Global Health & Environment
MONITOR
Spring 2001 Vol. 9, Issue 1

Sizing Up Alternative Medicine

Complementary Therapies Surge, Challenge Conventional Wisdom

by Dr. Andrew Vickers, Assistant Attending Research Methodologist, Memorial Sloan Kettering Cancer Center, New York

Complementary and alternative medicine (CAM) has come a long way since a *British Medical Journal* (*BMJ*) editorial in 1980, entitled "The Flight from Science," compared chiropractic with the "divination of the future by examination of a bird's entrails." In a subsequent issue, *BMJ* described "a new dawn" in complementary medicine stating that, "increasing evidence shows the effectiveness of some treatments in some conditions." This increasing acceptance of CAM in medical circles reflects the rise of evidence-based medicine, which emphasises empirical data over theory.

The growing popularity of CAM is now well documented. CAM generally comprises disparate treatment techniques which are not normally part of mainstream medicine, but which may complement it by addressing unmet needs. A 1998 *Journal of the American Medical Association* (*JAMA*) article stated that from 1990 to 1997, visits to CAM practitioners by Americans alone jumped almost 50 percent, exceeding the number of visits to all primary care physicians. Perceived effectiveness and safety, accessibility, a non-invasive, holistic approach and "high touch, low tech" techniques are among the chief reasons for CAM's public popularity.

Who Uses CAM?

Surveys in industrialised countries typically report that 10 to 15 percent of the population have visited a CAM practitioner in the previous 12 months. The most popular CAM treatments are acupuncture, osteopathy and chiropractic, botanical medicine, hypnosis, and in Europe, homoeopathy. If yoga, special diets or over-the-counter herbal, vitamin or other supplements are included, use of CAM is nearer 30 to 40 percent. Some estimate CAM usage has increased 50 percent in the last five years — with Americans spending as much as $27 billion and the British as much as £1.6 billion on CAM practices.

Courtesy of NCCAM, NIH, Bethesda, MD

NIH consensus statements support the use of acupuncture for nausea, and acute and chronic pain.

A number of studies have defined "typical" CAM users as the "worried well." However, the overwhelming evidence is

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Plant Power: Rediscovering the Roots of Modern Medicine

by Joel L. Swerdlow, an Assistant Editor, National Geographic Magazine, *National Geographic Society, Washington, D.C.*

The Western world, led by the United States, is the first culture to abandon plants as the core of its medicine. Some people see this as evidence of progress. But rather than justifying the *break* from plant medicine, advances such as mapping the human genome demonstrate that to *reunify* plant medicine and modern science would allow us to prevent and combat disease in ways hitherto impossible. Re-embracing plants could also allow Western medicine to better benefit from other cultures, and help erase much of the false distinction between modern and plant-based medicine.

While this assertion may seem absurd, Jacques Monod, who won the 1965 Nobel Prize, says that the scientific community often reacts in two stages to a new idea: First, people say it is absurd; then they call it obvious.

Medicinal plants are all around us -- and have been for centuries.

Where Has All the Flora Gone?

Modern medicine began to ignore plants in the late 19th century as it developed the capability to manipulate individual chemicals and manufacture synthetic drugs. U.S. pharmacopoeia entries based on plants peaked in 1890 at 59 percent; by 1940, they were down to 28 percent, and are now at less than 2 percent. In fact, since the early 1960s, the U.S. Food and Drug Administration has approved more than 5,000 prescription drugs, yet fewer than a dozen have been based on plants.

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CECheck-Up

"Within five to 10 years, complementary therapies will be part of the care in every major hospital and clinic across the country." So predicts the chairman of the White House Commission on Complementary and Alternative Medicine Policy, a 19-member presidential commission to develop recommendations to help physicians and consumers distinguish between effective and ineffective therapies, and integrate complementary and alternative medicine (CAM) into mainstream health care for Americans.

Such high-level attention has been precipitated by reports that an estimated four in 10 Americans use some form of CAM, including relaxation therapy, massage, spiritual healing, homeopathy, hypnosis, biofeedback and acupuncture. In fact, visits by Americans to CAM practitioners have increased almost 50 percent since 1990, exceeding visits to all primary care doctors — ~700 million visits to CAM practitioners compared with ~400 million to primary care physicians. And Americans annually spend over $20bn on alternative treatments; herbal, vitamin, and diet products; books; and classes. Furthermore, surveys indicate that American physicians increasingly seek scientific information about CAM to answer patients' queries.

This search for knowledge and improved health care is beginning to be addressed, with CAM making unprecedented inroads in the past decade into major institutions of mainstream medicine: medical schools, academic medical research centers, peer-reviewed medical literature, insurance companies and the federal government. In the United States, the Office of Alternative Medicine (now the National Center for Complementary and Alternative Medicine, or NCCAM) was established in 1992 by congressional mandate. In 1995, the National Library of Medicine expanded its repertoire to include journals on CAM practices and now lists more than 60,000 citations on CAM. Some 30 U.S. medical schools offer courses on alternative medicine, including Georgetown, Columbia and Harvard. In fact, a 1984 study found that 51 percent of CAM practitioners were trained physicians. Perhaps in response, insurance companies have begun offering plans that reimburse alternative practitioners.

Evidence tells us that certain CAM therapies work for certain problems; but others can be harmful or deadly, as demonstrated by repeated reports of CAM-related toxicity and deaths. So, how is the public, or even the physician, to know? The Spring 2001 *Global Health and Environment Monitor* has prevailed upon North American, European and Asian experts to assess how CAM measures up and help us distinguish fact from fiction.

-Sushma Palmer, D.Sc., Chairman

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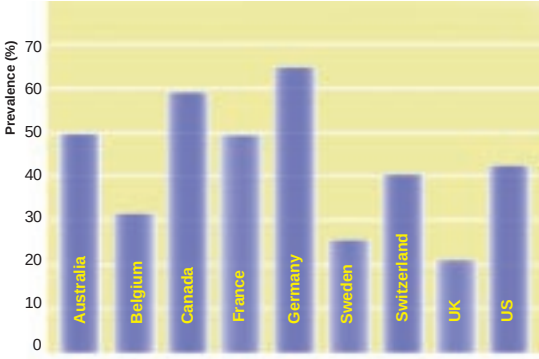
that CAM users are rational, using CAM for additional relief where conventional medicine has not provided them full satisfaction. CAM users are also often affluent. In America, according to *JAMA*, CAM usage is highest among white, university-educated females aged 35 to 49 with annual incomes above $50,000. Fortunately, few CAM patients totally reject conventional medicine in favor of CAM, as CAM can be harmful and has resulted in numerous deaths or disablement.



Estimated Prevalence of Alternative Therapies in Selected Countries

How Does CAM Measure Up?

The recent surge of CAM in industrialised countries has occurred primarily in the private sector, but questions about CAM's effectiveness and legitimacy also permeate the public realm. The major domains of CAM encompass:

- **Acupuncture**, the stimulation of special points on the body, usually with fine needles. Originally based on Chinese theories of body energy, acupuncture is starting to be understood in terms of neurophysiology and neurotransmitters such as endorphins, and clinical evidence shows that it is effective for nausea and acute and chronic pain.
- **Osteopathy and chiropractic**, therapies that diagnose and treat abnormalities of structure and function of bones, muscles and connective tissue, and which randomized trials indicate are effective for relieving back pain.
- **Herbal or botanical medicine**, the use of whole extracts from plants — and, therefore, multiple active compounds — to treat disease. While evidence suggests some botanicals are effective, most have not been sufficiently evaluated, and there is concern about adverse interactions between botanicals and drugs.
- **Hypnosis**, the use of therapeutic suggestions to encourage behavioural change or relief of symptoms after inducing a deeply relaxed and focused state and suspension of critical faculties. Hypnosis is known to be effective for anxiety, nausea and cancer-related pain.
- **Homoeopathy**, the use of low, often minute doses of common substances to treat disease. Although clinical evidence indicates homeopathy can be more effective than placebo, its scientific plausibility remains at issue.

Much evidence on CAM still involves small numbers of patients and is of poor methodological quality. More recently published systematic reviews, though, provide an increasingly reliable basis for making healthcare decisions, especially the *Cochrane Library* listing, which includes over 4000 randomised trials. A Cochrane review of St. John's wort (*Hypericum perforatum*) for mild to moderate depression, for example, included 27 trials with a total of more than 2000 participants, and while not fully tested for safety, St. John's wort was found to be superior to placebo and equivalent to tricyclic antidepressants, with fewer adverse effects.

Furthermore, better research has generated guidelines and consensus statements on CAM by authoritative medical bodies. In the United Kingdom, the Royal College of General Practitioners recommends physiotherapy, chiropractic treatment, or osteopathy within six weeks of the onset of persistent uncomplicated back pain. In the United States, the National Institutes of Health (NIH) have issued consensus statements supporting the use of hypnosis for cancer-related pain and the use of acupuncture for pain and nausea. The U.S. National Comprehensive Cancer Network has guidelines for using acupuncture, hypnosis and relaxation techniques for management of cancer pain.

Recognizing that rigorous scientific research and training are fundamental to integrating CAM into modern medical practice, many CAM training courses now include research skills. In response, conventional sources of funding, such as the United Kingdom's National Health Service research and development programme and major cancer charities, have become more open to CAM researchers. However, CAM still lacks both a research tradition and a research infrastructure; consequently, it attracts neither experienced researchers nor sufficient funding. Furthermore, poor quality studies often make data interpretation difficult, the results are often unavailable since many CAM publications are not on standard databases, and the existence of many different treatments within each CAM discipline compounds the problem.

Although many CAM practitioners can legally practise without any training, most have completed some further education in their chosen discipline. For the major therapies such as osteopathy, chiropractic, acupuncture, herbal medicine and homoeopathy, training institutions tend to be highly developed, some with university affiliation, degree-level exams and external assessment. Others, particularly those teaching less invasive therapies such as reflexology and aromatherapy, tend to be small and isolated, determine curricula internally and have idiosyncratic assessment

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Sifting Through Supplements:
Consumers, Industry Confront Myths and Realities of "Natural" Products

by Bruce Silverglade, Director of Legal Affairs, Center for Science in the Public Interest, Washington, D.C.

A generation ago, only "health nuts" consumed large amounts of vitamins and minerals, and herbal medicines were virtually unheard of. Today, half of all American adults take vitamin or mineral supplements, and one in three have tried herbs. Such products, now widely marketed under the banner "dietary supplements," include substances ranging from hormones to "glandulars" (processed animal organs in pill form), and can be found both in small health food stores and nationwide drugstore and supermarket chains.

Why the Supplements Surge?

The growing interest in dietary supplements is rooted in several developments. The aging "baby-boomer" generation of Americans likes the idea of so-called "natural" products, such as herbal medicines. Further, many Americans are disenchanted with a medical establishment that increasingly funnels patients through doctors' offices as if they were on an assembly line. Consumers also hear more and more about promising research that certain dietary supplements may hold the key to preventing cancer and other diseases. Many Americans thus want to take control of their own health and engage in self-medication.

Certain nutrient supplements are indeed necessary and beneficial. Millions of Americans need supplements or foods fortified with calcium to help reduce the risk of osteoporosis. Adequate folic acid intake by women of childbearing age can reduce the risk of neural tube birth defects in their unborn children. A growing number of studies also suggest that certain non-nutrient supplements can be beneficial. Saw palmetto, for example, can help men with benign enlarged prostates, and St. John's wort can be useful in treating cases of mild depression. The challenge for most consumers is to determine which supplements are beneficial and which are simply 21st century snake oil — or even dangerous.

Supplement manufacturers are largely to blame for this unfortunate situation. In 1994, the industry successfully lobbied the U.S. Congress for legislation that made it more difficult for the Food and Drug Administration (FDA) to regulate dietary supplements. The industry lobbying campaign was supported by hundreds of thousands of consumers led by health-food store retailers and whipped into a frenzy to write to Congress to oppose the FDA in the belief that it was about to require prescriptions for ordinary vitamins.

Congress responded, but not exactly along the lines that consumers expected. The 1994 Dietary Supplement Health and Education Act (DSHEA) freed manufacturers from the responsibility of demonstrating that supplements are safe before they are marketed. Although the FDA can still take dangerous products off the shelves, it must first prove that they are unsafe. That often means that people have to be injured before the FDA can act.

DSHEA also made it easier for manufacturers to make health-related claims for dietary supplements without FDA premarket approval. An avalanche of misleading claims has resulted; and since the passage of DSHEA, sales have tripled to more than $10 billion per year, with thousands of new supplements — some making outlandish promises — appearing on shelves. Such products are scooped up by unsuspecting consumers who erroneously believe "if it's natural, it must be safe."

Supplement sales have tripled, generating billions of dollars, more products, and a host of problems.

The Safety & Efficacy Dilemma

The safety problem is compounded by manufacturers who sell traditional herbal medicines for non-traditional purposes. An herb that may have produced minimal side effects when used for a traditional purpose may cause severe adverse reactions when used for a different purpose. For example, the Chinese herb *Ma huang* (also known as ephedra) was traditionally used in China to treat short-term respiratory congestion. In the United States it is sold as a stimulant and used for extended periods by consumers trying to lose weight. The FDA estimates that ephedra use in the United States has led to more than a dozen deaths and hundreds of serious injuries, including heart attacks and strokes. But because Congress restricted the FDA's authority, the agency has been unable to protect the public and institute limits on ephedra marketing.

Such problems, coupled with skepticism about exaggerated claims, may now be adversely affecting sales; recent figures suggest that supplement sales seem to have plateaued. By continuing to demand weak regulation, the dietary supplement industry is essentially "shooting itself in the foot." And as more and more adverse reactions to supplements are reported in the media, and false and misleading claims grow in the marketplace, consumers will increasingly turn away from supplements and sales will decline. Already, some vitamin and mineral supplements critically important to health, such as folic acid or iron for women of childbearing age, are not being consumed by enough people.

Next Steps

It is, therefore, incumbent upon both industry and consumers to support a systematic, comprehensive review of dietary supplement safety and efficacy. Such a review should be paid for by the industry and supervised by a public health agency. Panels of scientific experts not associated with industry should choose priorities for review based on risks to health and issue monographs setting forth conditions for safe use, potential health benefits, labeling requirements and manufacturing standards.

The U.S. National Academy of Sciences is beginning a government-funded project to develop seven prototype monographs on leading dietary supplement ingredients. That is a good start. But ultimately, Congress should require companies profiting from supplement sales to pay for a comprehensive review of all products now on the market and modify the law so that the FDA can act quickly to ban hazardous or useless ingredients. §

Religious belief is an integral part of Ayurvedic medicine, and many other traditional treatment approaches.

Ancient Treatm

Ayurveda's Ancient Ways Promote Contemporary Healthy Living

by Shri K. Mishra, A.B.M.S., M.D., M.S., Prof. of Neurology and Coordinator, Integrative Medicine, USC Keck School of Medicine, Los Angeles, and Chair, Committee for Integrated Medicine, American Association of Physicians of Indian Origin, Los Angeles

In India, knowledge of life isn't detailed in books or on billboards; it is rooted in a 5,000+ year-old system of traditional care that combines religion, philosophy and ancient beliefs. Comprised of *Ayush* and *Veda* (life and knowledge), Ayurveda and Ayurvedic medicine promote healthy living, treating physical, mental and spiritual illnesses, or dissonance, by restoring balance between body, mind and nature in a comprehensive, individualistic and holistic manner.

Like more conventional forms of medicine, Ayurveda consists of branches, including *Kaya Chikitsa* (Internal Medicine), *Shalya* (Surgery), *Shalakya* (Ophthalmology, Otolaryngology and Dentistry), *Agad Tantra* (Toxicology), *Bhoot Vidya* (Psychiatry), *Kaumar Bhritya* (Pediatrics, Obstetrics and Gynecology), *Rasayana* (Geriatrics, Rejuvenation) and *Bajikaran* (Sexology, Aphrodisiacs). While its spiritual, harmonic approach to disease, diagnosis and treatment have often placed Ayurvedic medicine outside the realm of mainstream care, the estimated 25,000 patients treated in Ayurvedic clinics in North America in the past decade signal the increasing integration of Ayurvedic principles into contemporary clinical practice.

Grasping the Fundamentals

Sushruta Samhita defines health in Ayurvedic medicine as, "a balanced state of the three biological humors, seven body tissues with proper metabolic processes and excretory system associated with the ultimate happiness of soul (spirit), mind and senses." Ayurveda is based on the theory of *Pancha Mahabhoota* or five elements: ether, air, fire, water and earth. Three primary life forces or humors (*Vata, Pitta* and *Kapha)*, known as *dosha*, characterize these five elements in their biological form. Every individual has a unique psycho-physiological nature or constitution called *prakriti* based on these three humors. Disease occurs when there is an imbalance in the humors in the form of aggravation or deficiency due to an external or internal cause. For example, accumulation of waste (*mala)* in the body causes many diseases. The blockage of *srotas*, channels transporting food and other bodily materials and fluids, also precipitates illness.

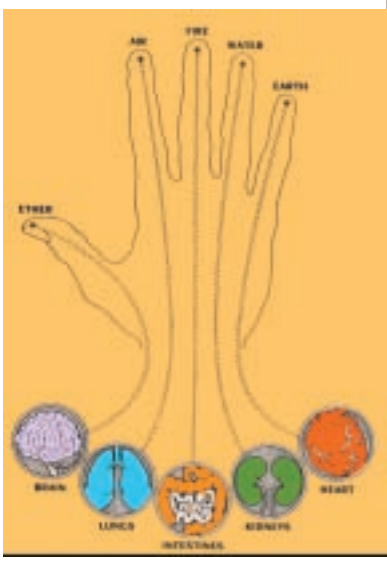
Diagnosing the Ailment, Treating the Patient

The Ayurvedic practitioner diagnoses disease by taking an elaborate history of causes, prodromal symptoms, cardinal signs and the precipitating and relieving factors of the complaints. Inspection, questions and touch are important elements of diagnosis, and eight methods of evaluation are used, including pulse examination and detailed inspection of the body's nine "doors" or openings and the secretions they emit. The patient's mental and family history is also taken into account before arriving at a diagnosis.

Ayurvedic treatment is aimed at restoring the equilibrium of the *doshas* through either elimination (*sodhana*) or palliation *(samana*). Treatment involves physical or medical methods with a naturalistic basis, including herbs, diet, bodywork (*Panchakarma*), acupressure (*marma* therapy) and yoga. Changing lifestyle activities (e.g., sleeping, waking, eating and sexual habits) and removing toxins through controversial means such as bloodletting, vomiting and bowel purging are also an important part of the therapeutic process. In extreme cases, mineral drugs or surgery may be required.

Although Ayurvedic medicine is used to treat many diseases, it is most effective in treating chronic ailments requiring a holistic approach, including rheumatological disorders such as rheumatoid and osteo arthritis, and degenerative, immunological, geriatric and neurological disorders. *Panchkarma* or cleansing oil massages and fomentation and purgation are the first steps before Ayurvedic medication is administered. For dementia, for example, *dhara* or a steady flow of oil over the forehead is the initial treatment.

Ayurvedic herbs have been used effectively as preventive, symptomatic, specific and rehabilitative treatment modalities for neurological disorders. *Centella asiatica* (Brahmi) and *Withania somnifera* (Ashwagandha) have been researched and proven efficacious in the treatment of senile dementia and Parkinson's disease respectively.



Many forms of herbal and internal and external therapeutic modalities have also been used to treat central and peripheral nervous system disorders such as headache, stroke and peripheral neuropathy. In addition, Ayurveda has an adjunctive therapeutic role in various chronic neurological disorders.

The role of Ayurvedic formulations and herbs in health promotion and disease prevention is a growing focus of scientific study. One such example is Chyavan Prash, a compound consisting of *Amla* (Emblica officinalis), a highly potent source of vitamin C and other vitamins and minerals that boosts the immune system.

No scientific data per se suggest that Ayurvedic techniques can be helpful in cancer; yet certain Ayurvedic meditations are effective for cardiovascular disease, and massage and yoga, important aspects of Ayurvedic healing, are widely documented to reduce stress and tension and improve general well-being in these chronic diseases.

While scant scientific evidence confirms Ayurvedic medicine's ability to address certain diseases, double-blind controlled studies are necessary to establish evidence-based treatment modalities in larger sample sizes.

Currently, basic, clinical and health services research is being conducted in India and other parts of the world to evaluate, and ideally validate, the efficacy of many Ayurvedic treatment modalities in a more scientific manner. §

Traditional Chinese Medicine Vies for Place in Western Medical Practice

by Dr. Boping Wu, Professor, Atlantic Institute of Oriental Medicine, Miami

Three years ago, the National Institutes of Health (NIH) heralded the legitimate integration of Traditional Chinese Medicine (TCM) into Western medical practice, reporting in its landmark 1997 Consensus Development Statement that, "*…promising results have emerged, … showing efficacy of acupuncture in adult postoperative and chemotherapy nausea and vomiting and in postoperative dental pain. There are other situations such as addiction, … in which acupuncture may be useful as an adjunct treatment or an acceptable alternative or be included in a comprehensive management program.*"

TCM, however, is more than acupuncture and herbal remedies. It is a centuries-old marriage of experience, theory and practice designed to protect and maintain good health. Like the ancient practitioners, today's acupuncturists use moxibustion, cupping, herbal remedies, Chinese massage (Tui Na), Qi Gong meditation, and tai chi and other movements and concentration exercises to regulate "qi" (pronounced "chee"), the body's life force and the basis of TCM.

Traditional Chinese Medicine uses acupuncture (above) to re-establish healthy balance. Ayurveda links energy flow to the five basic elements used to diagnose, and relieve, maladies (left).

The concept of *yin* and *yang* is perhaps the single most fundamental theory in TCM. In nature, yang represents all that is bright and hot (e.g., the sun, fire); yin represents all that is dim and cool (e.g., the moon, water). Too much of one and not enough of the other imbalances the qi, resulting, for example, in fever (yang) or edema (yin). The five elements (wood, fire, earth, metal and water), the inseparability of man and nature, and the importance of balance also figure in to TCM diagnosis and treatment. Chinese practitioners also pay close attention to the pulse, the tongue and its coating. Once a diagnosis is made, treatment options include:

- Acupuncture: the placement of hair-thin, stainless steel needles into the skin at certain acupoints along invisible channels called meridians through which the qi is believed to flow. In one eight-week acupuncture study, 53.8 percent of cocaine addicts treated five times a week with acupuncture (compared to 23.5 percent of addicts given sham acupuncture) tested free of the drug.
- Moxibustion: the burning on the body of a small mound of leaves of the Chinese mugwort near meridians related to the person's illness or places thought to have too little qi
- Cupping: the creation of suction above the part of the body requiring treatment by means of a vacuum created by warming air inside a glass jar and turning the jar over the treatment area
- Massage: the pressing by hand of acupoints to locate and fix too much, too little, or blocked qi
- Herbs: the use of more than 3,000 plants or plant parts in their natural state (without chemical processing) as medication for aches, pains and illness.

Although nearly 10,000 randomised controlled trials have been published in China prior to 1997 to evaluate the effectiveness of TCM, much of the information is inaccessible to Western doctors and difficult to compare with Western research because of methodological shortcomings. Thus, many TCM treatments have not been scientifically shown to cure cancer or other major illnesses. Nevertheless, some have proven effective complementary therapies, controlling pain and nausea and breaking addictive drug habits (acupuncture), improving balance and muscle tone (Qi Gong and tai chi), and lowering anxiety and promoting circulation (massage). In addition, moxibustion was found effective in helping correct breech presentation in primiparous women, and Chinese herbal medicine has helped people with irritable bowel syndrome, according to the *Journal of the American Medical Association*. Still, while herbs may promote health, in the West they are considered supplements not medicine, may contain toxic elements as they are unregulated, and are unproven for the treatment of major ailments.

Integral to traditional medicine, massage is popular today, reducing muscle tension and facilitating relaxation.

In China, Western medicine is considered "modern medicine," yet the notion of "alternative medicine" does not exist. In fact, Western medical facilities have coexisted with TCM in major Chinese cities dating back 200 to 300 years. And in the big cities where Western medicine is practiced, it is integrated with TCM. TCM universities offer studies in acupuncture and moxibustion, Chinese herbs, Tui Na, food therapy, nursing and degrees similar to those at Western universities. In addition, the more than 3,000 TCM hospitals in China typically have such departments as Internal Medicine, Surgical Medicine, Gynecology and Pediatrics, as well as Tui Na, Acupuncture and Moxibustion.

TCM is a precious part of Chinese culture that over the centuries has coexisted alongside "modern" medicine. It has now spread to more than 200 countries — and NIH's acceptance of acupuncture for some ailments is a signal that it is becoming an integral part of modern medicine worldwide.§

The *Monitor* is published by the:
Center for Communications, Health and the Environment (CECHE)
4437 Reservoir Road, N.W., Washington, DC 20007
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Reliance on synthetic chemistry led to drugs with a single active compound — as opposed to plant-based medicines, which often contain hundreds of chemicals that interact while affecting the human body. This single-active-compound approach, which has dominated Western scientific thinking for over a century, makes drugs easier to discover, standardize and patent. It also separates modern medicine from other cultures: The extensive Chinese and Ayurvedic pharmacopoeias have contributed to a total of three Western pharmaceutical drugs.

In fact, plants were discarded not because tests showed them to be harmful or ineffective, but because they were too complex. Now that science and technology have advanced, it is time to revisit how plants can benefit modern science.

CANCER: Does CAM Measure Up?

An American Cancer Society telephone survey of 36,000 American households indicated that 9 percent of patients nationwide used unconventional cancer treatments. Other surveys point to a prevalence of 6 to 23 percent. Popular alternative cancer therapies include: diet and nutrition, mind-body techniques, bioelectromagnetics, traditional and folk remedies, pharmacologic and biologic treatments, manual healing methods and herbal medicine.

Many clinical trials comparing CAM with conventional cancer treatment are underway including at: New York's Columbia Univ. (nutrition-based Kelley/Gonzalez protocol for advanced pancreatic cancer); Houston's M. D. Anderson Cancer Center (shark cartilage); the Univ. of Alabama (genistein in soybeans and breast and other cancers); LA's City of Hope Medical Center (bioelectromagnetics); New York's Memorial Sloan Kettering Cancer Center (low-fat, high plant food diet and prostate cancer); and many centers in Europe (e.g., for herbal cancer remedies such as Iscador, a mistletoe derivative).

Meditation, biofeedback, and yoga are increasingly recognized as effective in stress reduction— a secondary benefit for cancer. The San Francisco intercessory prayer study suggests that intercessory prayer has beneficial therapeutic effects.

Findings on CAM and cancer treatment to date range from cautiously optimistic to effectively inert to potentially dangerous, with recent reports of severe liver and kidney damage from certain remedies, including chaparral tea. These reports underscore the fact that "natural" products are not necessarily harmless.

Commonality and Multi-Modality

Flowering plants have evolved over 100 million years, developing an arsenal of substances that fight bacteria, fungi, viruses, insects and herbivorous animals. Plants' "systemic acquired resistance" (biochemical memory resembling the human immune system) includes salicylic acid, popularly known as aspirin. Studies show, it can significantly reduce the incidence of cancer, heart disease and strokes in humans. Many plants also use an amino acid, glutamate, for internal communications. Humans too generate glutamate, an important chemical messenger in the brain. Faulty glutamate signaling has been associated with Alzheimer's disease and schizophrenia. Salicylic acid and glutamate demonstrate a genetic commonality between plants and humans that dates back billions of years. Appreciating this commonality is an important step towards utilizing plants in modern medicine.

A plant compound, Cyclopamine, for example, can block the action of mutated human genes associated with various cancers. And as knowledge advances, such breakthroughs may come with increased frequency.

For those who remain skeptical, the stories behind some of today's most commonly used medicines — all discovered without the benefit of genetics — might be helpful. Among the first drugs for treatment of high blood pressure was reserpine from the herb *Rauwolfia serpentina*, described many centuries ago in Indian Ayurvedic monographs. Indeed, some of our most important drugs are derivatives of the active ingredients identified in herbal remedies. Such drugs of botanical origin include digitalis for the treatment of congestive heart failure, and vincristine and taxol to combat cancer. Thanks to the work of French scientists in the 19th century, plant chemicals from Amazon dart poisons have become drugs still used, among other things, to relax muscles during anesthesia. Cinchona bark, used by people in the Andes to combat chills, gave Western medicine quinine and all of its many derivatives. White willow bark, used by a British physician in the late 1750s to fight fever and chills, has given us aspirin. In the 1930s, Indian physicians began using a plant, Indian snakeroot, as a tranquilizer and high blood pressure treatment; synthetic drugs based on Indian snakeroot still serve the same purpose.

Such plants are among the few that have worked when reduced to a single active ingredient. But for the vast preponderance of healing plants, looking for their single active ingredients is much like opening a radio and trying to find the piece that produces sound. This difficulty in identifying individual healing agents is the main reason why "traditional" uses of plants have contributed very little to the Western pharmacopoeia since the isolation of artemisinin from an ancient Chinese malarial remedy about 30 years ago.

Nevertheless, multi-modal treatments, as complex as multi-plant remedies, increasingly permeate modern medicine. Most prominent is the "AIDS cocktail." Other combinations include treatments for cancer, tuberculosis, heart attacks, malaria, rheumatoid arthritis, hepatitis C, diabetes and depression. Emerging evidence demonstrates that most human diseases involve numerous genes, which may account for the effectiveness of these multi-component treatments.

Resistance to a productive partnership between plants and science is natural. It took a generation, for example, for Western medicine to fully accept evidence that germs exist. But scientific advances *should* lead us back to plant-based medicine and the wisdom offered by traditional healing systems. Absurd? No, it's obvious.§

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procedures. In some courses, direct clinical contact is limited, and many CAM practitioners train part-time for years.

These shortcomings are gradually stimulating funding and the establishment of CAM research units at sites of research excellence. In Germany, a centre for CAM research at the Technische Universität in Munich has produced a series of systematic reviews. The U.S. National Center for Complementary and Alternative Medicine at NIH has a $68 million annual budget and supports a large number of trials and research centres. The United States is also home to substantial research units on complementary medicine based at conventional research institutions such as the University of Maryland, Columbia University, Harvard University and the Memorial Sloan Kettering Cancer Center.

Where Is It Going?

To date, the flow of information about CAM has largely been from developing to industrialised countries: CAM practices found on many U.S. high streets—yoga, acupuncture, botanicals—originated in India and China. Could this information flow be reversed, with recent Western research on CAM benefiting developing nations? This is an attractive proposition because currently CAM is low cost and low-tech, and requires only moderate training. However, whether or not CAM can play an important role against major diseases such as diarrhea, malaria or malnu-

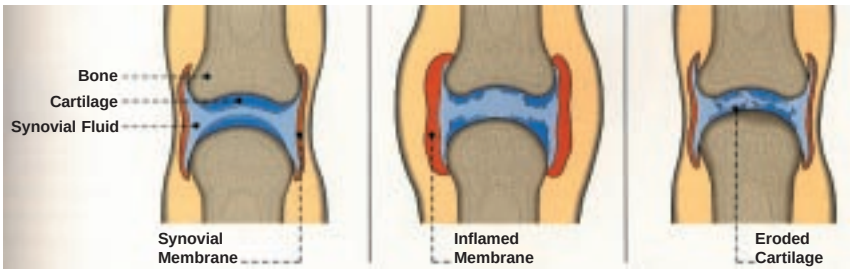
Scientists Tap CAM for Arthritis, Rheumatism Treatments

by Peter Fisher, M.D., Clinical Director and Director of Research, Royal London Homoeopathic Hospital, London

In developed countries with their aging populations, osteoarthritis is, or will soon become, the most prevalent of all diseases. In fact, 70 percent of people in their 70s currently have osteoarthritis (OA), and it affects 12 percent of the U.S. population aged 25 or over (more than 20 million individuals). Declaring this the Bone and Joint Decade, The World Health Organisation is challenging the world to reduce the expected increase in morbidity from chronic rheumatic diseases, including OA, by 25 percent by 2010.

OA is essentially a disease of cartilage, the tough, slippery tissue which allows smooth movement between and absorbs shocks in joints. OA particularly affects weight-bearing joints, and the most effective preventive measure is avoidance of obesity to reduce the load on these joints. However, conventional OA treatments, for the most part, are unsatisfactory. The non-steroidal anti-inflammatory drugs (NSAIDs) often used to treat OA have many side effects: In the United Kingdom, about 12,000 hospitalisations and 2000 deaths annually are attributable to these drugs, mostly due to stomach bleeding. Furthermore, while they relieve pain, NSAIDs do not slow or arrest progress of the disease — and some may even accelerate it. A new class of NSAIDs, COX-2 inhibitors, blocks one form of the enzyme cycloxygenase involved in inflammation. COX-2 inhibitors may cause less damage to the stomach, but are otherwise similar.

In their search for safe and effective medical interventions, increasing numbers of OA sufferers are trying complementary and alternative medicine (CAM). In fact, surveys have shown that, on average, well over half of arthritis and rheumatism sufferers use CAM. In the United States and United Kingdom, 92 and 71 percent of 1996 survey respondents used CAM, preferring prayer, ointments, food supplements and acupuncture to ease their suffering. What's more, recent scientific research suggests that patients' confidence in CAM is justified. Steadily growing evidence supports the effectiveness of CAM therapies such as acupuncture, manipulative therapies (including chiropractic and osteopathy), homoeopathy, phytotherapy (herbal medicine), food supplements and diets for a wide range of conditions, including OA.



Arthritis of the knee -- a common incentive for CAM therapy.

The most interesting prospect for OA to emerge from CAM to date is *glucosamine* and *chondroitin*. Extracted from animal cartilage or the shells of shellfish, glucosamine and chondroitin are "building blocks" from which the body can synthesise proteoglycan, an essential component of cartilage. They have been used, singly or combined, by CAM practitioners for many years, particularly in continental Europe.

More than 35 clinical trials have been conducted on these enzymes and their results pooled in a meta-analysis (*Journal of the American Medical Association*, March 2000). The best quality trial was by Mazieres and colleagues in France. This five-month, random, double-blind clinical study of 120 patients with OA of the hip or knee compared chondroitin given by mouth with inactive placebo tablets and showed a reduction of just over 50 percent in NSAID requirements in patients receiving chondroitin compared to placebo.

The meta-analysis indicated that glucosamine and chondroitin have a moderate to large effect in relieving OA symptoms. Even more provocative, in a multinational clinical trial conducted in Belgium, Italy, the United States and the United Kingdom over three years (*The Lancet*, January 2001), cartilage in the knee joints of patients treated with placebo narrowed, on average, by 0.3mm compared to a negligible 0.06mm in those receiving glucosamine, suggesting that glucosamine slows and possibly arrests the progress of OA. While more assessment is needed, *The Lancet* report is an important breakthrough. In contrast to some conventional treatments for arthritis and rheumatism, glucosamine and chondroitin are relatively inexpensive and safe; serious side effects are almost unknown.

Meanwhile, researchers look for similarly safe, effective and inexpensive treatments for rheumatoid arthritis (RA). A lesscommon but more devastating disease than OA, RA strikes at a younger age and runs a more aggressive course. Most current conventional treatments have many side effects and are very expensive. Clear evidence from clinical trials, however, indicates that supplements of omega-3 fatty acids, derived mostly from fish oil from sardine, mackerel and other oily fish and long used by CAM practitioners, give long-term benefit to RA sufferers. There is also evidence that other CAM therapies, including homoeopathy, may help in RA.

Clinical research has also shown that some CAM treatments promoted for arthritis and rheumatism do not work, including supplements of selenium with vitamins A, C and E, and New Zealand Green-lipped mussel. Controversy also surrounds acupuncture effectiveness: Many trials comparing acupuncture with "sham" acupuncture in OA/RA treatment have shown no difference, although both groups improved. Research is now focussing on finding better control treatments, and on answering more pragmatic questions on the risks and benefits of acupuncture.

The objectives and time course of CAM treatments are frequently different from those of conventional treatments, so relatively few trials directly compare conventional and CAM treatments for arthritis and rheumatism. In one such trial (*Rheumatology*, July 2000), 172 patients with OA of the knee were randomly assigned to one month's treatment with an NSAID gel or a homoeopathic gel containing *Symphytum* (Comfrey), *Rhus toxicodendron* (Poison ivy) and *Ledum* (Marsh tea). Homoeopathic patients reported twice as much pain relief and fewer side effects as those receiving NSAID gel.

This is a challenging time for complementary, alternative and traditional medicine. There is a world-wide surge of interest, and, although research is in its infancy, a number of effective and safe treatments for common and intractable medical problems have already been discovered. §

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trition currently seems unlikely.

As for the future of CAM, one widespread view is that it will all but die out, as effective techniques gradually become accepted as part of mainstream medicine and ineffective techniques are gradually abandoned. If, in 20 years, we come to consider all medicine simply in terms of scientific evidence rather than the historically and politically contingent concepts of "conventional" and "complementary" medicine, this indeed would be progress.§

Rigorous Research, Sound Policy-- Key to Integration of CAM and Conventional Medicine

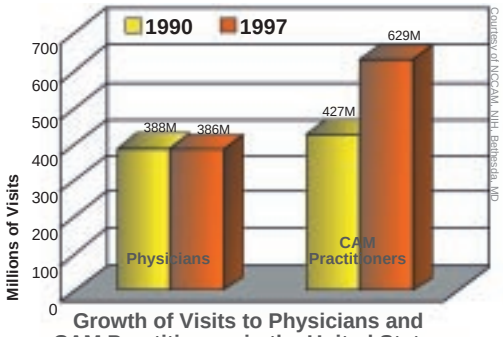
by Linda W. Engel, M.S., Special Assistant to the Director, and Stephen E. Straus, M.D., Director, National Center for Complementary and Alternative Medicine, National Institutes of Health, Bethesda, MD

Both an art and a science, medicine is an ever-evolving discipline. Biomedicine, the now-dominant and conventional basis for Western medicine, is being challenged by the popularity of ancient and venerable approaches offered as complementary and alternative medicine (CAM). In fact, as many as 42 percent of the American public, according to one recent estimate, are adopting CAM approaches. Between 1990 and 1997, the number of Americans using CAM increased by 38 percent, from 60 million to 83 million. (See related figure.) Indeed, the potential benefit of CAM therapies is great, but their expanded use in the absence of evidence that they are beneficial poses challenges for researchers and policy makers in the Western world.

Many countries are already responding to this challenge. Some European nations, notably Germany, provide broad access to CAM. In England, the House of Lords has just completed a yearlong comprehensive inquiry into the place of CAM in the British medical system (http://www.parliament.the-stationery-office.co.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm).

In the United States, CAM practices once considered unorthodox are increasingly competing to join the mainstream health care repertoire. Before President Nixon went to China in 1971, for example, and James Reston wrote his compelling memoir that same year, acupuncture was considered arcane. Today acupuncture is often prescribed to manage pain and other ailments, and is being studied for treatment of cocaine addiction. No doubt, further studies must pursue the validity of these and a multitude of other approaches.

In 1998, in recognition of both the potential of CAM modalities to expand the health care repertoire and the paucity of information regarding their safety and efficacy despite their widespread use, the U.S. Congress established the National Center for Complementary and Alternative Medicine (NCCAM) within the National Institutes of Health (NIH) with a budget of nearly $20 million (which today exceeds $68 million). NCCAM's purposes are the "conduct and support of basic and applied research (both intramural and extramural), research training, and dissemination of health information, and other programs with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic and prevention modalities, disciplines and systems." To proceed systematically, the center has developed its first five-year strategic plan, *Expanding Horizons of Healthcare* (http://nccam.nih.gov/strategic).



Growth of Visits to Physicians and CAM Practitioners in the United States

Rising visits to CAM practitioners have spurred scientific interest, and trials, including a $15m, six-year one on Gingko biloba (left).

Research Challenges

With clinical research as its centerpiece, NCCAM has initiated definitive Phase III clinical trials of CAM substances and modalities that appear from evidence-based reviews to be the most promising and important. In addition to several single-site Phase III trials, five multi-site Phase III trials are ongoing to test: St. John's wort to treat depression; acupuncture to treat osteoarthritis of the knee; glucosamine and chondroitin sulfate to alleviate osteoarthritis; shark cartilage to treat cancers of the lung, breast and colorectum; and *Gingko biloba* to prevent dementia.

In FY 1999, the University of Pittsburgh School of Medicine was awarded $15 million to coordinate the six-year multicenter study of the efficacy of *Ginkgo biloba* in preventing dementia in older individuals. This large study involving four clinical centers and almost 3,000 people will compare subjects who take *Ginkgo biloba* with a placebo group.

Many more widely used, promising therapies deserve definitive study, including milk thistle for chronic liver disease, Echinacea for respiratory viral infections, and melatonin for sleep disorders; however, a number of challenges must be overcome to ensure successful research outcomes. First, CAM must entice conventional researchers, such as neuroscientists, immunologists, endocrinologists, biochemists, and imagers, genomicists and physicists, to apply their extensive knowledge base and sophisticated technological tools to answer key questions pertaining to the field. In addition, motivated CAM practitioners, whose culture lacks a highly developed research infrastructure, must be trained to conduct research. There are also methodological barriers; the gold standard, double blind, placebo-controlled clinical trial is not the "one size that fits all" needed to test CAM therapies.

Policy Perspectives

CAM use also raises policy issues, especially: how best to enforce good manufacturing practices; how best to regulate and provide oversight of CAM products and devices; and how best to increase availability of reliable reagents to test complex herbal mixtures for the sake of assuring both public access and safety. In addition, while many agree in principle on the merits of an integrated health care delivery system, issues of cost-effectiveness, reimbursement for CAM treatments, education of young physicians and allied health professionals about CAM, and licensing and credentialing of CAM practitioners must be addressed before such a system can be fully implemented. Moreover, there is an emerging need for post-graduate training of conventional physicians so that they may understand and prescribe proven CAM approaches. The relative roles and responsibilities of multiple health care professionals also need to be defined so that these individuals may, as some have envisioned as globally beneficial, work as a team that merges CAM and conventional approaches into the practice of "integrative medicine."

While not in NCCAM's purview, these policy dilemma are being addressed through other channels. The legislation that established NCCAM also established the White House Commission for Complementary and Alternative Medicine Policy to develop a set of legislative and administrative recommendations to maximize the benefits of CAM for the general public. And the American Association of Medical Colleges and the Josiah Macy Foundation are deliberating issues surrounding medical education. However, policy decisions require sound scientific data. NCCAM-supported research promises to provide the evidentiary cornerstone on which to build an expanded health care system that incorporates the best of both validated CAM and contemporary medicine. §