

CAM AT PENN

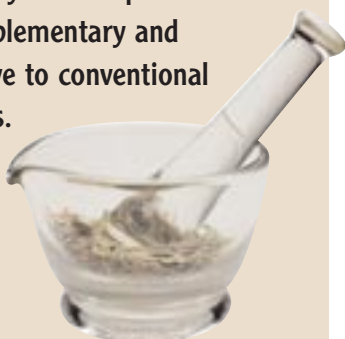
COMPLEMENTARY/ALTERNATIVE THERAPIES AT THE UNIVERSITY OF PENNSYLVANIA



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CAM Defined

CAM is a government inspired acronym that has become accepted shorthand in the U.S. for what is known as integrative medicine in much of Europe and much of which is considered mainstream medicine in many parts of the world. The acronym is derived from the name of the National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health. The abbreviation blankets a wide range of unconventional therapies, most of which are unproven by Western scientific standards. Although the NIH usage of the acronym "CAM" includes alternative therapies, at Penn CAM refers only to therapies that are complementary and adjunctive to conventional therapies.



The CAM Uprising

Recent surveys show that at least half of the population in the United States uses one of the diverse array of complementary and alternative medicine practices now known collectively by the acronym CAM. That use has grown dramatically over the past decades despite the fact that few insurance plans provide coverage for any of the many CAM procedures. Users pay an estimated \$27 billion a year out of pocket for these services and make more visits to the CAM providers than to primary care physicians.

As another indication of how firmly entrenched in the health care system



CAM has become, the National Center for Complementary and Alternative Medicine at the National Institutes of Health invests more than \$50 million a year to investigate the safety and efficacy of some of these approaches. Such well-known institutions as Memorial Sloan Kettering Cancer Center and a small, but growing, number of health maintenance organizations and insurance plans now offer some CAM procedures. Nor has big business

ignored the growing appeal of CAM, for herbal remedies, alone, have become a \$10 billion a year industry that is growing at a projected annual rate of 20-30 percent.

No single definition adequately captures the range of practices that fall under the CAM rubric. Even those that simply define CAM as practices that are not part of mainstream medicine, as practices used by patients to manage their own health care, or as therapies that are not widely taught in western medical schools or available in most hospitals, fail to capture the complexity of the field. CAM includes health care practices that range from the use of vitamins, herbal remedies and massage

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A Little History

The Beginnings of CAM at Penn

The practice of medicine in the Western World is rooted in scientific medicine. This is as it should be. Scientific medicine has improved health and prolonged life. Then, why are 40-50 percent of people in the United States turning to

unconventional therapies that do not satisfy Western criteria for scientific medicine?

In an attempt to unravel this enigma and to determine how it relates to the mission of the academic medical center, the CEO/Dean of the University of Pennsylvania Health System, Dr. William N. Kelley, commissioned a Working Group

in 1997 to examine the issues and to recommend solutions.

The Working Group was evenly balanced: six strong believers in Complementary/Alternative Medicine; six to whom the idea of unconventional therapies in a research university was anathema.

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The Broad Usage of CAM

While its growth has coincided with both the rise of multiculturalism and greater affluence, the appeal of CAM seems far broader, for the use of CAM therapies is not confined to any one segment of the population. According to recent surveys, use is slightly higher among women than men, slightly lower among African Americans, and slightly higher on the West Coast. Use is also slightly higher among those with more education and in the higher income brackets. These surveys also show that use cuts across age and economic barriers. "Baby boomers" are frequent users, more for prevention and lifestyle than therapeutic intervention; those under 30 in "generation X" are even more frequent users, again for lifestyle. At the same time, nearly one third of those over 65 have used at least one CAM intervention to treat a serious illness and about 20 percent have visited a CAM provider. And, though few CAM therapies are covered by any form of insurance, some 43 percent of people making less than \$20,000 a year spend at least \$250 annually for this kind of help.

Little information exists about use of CAM approaches among minority populations. What data do exist suggest that use patterns are very different, and that use is increasing. One study of Latino, Black, White and Chinese women with breast cancer showed at least half had used one alternative approach and one third had used two. Yet use differed along racial and ethnic lines. Blacks turned more to spiritual healing, Chinese to herbal remedies, and Latino women to dietary and spiritual approaches and the Whites to dietary and physical therapies like massage and acupuncture. Such differences, though, cloud the fact of heterogeneity within cultural and ethnic groups and ignore variations in use patterns in different parts of the country.

Because so many people are reluctant to admit to CAM use, existing studies underestimate the extent of CAM use. According to best estimates, the estimated 600 million annual visits to CAM practitioners are for massage and chiropractic procedures. Also, at least 10 percent of the population admits to using chiropractic, massage, herbal remedies, relaxation and meditation techniques.



And they are willing to pay for perceived benefits. People spend an estimated \$27 to 34 billion every year for techniques that include chiropractic, acupuncture and massage, biofeedback, megavitamins, homeopathy, relaxation and meditation, spiritual healing, folk remedies, lifestyle diets, herbal remedies and energy healing. Some CAM practices are no longer considered unorthodox having been accepted by mainstream medicine. An NIH consensus conference approved the use of acupuncture for certain types of pain, while federal guidelines recommend chiropractic techniques for low back pain. Psychosocial support for cancer patients is well established in many institutions. Even health maintenance organizations are starting to offer some CAM therapies for their patients though greater coverage has been slowed by worries about the broader implications of establishing a precedent for paying for unproven, experimental therapies.

CAM Research

In keeping with the mission of the Academic medical center, research on CAM has been approached at Penn in a variety of ways. These fall into two categories: training for research on CAM and research projects.

Penn is one of two institutions in the United States that has been awarded a training grant for CAM by the National Center for Complementary/Alternative Medicine of the NIH. Its approach to training is unique. The training grant, Alfred P. Fishman, M.D., Principal Investigator and Brian L. Strom, M.D., MPH, co-Principal Investigator, provides for dual mentoring of two trainees per year. To accomplish its goal, the trainee takes courses in the Center for Epidemiology and Biostatistics and embarks upon a research project supervised by two mentors: one expert in a particular CAM modality; the other a member of the Center for Epidemiology and Biostatistics. The program is designed to take two years and can lead to a Masters degree in Epidemiology and Biostatistics.

Research on CAM currently under way ranges from individual research projects to an NIH center, headed by Stephen R. Thom, M.D., Ph.D., devoted to unconventional uses of hyperbaric oxygen. In addition, several investigators have been recipients of NIH awards for CAM research. For example, John Farrar, M.D., of the Department of Neurology and the Center for Epidemiology and



Biostatistics, is conducting research on the efficacy of acupuncture and physical therapy in the treatment of osteoarthritis of the knee. A different approach has been taken by Sharon L. Kolasinski, M.D., of the Rheumatology Division of the Department of Medicine who is investigating the use of Yoga for the same problem. A variety of individual grants are supported by industry, e.g., Philippe Szapary, M.D. on the use of gugulipid in patients with moderate hypercholesterolemia and on the effects of platelets of turmeric extracts.

A project is also under way on the usage of CAM modalities in the community surrounding the University of Pennsylvania. Community leaders, working with Elizabeth MacKenzie, Ph.D. and Margaret Cotroneo, RN, Ph.D., are exploring the extent to which the population in the vicinity of the University is resorting to unconventional therapies and the nature of these therapies.

CAM and Scientific Medicine

The guiding principle for the introduction of CAM modalities into the University of Pennsylvania Health System is that proposed unconventional therapies and practitioners will be evaluated in the same way as conventional therapies. This doctrine is simply a reaffirmation of the commitment of the Academic Medical Center to practice scientific medicine.

Supplementation of this policy will be by way of the usual channels. The Office of Medical Affairs is the reviewing body for physicians. For non-physicians, the corresponding office is the Office of Human Resources.

This protocol for individual privileges is the same as for any proposed new therapy. It is exemplified by the process for privileges to perform acupuncture. A physician seeking to practice acupuncture within the University of Pennsylvania Health System currently submits his/her qualifications to the Chair of the department. These qualifications are reviewed by the Chair who may be unfamiliar with the proposed therapy. The Chair may then elect to seek the advice of the Steering Committee. After approval by the Chair, the application is forwarded to the Office of Medical Affairs en route to the Medical Board. At each step of the process, the Steering Committee and the Office of Legal Affairs is available for expert opinion.

It is anticipated that as more and more permission to practice less familiar unconventional therapies are sought; the Chairs and the Office of Medical Affairs will turn increasingly to the Steering Committee for advice.

Patients' Reluctance to Discuss CAM Use

Despite the increasing popularity of CAM, surveys show that patients are still reluctant to discuss their use of alternative approaches with their physicians. Even though 97 percent of CAM users also have a regular physician, more than 60 percent don't tell their physicians about their involvement with CAM either because physicians don't ask or because patients don't feel comfortable telling their physicians that they use unconventional therapies.

This communication failure has a negative impact on health and patient care. Not only does it erode trust, which is fundamental to a good doctor-patient relationship, but failure to communicate can also lead to serious complications. For example, physicians need to know about the patients use of herbal supplements which may enhance or diminish the effectiveness of prescribed medications.

A Little History

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At the first meeting, the Working Group reaffirmed its commitment to the principle and practice of Western scientific medicine and agreed to confine its deliberations to therapies that would be complementary to scientific medicine. Accordingly, the Working Group would deal with unconventional therapies that would complement scientific medicine in the care of patients but not with alternative therapeutic modalities.

This process for assessing the role of the unconventional therapies in an academic medical center was unusual.

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ADVERSE REACTIONS TO HERBS

In 1994, in response to intense lobbying, Congress passed the Dietary Supplement Health and Education Act, which shifted responsibility for proof of the safety of dietary supplements by the manufacturer to proof of unsafety by the FDA. Following this turn about, manufacturers were allowed to make general health claims about their products but were not allowed to ascribe to their preventive or curative roles for specific diseases. As a result, dietary supplements are now classified as "foods" and their sale is governed by the same standards as for vitamins. Also, because of this exemption from FDA control, herbs may vary considerably with respect to chemical composition, concentrations of effective agents and of harmful ingredients.

During the last few years, a steady trickle of case reports of herbal toxicity has appeared in the medical literature. Some of the herbs are widely used. One such popular herb is St. John's Wort, which is widely used by people who treat themselves for anxiety and depression. This population includes patients with AIDS. It has been shown that patients with AIDS who are taking the protease inhibitor, Indinavir, may suffer a sharp severe recrudescence of viral activity because of the sharp decrease in the blood level of Indinavir caused by St. John's Wort.

THE USE AND REGULATION OF

Despite the increasing sales of dietary supplements for health purposes, uncertainties remain about their safety and the need for governmental regulations. Concerns have been voiced both by physicians and the media about the potential health risks of dietary supplements, which are mostly untested and unregulated. Suspicion is also high that the use of these products may encourage patients to forego conventional therapies. Nonetheless, the ready availability of dietary supplements in drug stores and supermarkets has fostered a false sense of security about their safety.

A recent survey by the Harvard School of Public Health (Blandon, RJ et al. *Arch. Int Med.* 161: 805-810, 2001), a considerable number of Americans surveyed (16-18% of 1196 respondents) regularly take dietary supplements as part of their daily lives. One of 6 parents gives dietary supplements to their children. But, most do not discuss this routine usage with their physicians whom they generally considered to be uninformed about their value. Although on the one hand, many

RBS

St. John's Wort also diminishes the effectiveness of cyclosporine in preventing rejection of a transplanted organ. Thus, concomitant administration of St. John's Wort and cyclosporine diminishes the effectiveness of cyclosporine in preventing rejection of a transplanted organ.

Recently attention was called to an outbreak of Chinese herb nephropathy in Belgium, among patients seeking to lose weight. The toxic effect was attributed to human error, which resulted in the inadvertent substitution in the original formula of a more toxic herb. This error resulted in renal fibrosis and urothelial carcinoma.

Similar Chinese herb nephropathy has been reported from countries in Europe, Japan and the United Kingdom prompting the advice that patients with renal disease of unknown etiology or urothelial cancer should be queried about their use of herbal medicine.

An instructive review of the risk-benefit profile of commonly used herbal therapies recently appeared as part of a series in the *Annals of Internal Medicine on Complementary and Alternative Medicine* (Ernst, E. 136:42-53, 2002). This up-to-date review deals with Gingko, St. John's Wort, Ginseng, Echinacea, Saw Palmetto and KAVA.

OF DIETARY SUPPLEMENTS

reported that they would continue their practice even if scientific studies proved the supplements to be ineffective, on the other, many wanted the federal government to review the safety of dietary products, to increase government regulation of advertising claims, and to authorize the removal of unsafe products from sale.

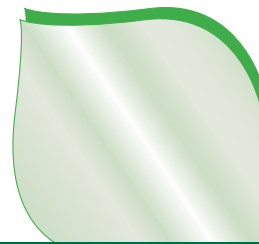


Education about CAM at Penn



Steps have been taken to introduce information about unconventional therapies into Curriculum 2000. Under the leadership of Gail Morrison, M.D., Vice Dean for Education, and her associate, Lisa Hark, Ph.D., teaching about unconventional therapies has been incorporated into various appropriate sites in the undergraduate curriculum. The Penn program is described at the web site of the Office of Complementary Therapies (<http://www.med.upenn.edu/penncam>). Individual components of the program will be detailed in future issues of this newsletter.

In addition to incorporation of CAM education into the undergraduate medical curriculum, arrangements have been made for graduate and continuing education in unconventional therapies of interest to practicing physicians. Medical house staffs are provided with teaching about CAM at conferences and workshops and the primary care residency program affords outpatient experience.



Macy Conference Addresses Questions

With its long-standing commitment to the education of health professionals, the Josiah Macy, Jr. Foundation convened a conference in November of 2000 to examine such questions. The conference, "Education of Health Professionals in Complementary/Alternative Medicine," brought together consumers, CAM and mainstream practitioners, medical school deans, and physicians and other health care professionals who have experience with CAM and have looked for ways to integrate these approaches into a mainstream medical education program. Alfred P. Fishman, M.D., Senior Associate Dean for Program Development at the University of Pennsylvania Medical School, served as Chair.

Presentations and discussions at the two- and a half-day conference explored the challenges to medical education posed by CAM from many directions, including a brief look at the history and ancient roots of traditional practices, the research that has been done to establish the safety and efficacy of some of these approaches, and the role of multiculturalism in the use of these therapies.

The conference ended with the following recommendations.

- Schools of medicine, nursing and pharmacy and academic health centers should integrate an awareness and knowledge of the most commonly used CAM theories and practices, with their potential for benefit and harm, as part of their curricula.
- Academic health centers should engage in rigorous collaborative, scientific research on the safety, efficacy and mechanisms of CAM, involving those with expertise in CAM practices in these research efforts.
- Academic health centers should also initiate the collection of data about the use of CAM therapies and approaches in diverse cultural and ethnic settings.
- Professional and education health care associations should make high quality, evidence-based CAM information widely available, include it in continuing education

programs and encourage the provision of this high-quality information on the internet and to the public.

- Professional licensing and credentialing bodies should include information pertinent to safety and efficacy of CAM procedures among their requirements.

The question of which and how to teach medical students proved difficult to answer. While the explosion of interest in CAM therapies requires that physicians need to know what patients are using and the potential problem areas, and also where to find reliable information to guide their patients, at the Macy Conference participants agreed physicians do not need to become competent in CAM therapies. They do, however, need to know when, where and how to refer their patients. Because of financial pressures and already crowded curricula, participants agreed any effort to introduce formal courses addressing CAM would be unworkable. Instead, the group favored integration of CAM concepts and modalities at strategic places in the curriculum by practitioners of relevant modalities. They also agreed that teaching physicians to be CAM practitioners

would be both impractical and unnecessary. But, they acknowledged that each institution would have to design its own strategies for teaching CAM.

Based on their own experiences integrating CAM approaches into a medical curriculum, several participants emphasized the need to teach students the art of communicating with and listening to patients. Account was taken of

time constraints imposed by both internal and external economic forces. Nonetheless, proper communication is essential for the physician-patient relationship and delivery of health care.

Having medical students actually experience some of these approaches has proven effective. In one program, for instance, students were hooked to a biofeedback device to experience how they could change their physiological parameters by changing their thinking; similar demonstrations are made using yoga and meditation. The experience effectively changed the way the students viewed



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A Little History

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In essence, the same evaluative process was to be used as that conventionally used to assess the need for a new institute, center or department. The Working Group's conclusions and recommendations would be reviewed by the usual review groups of faculty and administrators.

During the year that followed its creation, the successive reviews of the conclusions and recommendations of

the Working Group sailed uneventfully through meeting after meeting. The process ended with the acceptance of the Working Group's report to the CEO/Dean. Momentum was lost during the two-year period of changing leadership although viability of the report was sustained by the Interim Dean, Dr. Arthur K. Asbury, who created the Office of Complementary Therapies, under Dr. Alfred P. Fishman.

Meanwhile, the Working Group was reactivated as a Steering Committee. In this new capacity, it catalyzes pro-

grams in education, research and clinical approach. In each of these areas, considerable progress has been made. Other columns in this report describe these accomplishments. Moreover, national and international recognition has been awarded to the Penn program in CAM for its demonstration of how the conventional process, by which novel therapies are incorporated into the clinical, educational and research activities of the academic medical center, can be applied to the incorporation of unconventional therapies.

CAM Uprising

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therapies to the ancient traditions of Ayurveda and Chinese medicine, along with chiropractic, naturopathy, homeopathic medicine, meditation, hypnosis, acupuncture and a host of other lesser known approaches to health and health care.

Though their use is common and standard practice in much of the world, most CAM procedures have never been tested according to the rigorous, scientific standards of Western, evidenced-based medicine. Because of this, the response of medical practitioners to the growing CAM phenomenon has ranged from an outright dismissal of practices which have not been proven to be safe and effective to a gradual recognition that such widespread use can no longer be ignored. Several surveys suggest that at least half of practicing physicians want to know more about CAM so they can advise and guide their patients.

Other studies show that most CAM users are not abandoning Western medicine but want the best of both worlds – an alternative caregiver with strong ties to the medical establishment and a physician who both understands and will make appropriate referrals for CAM therapies. But this poses another problem for physicians, since many CAM users do not tell their physicians what they are doing and that most practicing physicians know little about the potential benefits or risks of CAM because their training has focused almost exclusively on Western scientific medicine.

Academic health centers have started to respond to the challenge of CAM, both by introducing CAM content into medical curricula and by considering research on some of these approaches. Yet it is still far from clear how teaching institutions should address what has, in effect, become a parallel system of health care. What should they teach and who should do the teaching? What research needs to be done, and for which CAM

approaches? And how should teaching institutions insert this admittedly controversial material into already crowded curricula? Although such questions remain, virtually all academic health centers have incorporated teaching about CAM into their Medical curricula.

The Macy Conference

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alternative approaches and also improved the way they interacted with patients.

In terms of who should do the teaching, those with experience in the field suggested that CAM practitioners be involved since few physicians have sufficient knowledge to teach about CAM. Also, as participants were reminded, definitions of health, illness and appropriate care differ by culture, religious and philosophical beliefs. Therefore, for the effective delivery of health care, students need to be exposed to, and taught about, differences in culture and beliefs.

Steering Committee on Complementary Therapies

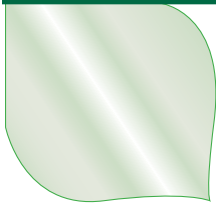
The Steering Committee for CAM at Penn operates through the Office of Complementary Therapies. It is constituted to provide expert advice about complementary therapies and is available to chairs and administrative personnel concerned with incorporating CAM modalities into the University of Pennsylvania Health System. Its range of interests extends from practice requirements to the legal and ethical aspects of CAM.

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