and briefly summarized in the foodconsumer.org story.

### Notes

**Stephen Kimmel, MD, MSCE**, Associate Professor of Medicine and Epidemiology, has been appointed Deputy Director of the Clinical Epidemiology Unit (CEU) of the CCEB and the Epidemiology Division of the Department of Biostatistics and Epidemiology. Dr. Kimmel has been a Senior Scholar of the CCEB since 1994 after having completed his cardiology and epidemiology training at Penn. He is internationally renowned for his outstanding contributions to the pharmacoepidemiology of cardiovascular disease, and has already served in several leadership roles in the CCEB’s graduate education programs. In this new role, Dr. Kimmel will be participating in all aspects of CEU leadership, working closely with Dr. Feldman and the epidemiology faculty on the research and educational efforts of the Division and Unit.

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**Shiriki Kumanyika, PhD, MPH**, Associate Dean for Health Promotion and Disease Prevention; Founding Director of the Graduate Program in Public Health Studies; Professor of Epidemiology in Biostatistics and Epidemiology and in Pediatrics (Nutrition); and Senior Scholar in the Clinical Epidemiology Unit of the Center for Clinical Epidemiology and Biostatistics, all at the University of Pennsylvania SOM, was notified at the end of June that she had won the 2006 Robert F. Allen Symbol of H.O.P.E. (Helping Other People through Empowerment) Award, which is presented annually to an individual who has made an outstanding

contribution to serving the health promotion needs of underserved populations or to promoting cultural diversity in health promotion. The award, presented at the National Wellness (Institute) conference on July 17<sup>th</sup> in Stevens Point, WI, is named in honor of one of the founding editors of the *American Journal of Health Promotion* who devoted his life to helping people empower themselves through harnessing cultural norms.

Dr. Kumanyika strives to reduce health disparities affecting ethnic minority and socially disadvantaged communities by applying cultural knowledge to develop and implement various initiatives, devoting particular energy to environmental and behavioral strategies to reduce obesity and related disorders in the African American population.



Shiriki Kumanyika, PhD, MPH, is the 2006 recipient of the Robert F. Allen Symbol of H.O.P.E. (Helping Other People through Empowerment) Award

The winner of the Robert F. Allen Symbol of H.O.P.E. Award, presented annually by the *American Journal of Health Promotion*, receives \$3,500 and a sculptured crystal statue. The cash award is made possible through grants provided by the California Wellness Foundation, the W.K. Kellogg Foundation, and individual donors. For more information on the award and

past winners, go to: <http://ajhp.com/resource/hope.htm>.

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**Brian Strom, MD, MPH**, received the Sustained Scientific Excellence Award from the International Society for Pharmacoepidemiology at a ceremony in Lisbon, Portugal in August. This award, presented on an occasional basis, recognizes an investigator for sustained scientific excellence in the field of pharmacoepidemiology as well as for active engagement in state-of-the-art pharmacoepidemiologic research. Dr. Strom gave an address to the Society, and received a plaque and a \$1000 award. He donated the award and the associated travel reimbursement back to the Society, to be used for student scholarships.

of the training program, graduates are well-suited for positions in academic medicine as independent clinical investigators. More than 100 former trainees hold faculty or instructor appointments at Penn.

Those seeking more information about this program may wish to consult the MSCE degree program web page: <http://www.cceb.upenn.edu/education/epi-degree/msce.php>. Those interested in applying for admission should contact Shanta Layton (215-573-2382, [slayton@cceb.med.upenn.edu](mailto:slayton@cceb.med.upenn.edu)). The application deadline for enrollment in 2007-08 is January 15, 2007.

## CCEB Photo Gallery



*Left, Justine Shults, PhD, Jonas Ellenberg, PhD, and Sarah Ratcliffe, PhD, and, right, Knashawn Morales ScD, Scarlett Bellamy, ScD, and Susan Ellenberg, PhD, gather at various stages to confer after the successful dissertations defenses by Julia Lin and Ben Leiby.*



Brian Strom, on behalf of the University of Pennsylvania Center for Clinical Epidemiology and Biostatistics, received an official certificate accompanied by the American Flag which was flown over by the Headquarters of Regimental Combat Team 5 at Camp Fallujah, Iraq. The flag was dedicated by Lieutenant Colonel Robert A. Sammel, U.S. Marine Corps, husband of Mary Sammel, ScD, Assistant Professor of Biostatistics at HUP, University of Pennsylvania SOM, pictured to the left. Lieutenant Sammel has served two tours in Iraq.

*- Jane Sinopoli*