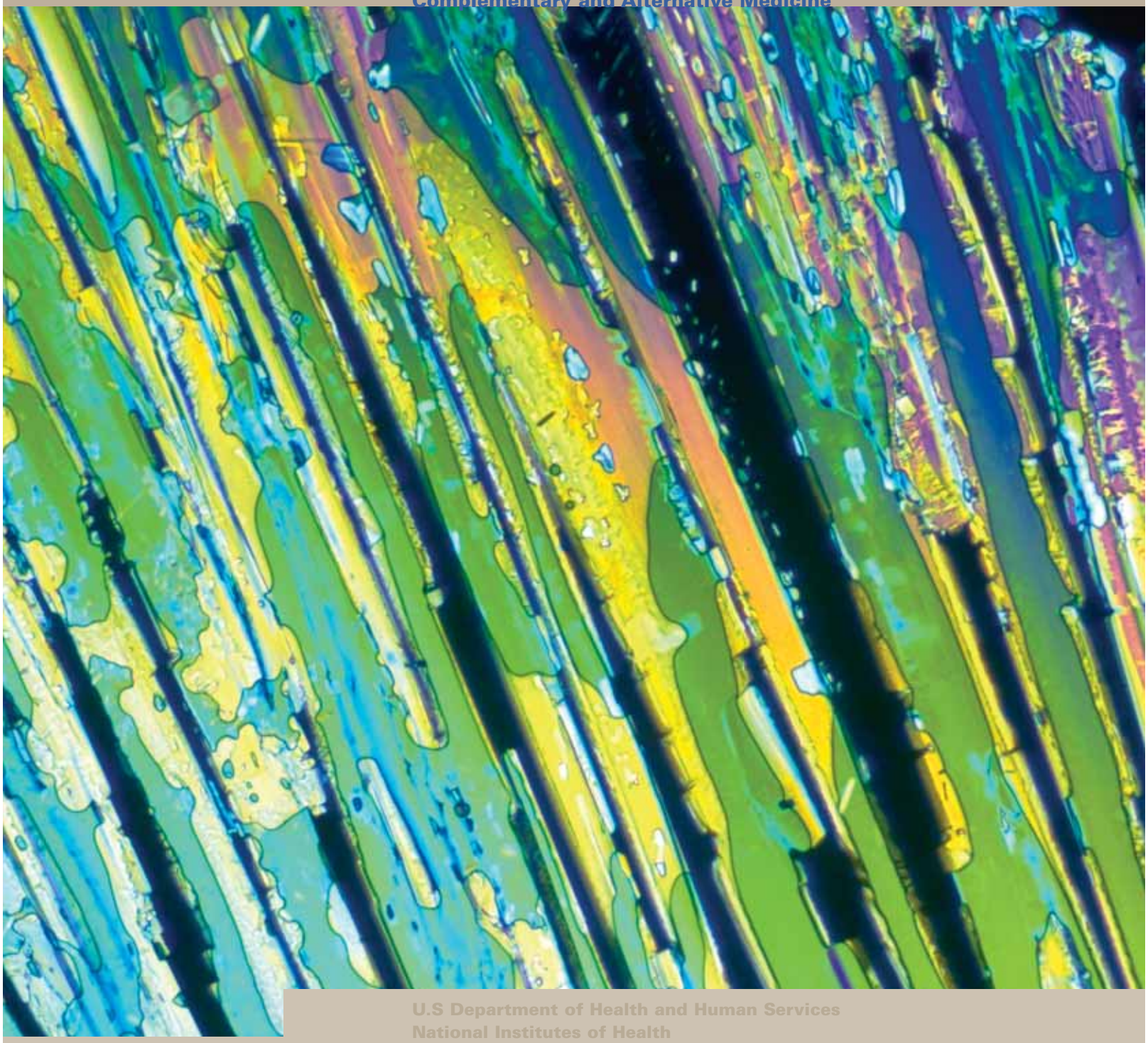
Expanding Horizons of Health Care

Strategic Plan 2005-2009

National Center for
Complementary and Alternative Medicine



U.S Department of Health and Human Services
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Many individuals and organizations contributed to the generation of this second strategic plan of the National Center for Complementary and Alternative Medicine (NCCAM). Their creative ideas, contributions, and critiques of successive drafts served as a constant stimulus to produce a document that articulates the directions the Center has charted for itself in the years ahead. We are deeply appreciative and grateful for their knowledge and advice and express our thanks to:

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- *The National Advisory Council for Complementary and Alternative Medicine and colleagues from other Government agencies within and beyond the National Institutes of Health*
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- *The hundreds of interested people and representatives of professional organizations who testified at regional strategic planning forums*
- *The many members of the public and professional communities who provided their comments on the draft plan posted on the NCCAM Web site*

Throughout, the leadership of NCCAM Director Stephen E. Straus served as inspiration and driving force.

The Strategic Plan Steering Committee:
Linda Engel, Chair
Margaret Chesney
Martin Goldrosen
Camille Hoover
Jane Kinsel
Richard Nahin
Chris Thomsen
Joan Wilentz, Writer

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A Message from the Director

Congress established the National Center for Complementary and Alternative Medicine at the National Institutes of Health to bring scientific rigor to studies of what we have come to call "cam." Indeed, this was a challenging mandate, given all that cam encompasses–from acupuncture to Ayurvedic medicine, Healing Touch to homeopathy, massage to meditation and more.

nccam accepted the challenge of building a comprehensive cam research enterprise aware that it was entering a field fraught with controversy. After 5 years we can feel proud that the Center has done much to assure cam critics and cheerleaders alike that our interests are their interests–and the public's interests–to establish the evidence that a cam practice works for the purposes that it was designed for and is safe to use, and if not, why not. We stated these principles firmly in the Center's first 5-year strategic plan, *Expanding Horizons of Healthcare*, published in September 2000. The title of the plan is an expression of our hope that bringing sound science to the study of cam would yield dividends–new therapies to benefit health, prevent disease, bring symptom relief, and enhance the quality of life for all people, young and old. But the document made clear that there would be no equivocation in the face of negative findings. The evidence would speak for itself, even more loudly than any number of anecdotes or advertisements.

At the outset, we built a significant communications program for the public and professional groups as an integral part of the Center's operations. This outreach effort, along with the all-important needs of building the research base, training research investigators, and facilitating integration–looking forward to a time when cam and conventional practitioners could work side-by-side in integrated health care programs–formed the four pillars of the Center's first strategic plan. Each of these four strategic areas specified goals to strive for and objectives to pursue.

Nearing the end of the first plan's timeframe, we initiated activities to inform and shape a second strategic plan, one that would take stock of all that happened in the start-up years and move on from there. As with the earlier plan, we sought advice from multiple audiences. We provided these groups with extensive background material on nccam's programs and budget, the results of several formal and informal evaluations, highlights of research and training over the years, and other data.

Part i of this document summarizes this background material to provide an overview of the Center's first 5 years. Importantly, it contains an appraisal of how nccam has measured up to the goals and objectives in the earlier plan, what lessons we learned, and what broad challenges remain.

This first section sets the stage for Part ii, the new strategic plan itself, designed to guide nccam through the second half of its first decade: 2005 to 2009–and beyond, given that many of the goals and objectives are far-reaching. At the same time we have set priorities in defining these goals. We want to limit investments to areas that appear the most promising, while remaining open to more high-risk ventures. In so doing, the plan aims to make the most prudent use of resources by a staff pledged to good governance. While we recognize there are practical limitations concerning what can be achieved in 5 years or more, there are no limits to the vision of the Center. The will to expand horizons of health care for the public, using advances from cam research remains foremost, as does the dedication to explore cam in the context of the most rigorous science.

Stephen E. Straus, m.d.
Director
National Center for Complementary and Alternative Medicine

Executive Summary

Introduction

In February 2004, the National Center for Complementary and Alternative Medicine (nccam) celebrated its fifth anniversary as 1 of 27 institutes and centers at the National Institutes of Health (nih). As stated in the law (Public Law 105-277) establishing nccam in fy 1999, its purposes are "the conduct and support of basic and applied research…research training, the 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."

With that legal mandate in place, nccam moved quickly to develop its first 5-year strategic plan for 2001–2005, *Expanding Horizons of Healthcare*. Guided by input from the public and from complementary and alternative medicine (cam) and conventional professional communities, the plan outlined a set of broad goals and objectives in four strategic areas: investing in research, training cam investigators, expanding outreach, and facilitating integration, while pledging a commitment to practice responsible stewardship.

As the fifth anniversary of the Center and the plan approached, nccam initiated steps to develop a new strategic plan. The process again entailed seeking advice from nccam's stakeholder groups, who were provided with background material and analyses of the first plan (described in Part i: "Five Years of History, Lessons & Challenges"). nccam's second 5-year strategic plan has used the lessons learned in meeting the challenges of the first plan to refine future directions–most importantly, to set priorities in all strategic areas–while affirming the original mission and vision statements.

Our Mission

We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training cam researchers, and disseminating authoritative information to the public and professional communities.

Our Vision

nccam will advance research to yield insights and tools derived from complementary and alternative medicine practices to benefit the health and well-being of the public, while enabling an informed public to reject ineffective or unsafe practices.

Priority Setting

nccam's intent in managing its portfolio in the future is to concentrate on efforts likely to yield the greatest impact on the health and well-being of people at every stage of life, using the following set of master health goals as important, but not exclusive, selection criteria:

- Enhance physical and mental health and wellness
- Manage pain and other symptoms, disabilities, and functional impairment
- Have a significant impact on a specific disease or disorder
- Prevent disease and empower individuals to take responsibility for their health
- Reduce selected health problems of specific populations

Toward those goals, we also see as high priority the need to increase research geared to elucidating mechanisms of action underlying CAM practices. Indeed, the plan states as a guiding principle that "When there is evidence that a specific cam practice works, it is a high priority to study why it works." This is in keeping with the importance of supplying consumers with the information they need to make informed decisions on their health care.

The Short and Long View

Our new plan presents priority goals and objectives in research, research training, outreach, and in the area of governance, indicating what we hope to accomplish in the short and long term. There is some overlap–objectives that are common to several areas–and our aims are very ambitious. nccam does not expect to achieve all its objectives in the next 5 years; some will be completed, while others will only have started. By establishing these aims as nccam's priorities, however, nccam is informing the public that these are the directions we have chosen to follow in the years ahead. These priorities will be widely publicized and regularly updated to reflect research advances, new needs, and opportunities. To facilitate nccam's efforts, the Center will again look to its partners at the nih and beyond for collaborations for the mutual benefit of shared resources and intellectual expertise in many areas of common interest. In addition, nccam is encouraging its stakeholders to aid the Center in building resources–tools, technologies, equipment, models, databases, and the like–as well as recruiting the diverse intellectual capital needed to conduct cam research.

Goals

The major investment of nccam's budget is the support and conduct of research, so Strategic Area 1, *Investing in Research*, represents the largest set of goals and objectives in the plan. Since its inception, nccam has funded more than 1,000 research projects at over 200 institutions, with grantees publishing widely in major peer-reviewed journals. Much of this research is clinically oriented, including studies of herbal/botanical products, acupuncture, Reiki, chiropractic manipulation, and a variety of mind-body practices. Depending on the cam approach selected for study, clinical research focuses on children, adults, or the elderly; men or women (including women in pregnancy); or members of racial or ethnic groups. Also of interest to nccam are the effects of cam practices on fertility and on the health of the fetus and mother during pregnancy.

The new plan specifies eight sets of research goals, organized by the four principal cam domains and whole medical systems, with an additional three sections on health services research, international health research, and ethical, legal, and social implications of cam research and integrated medicine. The latter is a newly articulated area of research investment for nccam. It is based on the realization that the integration of proven cam practices with mainstream medicine, while a desired outcome of cam research, is restrained by a number of ethical, legal, and social issues. As well, many of these same issues arise in the conduct of cam research itself.

The eight research sections are not represented equally in nccam's investment portfolio. The domain of biologically based practices has dominated nccam's research portfolio and will continue to do so in the future. High priority for nccam investment has also been assigned now to mind-body medicine. Not only do these two domains encompass a broad range of cam practices in widespread use, but at least for some practices, there is a considerable research base on which to build, trained investigators to do the work, and well-defined hypotheses that can be tested. Ultimately, nccam would like to see progress in all eight research sections, and it is with that aim in mind that each has been presented with its complement of goals and objectives.

A number of goals and objectives presented are a direct reflection of lessons learned over the past 5 years, such as the need for better quality control of the herbal/botanical products studied and the importance of conducting research to identify optimal doses and appropriate subject populations before investing in large clinical trials. Without these preliminary studies, there is a risk that clinical trials could prematurely conclude that a cam approach is ineffective.

Following is the list of the goals specified for the strategic areas of investing in research, research training, outreach, and governance in nccam's second strategic plan. The goals in the research area are organized according to the four cam domains and whole medical systems, with three additional areas on health services research, international health research, and ethical, legal, and social implications of cam research and integrated medicine. Note that goals stating a broad aim, such as "verify and define the composition of botanicals," are not intended to apply to the universe of all botanicals, but to selected products or practices of importance to cam research because of the need to explore safety and efficacy/benefits and risks to the public.

Mind-Body Medicine

Goals

1. Identify the common and specific features of widely used mind-body medicine practices.
2. Discover means of enhancing and accelerating the healing process beyond the effects provided by conventional medicine.
3. Explore the value of cam therapies to reduce the burden of stress-related chronic illnesses.
4. Explore the ability of cam therapies to enhance resilience, positive affect, and coping in order to improve health and well-being, prevent or slow disease progression, and treat diseases and disorders and their symptoms.

Biologically Based Practices

Goals

1. Verify and define the composition of botanicals.
2. Determine the mechanisms underlying the biological actions of selected cam products and diets.
3. Determine the pharmaceutical and pharmacokinetic properties of selected cam products.
4. Ensure the safety of selected cam products and practices.
5. Establish the efficacy of selected biologically based practices to maintain health, prevent disease, and treat conditions of public health importance.

Manipulative and Body-Based Practices

Goals

1. Elucidate mechanisms of action operative in manipulative and body-based practices.
2. Determine the disorders and states of wellness for which selected manipulative and body-based practices may offer meaningful benefits and specify the optimal circumstances under which the chosen manipulative and body-based practices are performed.
3. Study manipulative and body-based practices to determine their potential therapeutic or wellness benefits.
4. Determine the extent to which patient expectations prior to treatment and satisfaction following manipulative and body-based practices are related to objectively measured biological endpoints.

Energy Medicine

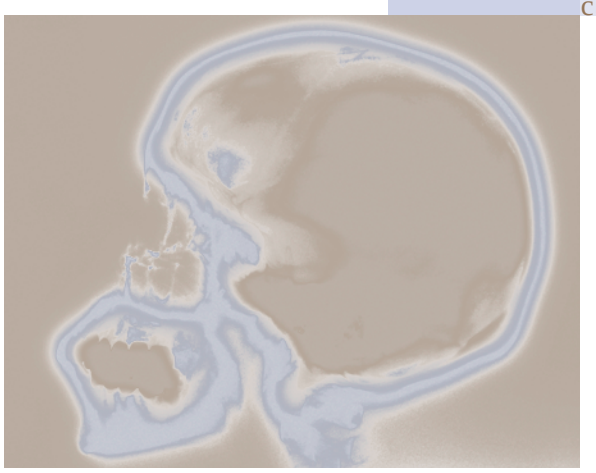
Goals

1. Apply in studies of energy medicine the same standards used in designing experiments in physics, chemistry, and other scientific disciplines.
2. Accelerate progress in understanding the source and biological effects of putative energy fields.
3. Enhance understanding of what transpires in the course of energy healer-patient interactions.

Whole Medical Systems

Goals

1. Acquire a richer understanding of cam whole medical systems and how they operate within their indigenous and dispersed settings.
2. Document the benefits of some cam whole medical system treatments for selected health conditions.
3. Elucidate mechanisms underlying successful multimodal treatments used in cam whole medical systems.



International Health Research

Goal

1. Advance understanding of traditional/indigenous medical systems through international collaborative studies.
2. Contribute to the preservation of irreplaceable and valuable traditional/indigenous cam knowledge and resources.
3. Enhance understanding of how safe and effective cam interventions are integrated with non-cam interventions abroad and in the United States.

Health Services Research

Goal

1. Determine how cam services affect the health care marketplace.
2. Enhance the design of cam clinical studies and trials by adding instruments to collect health services research data.
3. Explore models of organized health care delivery that integrate cam with conventional care.

Ethical, Legal, and Social Implications of CAM Research and Integrated Medicine

Goal

1. Enhance understanding of the social, cultural, and economic factors relating to the use of cam.
2. Describe the framework needed to enable the creation of integrated, multidisciplinary research teams.
3. Encourage the creation of integrated research environments and practice communities.
4. Define and address ethical and legal issues related to the conduct of cam clinical trials domestically and internationally.

Training CAM Investigators

nccam has succeeded in attracting many conventional investigators to cam research but not enough cam-trained professionals. The Center is completing an external evaluation of its research training and career development programs to suggest new, more effective approaches for enlisting cam professionals in research endeavors. The development of mutually beneficial partnerships between cam and conventional training institutions is one strategy that is showing promise.

Goals

1. Tailor a portfolio of research training programs reflective of the evolving needs of cam research.
2. Continue to foster a research culture and the necessary resources to enable both cam-trained and conventionally trained individuals to build successful careers in cam research.

Expanding Outreach

From the outset, nccam recognized the importance of communicating cam research findings to the public and practitioners to help them make better-informed choices. The Center operates an information clearinghouse, partners with the National Library of Medicine to maintain and update cam on PubMed (www.nlm.nih.gov/nccam/camonpubmed.html), and provides an award-winning Web site (www.nccam.nih.gov), rich in information and resources to serve the public, health care providers, and investigators.

Goals

1. Help the public and health care professionals make informed health care decisions about cam.
2. Enrich the pool of multidisciplinary cam researchers.

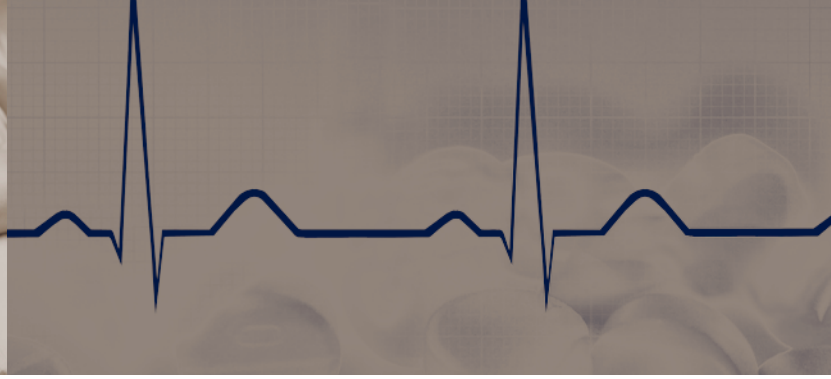
Advancing Our Organization

Goals

1. Promote organizational growth.
2. Encourage and empower nccam's staff.
3. Optimize effective management of the public's investment in cam research.

Five Years of History, Lessons & Challenges

The law (Public Law 105-277) creating the National Center for Complementary and Alternative Medicine in October 1998 (fy 1999) states that the Center's purposes are "the conduct and support of basic and applied research…research training, the 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." The Center was the successor to the National Institutes of Health Office of Alternative Medicine (oam), which had been established in 1991. The impetus for oam had come from congressional leaders who recognized the growing popularity of complementary and alternative medicine and wanted nih to bring its scientific expertise "to more adequately explore unconventional medical practices." oam held a series of workshops to develop baseline information about the field and was able to initiate research studies by collaborating with and providing funds to other components of nih. oam resources and authorities were limited, however, prompting Congress to create a *Center*. Elevation to Center status enabled nccam to take its place as 1 of now 27 relatively independent nih institutes and centers (ics), able to support an extramural research program through grantmaking authority and an intramural research program–which nih offices lack. The move was accompanied by a boost in the budget from $19.5 million for oam in fy 1998 to $50 million for nccam in fy 1999.



Early Days

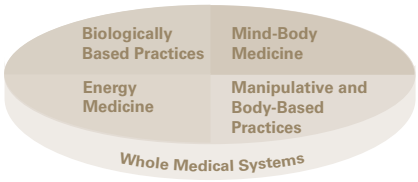
Recruitment immediately began for a Director for the new Center, resulting in the appointment of Stephen E. Straus, m.d., in October 1999. Dr. Straus is board-certified in internal medicine and infectious diseases and has had a distinguished career as an investigator at nih in the National Institute of Allergy and Infectious Diseases, most recently as Chief of its Laboratory of Clinical Investigation (see Appendix ii). With its new Director in place, nccam set about building an organizational structure and initiating strategic planning activities to guide Center activities.

Since the time of Dr. Straus's appointment, nccam staff has grown from 16 to over 90 individuals. The current structure and organization of the Center reflect a commitment to fulfill the mission, vision, goals, and objectives articulated in nccam's first 5-year strategic plan for 2001–2005, *Expanding Horizons of Healthcare*. The plan, produced with widespread input from public and professional communities, was designed in part to allay the fears of cam enthusiasts and skeptics by assuring them that the Center would neither condemn nor condone cam, but was dedicated to the highest standards of rigorous science. In this context it would pursue goals and objectives in four strategic areas: *Investing in Research, Training CAM Investigators, Expanding Outreach, and Facilitating Integration.* nccam's second 5-year strategic plan is both a response to how nccam has measured up in relation to the earlier plan and a statement of how the Center has refined its directions and priorities.

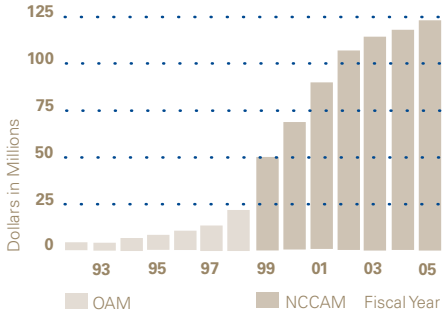
Defining the Scope of Research

nccam began by defining cam as practices that are unproven by science and not presently considered an integral part of conventional medicine (also referred to as biomedicine, or mainstream or allopathic medicine). The definition of cam acknowledges the dynamic nature of cam, implying that as cam practices are proven safe and effective, they will be integrated with mainstream health care. Within this definition, nccam groups cam practices into four domains:

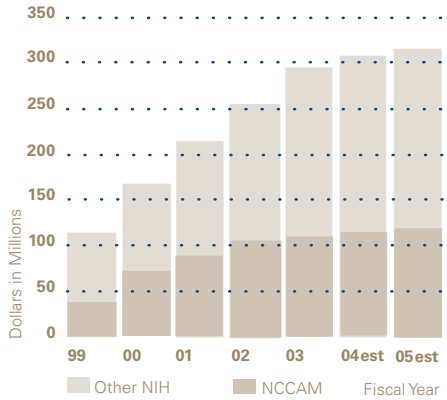
- Mind-body medicine, including meditation, yoga, and practices associated with spirituality
- Biologically based practices, largely the use of herbal or botanical products; selected compounds such as vitamins, minerals, and other molecules assumed to have therapeutic value; probiotics, strains of bacteria thought to be benign and to have healthful effects; and selected strict dietary regimens purported to improve health and well-being
- Manipulative and body-based practices, exemplified by chiropractic and osteopathic manipulation and massage
- Energy medicine, involving the use of verifiable energy fields, such as electromagnetic radiation and sound, as well as biofields presumed to convey healing energies from master practitioner to patient



1 Common cam Practices



2 nccam Appropriations History



3 nih and nccam Spending on cam

Health Condition	Dollars in Thousands
Cancer	12,788
Endocrine	12,269
Mental Health	11,511
Pain	10,286
Infectious Diseases	8,945
Cardiovascular	8,635
Digestive	6,952
Immunology/Allergy	5,804
Urologic	4,951
Diabetes	3,364
Lung	3,363
AIDS/HIV	2,800
Obesity	2,479
Dental/Oral	295

4 nccam Portfolio
Distribution by Health Condition, FY 2004
The conditions in the list are not mutually exclusive nor exhaustive of all categories of science NCCAM supports. For example, AIDS research is listed independently but is also included under infectious diseases.

In addition, nccam studies whole medical systems, such as Indian Ayurvedic medicine, traditional Chinese medicine (which includes acupuncture), and homeopathy. In the earlier plan, these systems constituted a fifth domain called "alternative medical systems." But since whole medical systems employ practices drawn from the four domains described above, it is more appropriate to place these systems in a class by themselves, as shown in figure 1. Conventional medicine is also a whole medical system employing practices within these domains, such as psychotherapy in mind-body medicine, pharmaceuticals in biologically based practices, physical therapy in manipulative and body-based practices, and radiation therapy in energy medicine.

Funding CAM Research

The Center's budget[1] continued to grow substantially after the transition from the Office of Alternative Medicine to Center status. The initial $50 million appropriation more than doubled to reach $104.6 million in fy 2002. Recent increases have been more modest, however, reflecting a general trend across nih. The nccam fy 2004 appropriation of $117.8 million is 3 percent over fy 2003 and 0.4 percent of the total nih appropriation of $27.8 billion for fy 2004 (figure 2).

In addition to nccam, other nih components also fund cam research, both independently and increasingly in partnership with nccam. Total nih funding for cam in fy 2004 is estimated at $305 million (figure 3). At present, nccam is collaborating with 19 other ics and the nih Office of the Director on studies of cam interventions for conditions either directly related to the missions of the other ics, such as cancer, mental illness, and heart disease, or that involve health problems that are trans-nih in nature, such as obesity, hiv/aids, and women's health.

Operating in a collaborative and cofunding mode is very much nih policy today, not only because of the perceived benefits of sharing resources and expertise across ics, but also in light of nih's Roadmap for Medical Research, meant to chart the course of medical research for the 21st century. The Roadmap, an initiative of nih Director Elias A. Zerhouni, m.d., puts great emphasis on building interdisciplinary teams to advance medical progress and on reengineering clinical research to develop new partnerships–themes that are already a part of nccam's approach.

The Research Portfolio

nccam's ability to build partnerships across nih reflects the broad purposes for which complementary and alternative medicine practices are used. Thus, the research projects that nccam supports cover a wide range, enabling the portfolio to be displayed across a number of important dimensions.

By Health Condition

Research on the use of cam in relation to cancer dominates nccam funding by categories of diseases or disorders. The next highest categories are endocrine, mental health and pain research, followed by investments targeting a number of other major health conditions (figure 4).

1 *There are slight variations in NCCAM budget figures in historic series and in various line items in the budget. These result from changes in accounting procedures or later revisions/corrections. They do not affect the overview of NCCAM's budget and the ways it is distributed as presented in this document.*

By CAM Domain and Whole Medical Systems

Interestingly, the proportion spent for each of the four cam domains has remained relatively stable since nccam's founding (figure 5). Studies of biologically based practices (mostly herbal medicines) and whole medical systems research still dominate the portfolio.

By Gender

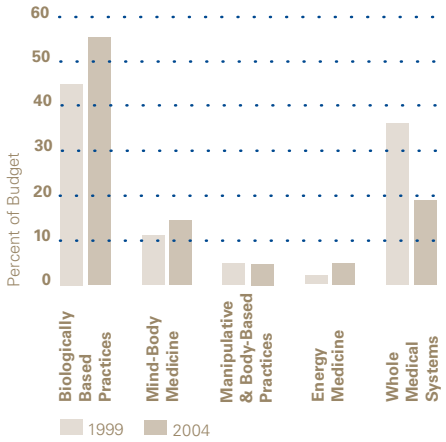
nccam research in relation to women's health has shown significant increases, from $14.8 million in fy 1999 to $29.3 million in fy 2004. The emphasis on women's health research correlates with their greater use of cam practices, particularly in middle age, as revealed by the Study of Women Across the Nation, which nccam cofunds with the National Institute on Aging and other ics. The outcomes of the Women's Health Initiative, which documented significant risks of prolonged hormone therapy, further stimulated nccam's investment in women's health. For example, the Center currently supports multiple studies looking at the potential of plant-based estrogens to relieve menopausal symptoms and for other health benefits.

By Vulnerable Population

nccam participates in the nih-wide initiative to reduce or eliminate health disparities among America's vulnerable populations, particularly racial and ethnic minorities. nccam is focusing on diseases like asthma, which are more prevalent in minorities, as well as studying why and how ethnic and racial minority populations use cam. Funding for health disparities research has risen from $7.8 million in fy 2002 to $12.8 million in fy 2004.

By Life Stage

Many cam therapies are used to relieve symptoms as well as cure or prevent age-related diseases–or at least prevent the progression of diseases such as arthritis, heart disease, cancer, and degenerative neurological diseases, including the dementias. nccam funding for aging-related cam studies has shown a steady climb from $3.1 million in fy 1999 to $36.6 million in fy 2004.

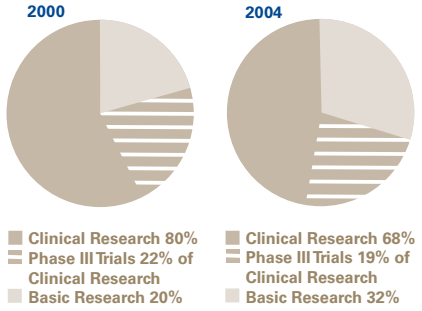


5 nccam Portfolio
Distribution by CAM Domain and Whole Medical Systems

The Balance of Basic and Clinical Research

nccam differs from other nih components in the relatively higher investment it makes in clinical research, a commitment the Center deemed essential in order to test the safety and efficacy of cam products and procedures already in use by many Americans. While clinical research accounts for about a third of funding across nih, nccam's clinical investments have been as high as 80 percent. But by putting increasing emphasis on basic research and preclinical studies, nccam's clinical investments are falling more in line with the norm at nih (figure 6).

At the same time, the number of patients enrolled in nccam-sponsored clinical trials has been growing from a mere handful in fy 1999 to nearly 11,000 in fy 2003. Over 50 percent of these participants were enrolled in phase iii trials, allowing the Center to reach enrollment totals to support rigorous statistical analysis. nccam's policy of pursuing collaborations with its nih partners has been a particularly critical factor enabling support of a number of these complex and costly trials (figure 7).



6 nccam Portfolio
Distribution by Type of Research

7 Collaborative Phase iii Clinical Trials

Therapy	Condition	Sponsor	Co-Sponsors
Acupuncture*	Osteoarthritis	NCCAM	NIAMS
St. John's Wort*	Major Depression	NCCAM	NIMH/ODS
Glucosamine-Chondroitin	Osteoarthritis	NCCAM	NIAMS
Ginkgo Biloba	Dementia	NCCAM	NIA/NHLBI/NINDS
Shark Cartilage	Lung Cancer	NCCAM	NCI
EDTA Chelation Therapy	Coronary Artery Disease	NCCAM	NHLBI
Saw Palmetto-African Plum	Benign Prostate Hypertrophy	NIDDK	NCCAM/ODS
St. John's Wort	Minor Depression	NIMH	NCCAM/ODS
Vitamin E	Down Syndrome	NICHD	NCCAM/NIA
Vitamin E-Selenium	Prostate Cancer	NCI	NCCAM

**Study completed*

Acronyms are listed in Appendix VI.

Prevention Priorities

A common reason people use cam is to preserve health and quality of life. Accordingly, nccam's research portfolio includes funding to prevent major causes of morbidity and mortality. For example, the phase iii trial of glucosamine is, in essence, a prevention trial intended not only to learn if glucosamine can relieve the pain and debility of degenerative arthritis of the knee, but also whether it can preserve joint cartilage and prevent disease progression. Similarly, the study of saw palmetto aims not only to improve urinary symptoms in men with enlarged prostates, but also to prevent the need for prostate surgery. And the edta (ethylene diamine tetra-acetic acid) chelation therapy trial aims to prevent heart attacks and death in people with preexisting heart disease.

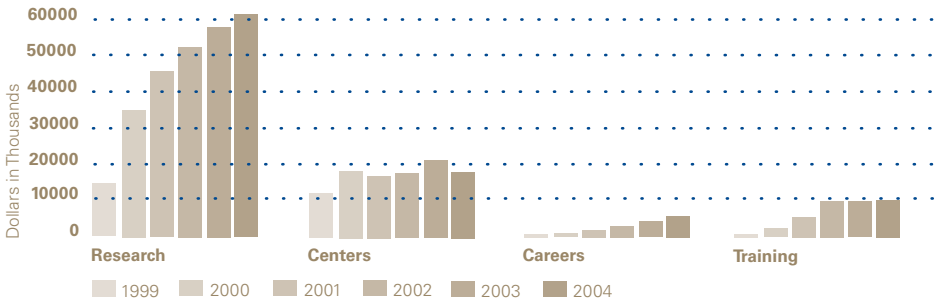
The Role of Intramural Research

Soon after achieving Center status, nccam initiated steps to develop an intramural research program where staff scientists could conduct research and research training on the nih campus–home to over 4,000 scientists conducting cutting-edge research. In this way nccam could capitalize on a resource-rich environment and cultivate cross-nih collaborations. Today, nccam's Division of Intramural Research, currently funded at 4 percent of the Center's budget, focuses on research related to endocrine system factors associated with stressors of aging, such as depression, cognitive decline, pain, frailty, and sleep disorders. The Division partners extensively with other scientists both within and beyond nih. At present, its Laboratory of Clinical Investigation has extensive collaborations with nih scientists in studies of cancer, depression, hypertension, diabetes, obesity, and arthritis. Plans call for additional emphasis on mind-body medicine, now a high-priority area of nccam research. Toward that end, nccam will seek an outstanding neuroscientist to lead the intramural research program. Future growth will entail clinically oriented research and studies to define the nature, mechanisms of action, safety, and efficacy of cam modalities that affect interactions of mind, body, and behavior.

2 *Visit http://nccam.nih.gov/research/types/index.htm for a description of types of NCCAM grants (award mechanisms).*

Research and Training Programs

nccam uses a broad array of nih funding methods[2] to support its extramural research program, including research centers, individual investigator-initiated research project grants, and research training and career development programs (figure 8). Research centers are employed at nih as a means of bringing multidisciplinary teams of investigators together to implement research projects on a common theme, train new investigators, and, in general, hope for the kind of synergy that can advance research when scientists with different perspectives share ideas. In its early years, nccam expanded a developing centers program that Congress had urged oam to establish, seeing the value of centers not only to advance science, but also as a means of giving visibility to cam research, attracting new investigators, and building research infrastructure.



8 nccam Portfolio

The distribution of investment by broad program during the last 5 years illustrates the growth that NCCAM achieved in individual research awards and in the research training and career development programs, while maintaining a commitment to research centers.

Note that centers funded as "program project grants" are classified as research project grants for official budgeting purposes, but they are counted here as centers. Grouping activities in this way allows the data to be presented in a more meaningful way for analysis.

The First Strategic Plan: Lessons Learned and Challenges Ahead

This overview of nccam's first 5 years would be remiss were it not to include an appraisal of how well the Center has met the goals and objectives of the first strategic plan–including the lessons learned and key remedies undertaken. What follows is a brief summary of how well nccam has measured up.

Investing in Research

Two of the four goals articulated in this area in the first strategic plan–create an nccam intramural research program and establish a global nccam research enterprise–have been achieved. As indicated earlier, nccam now has its own intramural program, and an Office of International Health Research was created to develop grant programs fostering international collaborative research and training.

The two other research goals in the plan were more general–stimulate the submission of high-quality applications by both cam and conventional investigators and expand the scope of the nccam extramural research portfolio and participation by research subjects. Substantial progress has been made toward both goals–as witness the fact that to date, the Center has funded more than 1,000 projects at over 200 institutions to advance understanding of diverse cam practices, and to determine, with unprecedented rigor, which among them may prove beneficial. nccam has also expanded opportunities for research through the creation of focused organizational units such as the Office of Special Populations and the Office of International Health Research. That nccam-supported scientists have been productive is indicated by their record of publication. Scientists among nccam's staff have made substantial contributions to the literature,[3] and since 1999, the number of cam papers published in scientific journals by nccam grantees has risen dramatically, from 55 in 1999 to more than 1,100 in 2004.[4] As an example, nccam grantees have contributed significantly to the literature in such high-impact journals as the *Proceedings of the National Academy of Sciences, New England Journal of Medicine, Journal of the American Medical Association, and Annals of Internal Medicine.* Table 1 summarizes a number of key research findings.

Clinical Research Issues

The path of cam research has not always been as smooth as the Center would have liked, however, particularly with regard to conducting clinical studies. Initially, nccam invested in large clinical trials to determine the safety and efficacy of popular cam practices–as Congress had urged. In the process, however, nccam encountered a series of problems, learned a number of important lessons, and developed approaches to resolve them.

To begin with, and to some extent continuing today, nccam found itself in the center of a debate concerning whether it is fair to apply accepted mainstream research methodologies to tests of complementary and alternative medicine, the argument being that such approaches force cam practices, many of which have been used since ancient times, to adhere to an unreasonably high standard of proof. nccam agrees that the gold standard of the double-blind, placebo-controlled clinical trial is neither appropriate nor feasible for all cam therapies, but it is also not an appropriate design for all conventional therapies. For example, the uses of surgical procedures or behavioral approaches such as psychotherapy are interventions that cannot easily be blinded. These are among issues that have been debated in numerous scholarly articles, along with discussions of the ethical criteria that should be applied in determining whether a proposed clinical trial should be conducted in the first place.[5] From both ethical and methodological perspectives, nccam believes firmly that cam research should not be privileged, but be subjected to the same ethical criteria and methodological standards as are applied in conventional research. While certain classes of interventions can be challenging to study–in both cam and conventional medicine–existing methodologies usually suffice to allow fair and credible, yet rigorous, tests of cam therapies.

3 *Visit http://nccam.nih.gov/research/intramural/bibliography.htm.*

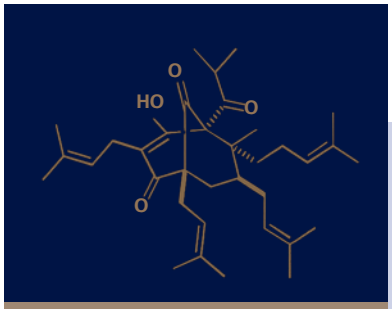
4 *Data from NCCAM Grantee Publications Database. Accessed at http://nccam.nih.gov/cgi-bin/bibliography.cgi, November 2004.*

5 *An example is Miller FG, Emanuel EJ, Rosenstein DL, Straus SE. Ethical issues concerning research in complementary and alternative medicine. Journal of the American Medical Association. 2004; 291(5):599-604.*

Table 1

Research Highlights

- An nccam, National Institute of Mental Health, and nih Office of Dietary Supplements study showed that St. John's wort was no more effective than placebo or sertraline for treatment of major depression of moderate severity; an ongoing three-center study is assessing its value in treating minor depression.[1]
- Multiple herbal preparations alter the expression and activity of the hepatic cyp450 enzymes that strongly influence the serum levels of many common drugs.[2,3,4,5,6]
- Formal analyses found that herbal products differ widely in content and may be contaminated by drugs or heavy metals.[7]
- An nccam, National Institute on Aging, and National Heart, Lung, and Blood Institute study of *Ginkgo biloba* is the largest randomized, placebo-controlled trial of an herbal medicine ever conducted and among the largest ever to seek a way to prevent age-related dementia.[8,9,10] While awaiting completion of this historic study, we have begun to define mechanisms of action of *Ginkgo biloba*.
- Analyses of products used to treat menopausal symptoms indicate that those containing red clover, hops, and chasteberry show significant estrogen activity. Questions of safety and efficacy remain.[11]
- Results from the longest, largest randomized controlled phase iii clinical trial of acupuncture ever conducted showed that when used as adjunctive treatment for treating osteoarthritis of the knee, acupuncture reduces pain and improves function significantly better than either of a pair of control interventions: sham acupuncture or participation in an educational control group following a self-help course. (The 570 participants in the nccam trial were allowed to continue taking their standard arthritis medications.)[12] Acupuncture is increasingly being integrated with mainstream methods of pain control. nccam's studies using brain imaging are providing some understanding of the neurobiological actions of traditional needling practices and further illuminating the nerve cells, pathways, and areas of the brain involved in the perception of pain.[13,14]
- nccam- and nih Office of Dietary Supplements-funded analyses, conducted by the Agency for Healthcare Research and Quality's rand Southern California Evidence-Based Practice Center, provided key data used by the u.s. Food and Drug Administration (fda) to ban the sale of ephedra for weight loss and enhanced athletic performance.
- A trial of a 15-week program of tai chi exercise, especially tailored to adults over 60, found that the traditional Chinese medicine regimen of exercise and meditation boosted immunity to shingles, as shown by a 50 percent increase in immune cells that suppress shingles in the exercise participants compared with controls. Shingles is a painful infection caused by reactivation of the chickenpox virus *(varicella zoster)*, which lies dormant in the nervous system after initial infection in childhood. Older adults are particularly vulnerable to shingles as a result of a decline in immune system function with aging. In addition, the exercise group also improved significantly in everyday physical activities, with those who had been most impaired showing the greatest improvements.[15]
- Use of an echinacea product to treat upper respiratory infections (uris) in children is not effective. In the nccam randomized, controlled clinical trial, 407 healthy 2- to- 11-year-olds were given either the echinacea product or a placebo at the onset of uri symptoms. No differences were observed between the two groups in the duration, severity, number of days with fever, and rate of adverse events, except for an increased incidence of rashes in children given echinacea.[16]



1 *Hypericum Depression Trial Study Group. Effect of Hypericum perforatum (St. John's wort) in major depressive disorder: a randomized controlled trial. Journal of the American Medical Association. 2003;290(11):1500-1504.*

2 *Markowitz J, Donovan J, DeVane CL, et al. Effect of St. John's wort on drug metabolism by induction of cytochrome P450 3A4 enzyme. Journal of the American Medical Association. 2003;290(11):1500-1504.*

3 *Markowitz JS, DeVane CL, Chavin KD, et al. Effects of garlic (Allium sativum L.) supplementation on cytochrome P450 2D6 and 3A4 activity in healthy volunteers. Clinical Pharmacology and Therapeutics. 2003;74(2):170-177.*

4 *Donovan JL, DeVane CL, Chavin KD, et al. Siberian ginseng (Eleutheroccus senticosus) Effects on CYP2D6 and CYP3A4 activity in normal volunteers. Drug Metabolism and Disposition: The Biological Fate of Chemicals. 2003;31(5):519-522.*

5 *Wadsworth T, Poonyagariyagorn H, Sullivan, E, et al. In vivo effect of PC-SPES on prostate growth and hepatic CYP3A expression in rats. The Journal of Pharmacology and Experimental Therapeutics. 2003;306(1):187-194.*

6 *Chang TKH, Chen J, Benetton SA. In vitro effect of standardized Ginseng extracts and individual ginsenosides on the catalytic activity of human CYP1A1, CYP1A2, and CYP1B1. Drug Metabolism and Disposition: The Biological Fate of Chemicals. 2002;30(4):378-384.*

7 *Harkey MR, Henderson GL, Gershwin ME, et al. Variability in commercial ginseng products: an analysis of 25 preparations. American Journal of Clinical Nutrition. 2001;73(6);1101-1106.*

8 *Luo Y, Smith J, Paramasivan V, et al. Inhibition of amyloid-beta aggregation and caspase-3 activation by the Ginkgo biloba extract EGb761. Proceedings of the National Academy of Science 2002;99(19):12197-12202.*

9 *Smith JJ, Burdick AJ, Golik P, et al. Anti-apoptotic properties of Ginkgo biloba extract EGb761 in differentiated PC12 cells. Cellular and Molecular Biology. 2002;48(6):699-707.*

10 *Wu Z, Smith J, Paramasivan V, et al. Ginkgo biloba extract EGb761 increases stress resistance and extends life span of Caenorhabditis elegans. Cellular and Molecular Biology. 2002;48(6):725-731.*

11 *Liu J, Burdette JE, Xu H, et al. Evaluation of extracts of plant extracts for the potential treatment of menopausal symptoms. Journal of Agricultural Chemistry. 2001; 49(5):2472-2479.*

12 *Berman BM, Lao L, Langenberg P, et al. Effectiveness of acupuncture as adjunctive therapy in osteoarthritis of the knee: a randomized, controlled trial. Annals of Internal Medicine. 2004;141(12).*

13 *Langevin HM, Churchill DL, Fox JR, et al. Biomechanical response to acupuncture needling in humans. Journal of Applied Physiology. 2001;91(6):2471-2478.*

14 *Langevin HM, Churchill DL, Cipolla MJ. Mechanical signaling through connective tissue: a mechanism for the therapeutic effect of acupuncture. FASEB Journal: Official Publication of the Federation of American Societies for Experimental Biology. 2001;15(12):2275-2282.*

15 *Irwin MR. Pike JL, Cole JC et al. Effects of a behavioral intervention, tai chi chich, on varicella zoster-virus specific immunity and health functioning in older adults. Psychosomatic Medicine. 2003;65(5):824-30.*

16 *Taylor JA, Weber W, Standish L, et al. Efficacy and safety of echinacea in treating upper respiratory infections in children: a randomized controlled trial. Journal of the American Medical Association. 2003;290:2824-2830.*

That said, nccam has also faced a number of problems with regard to the particular intervention to be tested in a cam clinical trial.

Determining Dose, Product, and Patient Population

First, it was assumed that traditional wisdom and data from prior studies dictated the right dose, product, and patient population.

Lessons Learned. Only through subsequent analysis did it become apparent that there is rarely a consensus among cam experts on the optimal product, dose, or intended users. Unfortunately, to make less-than-optimal choices with regard to any of these variables in a trial runs the risk of seeing the trial fail–and the cam therapy dismissed–not because of a lack of merit, but because the wrong dose was chosen for the wrong set of patients.

Key Remedy. To avoid these problems nccam resolved, with the advice of its Council members and consultants, to place greater emphasis on phase 1 trials (to test product safety and establish optimal dosage and route of administration) and phase ii trials (to test efficacy), regarding them as essential if nccam is to evaluate cam therapies under the best possible circumstances. Should the results of these early phase studies be promising and the decision to mount a phase iii trial be made, nccam will also ensure that experts with a range of viewpoints are included on the steering committee planning the trial, in order to reach consensus on what constitutes a fair test of the CAM therapy in question.

Purity and Manufacturing Issues

A second issue arose in connection with biologically based practices, such as herbal and botanical compounds, which were frequently the focus of nccam's initial clinical trials. These products, sold as dietary supplements, are subject to less stringent controls over purity and manufacturing processes under the guidelines of the Dietary Supplement Health and Education Act of 1994 than would be the case had the products gone through the level of substantial study and regulatory review required for the marketing of a drug.

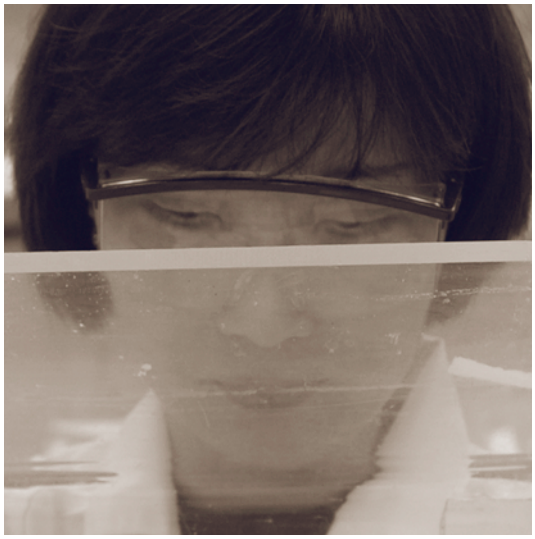
Lessons Learned. As a result, nccam found that off-the-shelf dietary supplement products could be contaminated with unwanted ingredients. As well, the concentration of active ingredients could vary widely.

Key Remedy. nccam now requires that cam products be characterized before they are studied and that only research-grade materials be used in clinical trials. To help investigators, nccam has begun to submit samples of the reagents they are using to contract facilities for independent testing. Plans are also under way to fund a resource to perform analyses appropriate to the products under study, including stability, bioavailability, pharmacokinetics, and drug interactions.

IRB Issues

Lastly, nccam experienced delays in implementing clinical trials due to the lengthy reviews of trial protocols. Before any federally funded clinical research project can begin, it must be approved by an Institutional Review Board (irb), a committee of local physicians, investigators, patient advocates, and others, charged with ensuring that the study's participants will be appropriately protected. irb members also perform oversight during the course of the conduct of the trial itself.

Lessons Learned. nccam found that irb members were sometimes unfamiliar with cam and uncomfortable with the body of background data, and so might opt to disapprove a proposed trial. irb members have also raised questions about the ethics of testing products where potential risks or benefits were unknown, or where products lack formal analyses of their composition, mode of action, and safety in human subjects.



Key Remedy. nccam created an Office of Clinical and Regulatory Affairs to perform oversight on all phases of clinical trial design, implementation, and analysis. In addition, nccam staff has met with fda officials to offer perspectives on the promulgation of guidelines on botanical investigational new drugs and with national leaders in irbs and bioethics to develop a framework to facilitate protocol review.

Research Center Issues

A research centers program was initiated by oam in 1994, and nccam inherited and began to build upon that portfolio of exploratory centers. By late 1999, more than half of nccam's extramural research budget was committed to centers focusing on conditions for which cam practices are frequently used, selected forms of cam, or the use of cam in relation to specific study populations. Accordingly, the themes included: addiction, aging and women's health, arthritis, botanicals, cancer, cardiovascular disease, chiropractic, craniofacial health, minority aging and cardiovascular disease, neurological disorders, and pediatrics.

This early emphasis on centers allowed nccam to cultivate research, resources, and new investigators at a time when nccam was newly established and just beginning to build its research program.

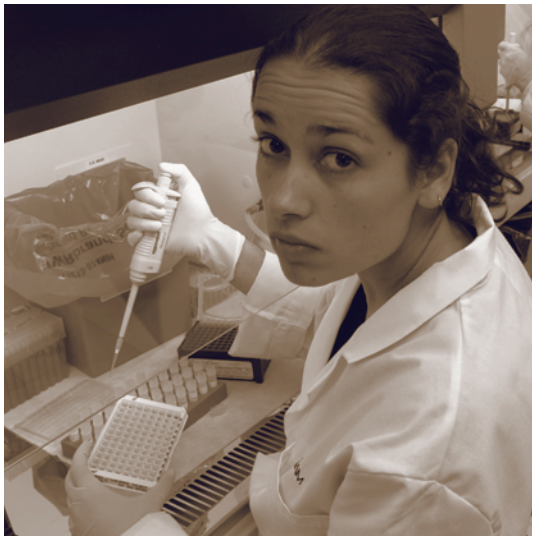
Lesson Learned. By 2002, it was clear that nccam's centers were achieving only a mixed record of scientific productivity.

Key Remedy. To address the issue, nccam convened an expert panel, which advised a more flexible approach to funding cam centers. nccam followed this advice and has begun to fund centers structured as program project grants for investigators with proven research records, exploratory centers that require collaboration between investigators at cam institutions and research-intensive universities, and planning grants for collaborative centers in which u.s. institutions are paired with a foreign cam institution. A second expert panel advised on the future of nccam's botanical research centers, recommending that the next generation of centers increasingly focus on the safety and efficacy of botanicals for human use.

Training CAM Investigators

When Congress established nccam, it authorized the Center to use the existing nih research training and career development award mechanisms to ensure that there would be an ample pool of both cam and conventional investigators to carry out nccam's research mission. nccam followed suit, and in addition, funded educational grants to cam and conventional schools to increase mutual knowledge and understanding. Again, nccam cast its net widely in efforts to recruit and retain new investigators. The Center also drew investigators into the field by offering loan-repayment programs and by opening cam research to conventional researchers through recruiting them to collaborate in clinical trials and other programs conducted at selected research centers. nccam's intramural research program has also played its part in funding fellowship programs through the nih visiting scientist program, intramural research training awards, and postbaccalaureate programs.

These efforts have been successful in increasing the numbers of conventional investigators engaged in cam research. While many of these grantees have long records of dedicated engagement in cam activities, few possess cam degrees. The majority hold traditional m.d., ph.d., or joint m.d.-ph.d. degrees. The Center has not been able to meet, as well as it wished, the goals set for enlisting cam-trained professionals in research efforts. Efforts to increase the number of underrepresented minorities in cam research have also been problematic.



Lessons Learned. In retrospect, it appears that the goal of building a cadre of cam professionals engaged in cam research may be a more long-term process than initially thought. Because the traditional focus of cam schools has been on education for practice–that is, to train students to be proficient in a particular cam system or practice, following time-honored traditions and precepts taught by experts–undertaking research training has required many cam institutions to adopt a wholly new approach. And not only does research training require courses and curricula, it also requires resources: successful investigators who can serve as role models, well-equipped laboratories and libraries, support structures, and personnel. Even as cam institutions demonstrate their interest in conducting cam research, the lack of materiel and mentors remains a daunting challenge. Much the same can be said about conventional settings, however. cam research remains somewhat novel and successful research training in cam requires access to the full range of institutional resources.

Key Remedy. With these observations in mind, nccam engaged a panel of experts to independently reflect on nccam's approach to cam research training and career development and how the Center might increase the impact of its investments. In particular, the panel was asked to consider issues such as how nccam can best target its research training resources and use the most effective approaches for preparing particular groups of researchers, such as cam practitioners and underrepresented minorities.

Expanding Outreach

The public law establishing nccam emphasized the importance of disseminating information on the safety and efficacy of cam products and practices. The two goals for outreach in the first strategic plan spoke to this mission: enhance nccam's capacity to provide information to consumers, practitioners, and investigators and establish an effective dialogue with cam stakeholders.

Early on, nccam leadership saw that it was vital to establish a robust Office of Communications and Public Liaison if nccam were to succeed in becoming recognized as *the* authoritative source of cam information in the United States. Beyond the Office, outreach responsibilities extend throughout the entire nccam organization. As a result, the Center's extensive communications enterprise has reached out to the public and professional audiences directly–through fact sheets, alerts and advisories of immediate import, quarterly newsletters, monthly updates, an information clearinghouse, the nccam Web site, chat rooms, lectures and presentations–and indirectly–through media contacts that have led to featured radio, tv, and print stories. Professional audiences (as well as the public) are further served by the listing of cam publications on PubMed, a listing of publications by nccam grantees on the nccam Web site, and nccam's presence and presentations at professional meetings. Many of these occasions are opportunities for dialogue. In addition, nccam meets regularly with stakeholder groups such as patient advocacy groups.

Lessons Learned. One of the challenges in outreach and communications is the relatively low public recognition of nih in general and nccam specifically. Its stakeholders are forced to sort through myriad and conflicting messages about cam. Some already have very strong feelings about cam, both positive and negative. nccam's role is to communicate objectively, providing the best, most accurate evidence-based information. Unfortunately, much of the research to support evidence-based information is inconclusive, nonexistent, not rigorous, or still under way. nccam is still learning how best to convey research findings that conflict with popular beliefs and marketing claims.

Key Remedy. By employing the same rigor in its public pronouncements as it does in the support and conduct of cam research and training, nccam has succeeded in gaining the trust of its disparate stakeholders. nccam is seeking partners among other Government and non-Government agencies to reach wider audiences and increase dialogues with constituents to keep alert to issues and concerns of the public as they occur.

Facilitating Integration

nccam has stated that it would "work to facilitate a more integrated practice of medicine" establishing two goals in this fourth strategic area: facilitate development of health education curricula that respect and incorporate insights and opportunities afforded by safe and effective cam and conventional practices and facilitate coupling of effective cam and conventional practices within a coordinated, interdisciplinary health care delivery system. Toward these goals nccam has awarded a number of education project grants to enrich cam-related curricula in conventional professional schools and has begun an initiative to strengthen research curricula in schools that train cam practitioners.

Lessons Learned. It is now evident that the ideal of a health care system in the United States in which integrated teams of practitioners draw upon both conventional and proven cam therapies in providing health care must be preceded by a careful examination and resolution of many ethical, legal, and social issues, especially ones that fall well beyond the purview of nih. Just as these issues have arisen in the conduct of cam research, they also arise in the context of the feasibility of integrating cam practices into the overall health care delivery system in the United States. Among the concerns are legal issues pertaining to the wide variation in state licensing and credentialing of cam practitioners, safety concerns about cam practices and products that are only loosely regulated or not regulated at all, and questions of insurance liability and third-party payers–all in the context of a changing social and cultural climate in which the public is receptive to therapies whose safety and efficacy are yet to be proven.

Key Remedy. In order to benefit from the nation's best thinking with regard to a number of questions that have arisen with regard to integration of complementary and alternative medicine, nccam, joined with 16 nih partners and the Agency for Healthcare Research and Quality (ahrq), engaged the Institute of Medicine of the National Academies in a comprehensive study. Accordingly, the Institute of Medicine charged a panel of experts to address a range of cam science, policy, and practice issues. They were asked to describe the use of cam therapies by the American public, providing a comprehensive overview–to the extent that the data are available–of the therapies in widespread use, the populations who use them, and how they are provided. They were also asked to identify the major scientific, policy, and practice issues related to cam research and the translation of validated therapies into conventional practice. Finally, the charge to the panel included the development of conceptual models or frameworks. These would serve to guide public- and private-sector decisionmaking as research and practice communities confront the challenges of conducting research on cam, translating research findings into practice, and addressing the distinct policy and practice barriers inherent in that translation.

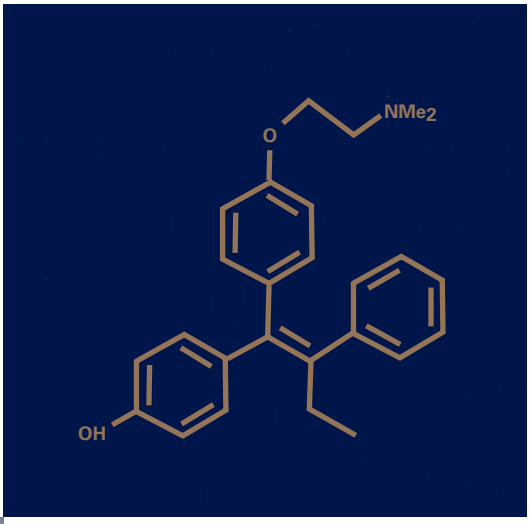
nccam considers facilitating the integration of cam with mainstream medicine to be a central and overarching goal for the Center–one that will depend in large part on the success of nccam's efforts in research, research training, and outreach. To further the goal, the new plan concludes the research strategic area with a new section on ethical, legal, and social implications of cam research and integrated medicine, highlighting the critical issues and proposing goals and objectives.

Broader Challenges

Defining CAM. At its outset, nccam deliberately chose an evolving definition of cam in terms of practices "unproven and not presently considered an integral part of conventional medicine." However, this poses a continual challenge in terms of determining the boundaries of what is–or is not–cam. While there is agreement that homeopathy is cam, there is an ongoing debate whether lifestyle changes that already are gaining broad acceptance constitute cam. Botanicals are cam; but what about their single most active ingredients? If nccam's horizons extend to what everyone will agree is cam, it could drain energy and resources into studies with more limited potential for success. To avoid the problem that would be created by too restrictive a definition of cam, nccam has deliberately focused on studies that have greater potential for success and benefit to public health, wherever the study might lie in relation to some definitions of cam. For example, in the current effort to combat obesity in America, nccam has subjected a popular low-carbohydrate diet to controlled trials, even though some have argued that this lifestyle change through diet should not be categorized as cam.

Resource Realities. nccam is able to support only a small fraction of all applications it receives. Indeed, this percentage is among the lowest of any nih component (17 percent in fy 2004). This can have serious consequences for cam research. Applicants may become discouraged and go elsewhere, and nccam will not be able to pursue all the opportunities that should arise from successful exploratory studies.

These constraints make priority setting even more essential. The timing of the current strategic planning process, with the aim of setting priorities within and among strategic areas, is therefore especially opportune.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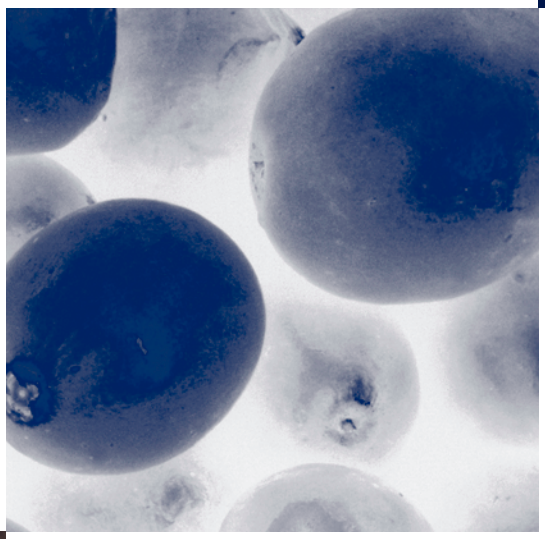
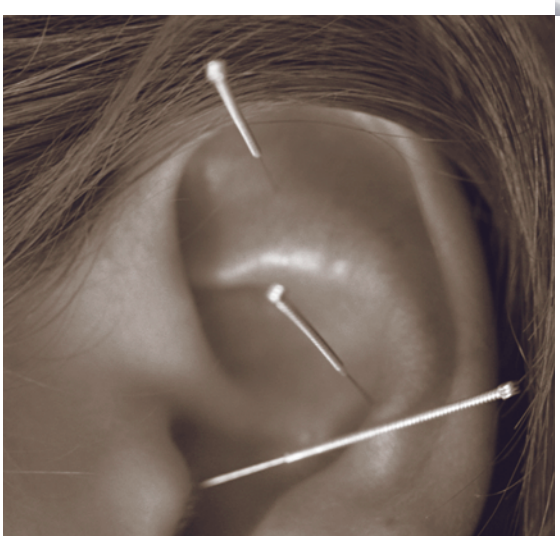
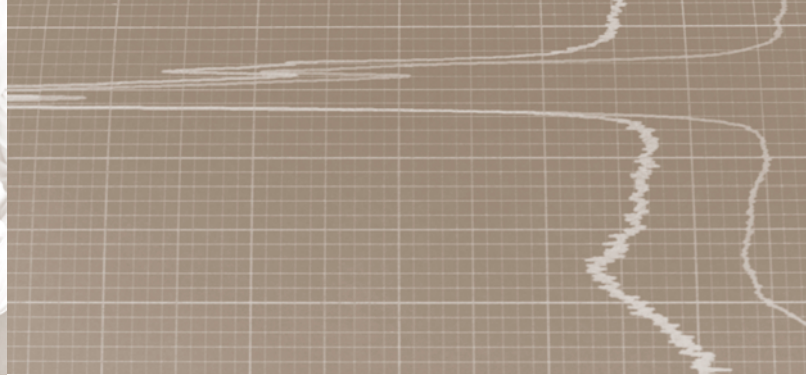




NCCAM Strategic Plan 2005–2009

Five years ago nccam assumed responsibilities as an nih Center with grantmaking authority, urged by Congress to advance the science of complementary and alternative medicine, train research investigators, and inform the public on matters of cam safety and efficacy. The Center embarked on this mission in the hope that nccam research would yield ways to enhance the health and well-being of the public. We stated our commitment toward that end in principles we again articulate in our mission and vision statements.



Our Mission

We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training cam researchers, and disseminating authoritative information to the public and professional communities.

nccam will strive to develop a cadre of both conventional and cam-trained professionals to conduct cam research and encourage their working together in multidisciplinary teams to facilitate cam research.

Our Vision

nccam will advance research to yield insights and tools derived from complementary and alternative medicine practices to benefit the health and well-being of the public, while enabling an informed public to reject ineffective or unsafe practices.

nccam is committed to studies to establish the safety and efficacy of particular cam practices, guided by the imperative to inform the public of what cam practices work and–alternatively–what practices do not work. It is especially important that nccam be recognized as an authoritative voice in advising the public, given the rise of consumer interest in health and a growing sense of autonomy: individuals increasingly are ready and willing to assume responsibility for their own health.

A New Agenda

Our first strategic plan elaborated on general approaches for investing in research, training cam investigators, expanding outreach, and facilitating integration, with ambitious goals and objectives–but without indicating explicitly what we would do. We wanted to keep our options open, encourage researchers to enter the field, and observe which research directions appeared to be the most fruitful. We also pledged our commitment to good governance, articulated in a section of the plan called practicing responsible stewardship.

Now, with 5 years of experience we are poised to refine our efforts. Our second strategic plan retains the research, training, and outreach areas of the first plan and adds a section under research: ethical, legal, and social implications of cam research and integrated medicine. Hindsight has taught us that all three of these original strategic areas are necessary to achieving an integrated practice of medicine, which would employ both cam and conventional health practitioners and draw upon proven cam and conventional therapies in the provision of health care. At present, however, there are complex ethical, legal, and social issues that must be addressed, not only to overcome barriers to the conduct of cam research, but also to enable the desired integration.

Our new agenda has benefited not only from the lessons we have learned, but also from the extensive advice provided by experts (listed in Appendix iv) and discussions we have held with staff and outside groups. (The process is described in Appendix iii.)

Priority Setting

The new plan is noteworthy in its emphasis on priority setting. Our advisory groups urged us, and we agree, that we need to manage our research portfolio in ways that are likely to yield the greatest impact on the health and well-being of the public at every stage of life. Accordingly, we have identified a set of master health goals as important, but not exclusive, criteria in setting priorities:

- Enhance physical and mental health and wellness
- Manage pain and other symptoms, disabilities, and functional impairment
- Have a significant impact on a specific disease or disorder
- Prevent disease and empower the public to take responsibility for their health
- Reduce selected health problems of specific populations

Toward those goals, we also see as high priority the need to increase basic research, and in particular, to work toward elucidating mechanisms of action underlying cam practices.

The Short and Long View

Our new plan presents priority goals and objectives in research, research training, outreach, and in the area of governance, indicating what we hope to accomplish in the short and long term. There is some overlap–objectives that are common to several areas–and our aims are very ambitious. We know we will not be able to achieve all our objectives in the next 5 years; rather, it is our hope to have completed a number of key objectives while initiating the others. Thus, by defining our priorities, we are telling ourselves–and the world–that these are the directions we have chosen to follow in the years ahead. We will publicize these priorities widely, aware that as research proceeds and new opportunities or needs emerge, we will need to refine and update them.

Operating Principles

The research that nccam conducts and supports overlaps the mission and goals of every other component of nih, enabling us to capitalize on these shared interests and leverage both intellectual and financial resources. Not only does this make good sense, but it also has become a high priority for nccam. Thus, the Center will continue to look to partnerships at nih in the future and work to build links beyond nih to other Government agencies and to nccam's many stakeholder groups.

Strategic Areas

nccam's major investment is the support and conduct of research, so Strategic Area 1, *Investing in Research*, represents the largest set of goals and objectives in the plan. Since its inception, nccam has funded more than 1,000 research projects at over 200 institutions, with grantees publishing widely in major peer-reviewed journals. Much of this research is clinically oriented, including studies of herbal/botanical products, acupuncture, Reiki, chiropractic manipulation, and a variety of mind-body practices. Depending on the cam approach selected for study, clinical research focuses on children, adults, or the elderly; men or women (including women in pregnancy); or members of racial or ethnic groups. Also of interest to nccam are the effects of cam practices on fertility and on the health of the fetus and mother during pregnancy.

NCCAM Has Identified Four Strategic Areas

1 Investing in Research
2 Training CAM Investigators
3 Expanding Outreach
4 Advancing Our Organization

The research area of the plan embodies eight sections organized according to the four principal cam domains and whole medical systems (see the descriptions on page 2 and also in the glossary, Appendix v) with three additional sections on health services research, international health research, and the ethical, legal, and social implications of cam research and integrated medicine. These eight research sections are not represented equally across the portfolio of investments. The domain of biologically based practices has dominated nccam's research portfolio and will continue to do so in the future. We now assign high priority to mind-body medicine, so that our investments in this area will grow substantively in the coming years. Not only do these two domains encompass a broad range of cam practices in widespread use, but also at least for some practices, there is a considerable research base on which to build, trained investigators to do the work, and well-defined hypotheses that can be tested. Ultimately nccam would like to see progress in all eight research areas, and it is with that aim in mind that each has been presented with its complement of goals and objectives.

Priority goals and objectives are also presented for Training cam Investigators, Expanding Outreach, and Advancing Our Organization. Advisors and staff contributed significantly to the development of the research agendas that follow. (See Appendix iv for the working group rosters and Appendix iii for a description of the planning process.)

Strategic Area 1

Investing in Research

Two guiding principles emerged in the course of generating the agenda for the cam research sections that follow. They reflect the importance of supplying consumers with the reliable information they need to make informed decisions on their health care.

- It is of paramount importance that investigators find out if a particular cam practice works.
- When there is evidence that a specific cam practice works, it is a high priority to study why it works. In some cases, mechanistic studies (why a practice works) may proceed in parallel with studies to determine if it does work (efficacy).

Building Resources. Also emergent as a dominant theme is the need to enrich the tools and technology supporting the science base for cam and to diversify the pool of investigators. The result is a set of generic resource requirements, listed below. The discrete technologies needed and the range of interdisciplinary scientific expertise relevant to each area in the plan are enumerated prior to the goals and objectives for that area.

While these resources are instrumental to the pursuit of particular goals, nccam is limited in the extent to which we ourselves can develop them. We therefore encourage our stakeholders and partners to make investments here as valuable contributions to the research enterprise:

- New or improved tools, methodologies, technologies, and models for the conduct of research
- Better metrics in basic and translational research as well as standardized protocols and outcome measures for clinical studies
- Databases of cam research studies and repositories of selected research materials accessible to qualified investigators elsewhere
- A scientific workforce that reflects the full range of expertise needed in cam research

Mind-Body Medicine

Of all cam domains, the most widely practiced is mind-body medicine,[6,7] which involves the interplay of mind, brain, other body systems, and behavior. Research in this domain encompasses mechanistic studies on how the mind and body communicate and interact, epidemiological studies of the key psychological characteristics and health of a given population, and clinical studies of how mind-body interactions affect health and disease. Included are studies of how negative emotional states may contribute to disease initiation and progression, and alternatively, how positive states may enhance well-being and mitigate the progression of disease. Examples of mind-body interventions that may be deemed cam are disciplines such as yoga; lifestyle behaviors such as tai chi exercise; meditative strategies such as mindfulness meditation; and psychological strategies such as guided imagery to manage stress. These interventions are employed for the prevention, treatment, and amelioration of disease as well as for the enhancement of health and well-being.

As with a variety of cam practices, many mind-body techniques are ancient. Some remain intrinsic to Eastern systems of healing. In the West, they formed a part of the Greek and Roman tradition of medicine, which survived at least through the 17th century. At that time, nascent discoveries in science, along with the separation of mind and body (and soul) espoused by Descartes, ushered in an era of dualism. In time, wave after wave of discovery would lead to a partitioning of the body, seeing it in terms of ever smaller units–systems, organs, cells, and finally molecules of dna–whose functioning in living organisms could be reduced to the fundamental laws of physics and chemistry. The success of this reductionist approach in biology has led to its dominance in Western medical science. Nevertheless, the very advances in technology that enabled descriptions of the body's discrete organs and systems and their activities began to reveal connections. Pioneers like Walter Cannon[8] and Hans Selye[9] pointed to the effects of stress on the body, for example, which are now more fully described in terms of reciprocal connections between the brain and body structures such as the pituitary and adrenal glands and the immune system.

Today, there is evidence that patients faced with chronic and even terminal illnesses–particularly conditions like heart disease and cancer–can learn and employ a variety of mind-body practices to achieve a level of symptom relief and a better quality of life, and in some cases, improvements in health outcomes. Importantly, the clinical reports of these effects are supported by a growing body of basic and clinical research, much of it in the neurosciences, psychoneuroimmunology, and behavioral medicine. These studies are aimed at elucidating the underlying mechanisms of action, using a variety of biochemical markers and physiological measures, as well as advances in brain imaging technology.

Such tools have been used to document the ability of people skilled in yoga or various forms of meditation and stress management approaches to lower heart rate and blood pressure,[10] and of tai chi to enhance immunity.[11] In addition, new methods to establish the magnitude of physiological functioning during the meditative state can assist in identifying the biological mechanisms of action of mind-body techniques.[12] Mindfulness meditation has also been shown to improve antibody response to a flu vaccine, with the magnitude of measured brain activity in the meditative state predictive of the level of immune response.[13] Innovative monitoring strategies have established that specific psychological characteristics like optimism and positive affect are linked to faster recovery following heart transplant surgery and to greater longevity.[14,15] The latter investigations have underscored the apparent value of resilience and positive emotions to health and well-being.

6 *Barnes PM, Powell-Griner E, McFann K, Nahin RL. Complementary and alternative medicine use among adults: United States, 2002. CDC Advance Data Report Number 343. 2004.*

7 *The following practices were listed under mind-body therapies: biofeedback, meditation, guided imagery, progressive relaxation, deep-breathing exercises, hypnosis, yoga, tai chi, qi gong, prayer (prayed for own health, others ever prayed for your health, participate in a prayer group, healing ritual for own health).*

8 *Cannon WB. The Wisdom of the Body. 2nd ed. Magnolia, MA: Peter Smith Publishing; 1978.*

9 *Selye H. The Stress of Life. 2nd ed. New York, NY: McGraw-Hill; 1978.*

10 *Schmidt T, Wijga A, Von Zur Muhlen A, et al. Changes in cardiovascular risk factors and hormones during a comprehensive residential three month kriya yoga training and vegetarian nutrition. Acta Physiologica Scandinavica. Supplementum. 1997;640:158-162.*

11 *Irwin MR, Pike JL, Cole JC. et al. Effects of a behavioral intervention, tai chi chih, on varicella-zoster virus specific immunity and health functioning in older adults. Psychosomatic Medicine. 2003; 65(5):824-830.*

Pain research has been useful in exploring the placebo effect. In one experiment volunteers were first subjected to a painful stimulus and then told that an "analgesic" cream (actually a placebo) would be applied to the skin at the pain site. When a pain stimulus of the same intensity as the original one was then applied to the skin, many subjects reported significantly less pain.[16]

Similar manipulations of expectations in patients taking prescription drugs for chronic diseases have shown that they, too, can be conditioned, so that following an initial dosage of a drug at typical therapeutic levels, a subsequent administration of a subtherapeutic dose or even a placebo can result in sizable physiological effects–such as the release of dopamine in the brains of Parkinson's disease patients.[17] These investigations have highlighted the potential value of expectation in the treatment of disease. Ways to harness this phenomenon to enhance the healing process should be considered, while preserving the integrity of the patient-provider interaction.

This growing body of physiological evidence is helping to shatter the long-held cultural belief in the West that mind and body are separate, especially since these studies are occurring at a time when the very leaders of reductionist biology are pointing to a need to move to an integrative approach in order to understand how complex systems work. Indeed, the potential is there for safe and effective mind-body practices to add to the repertoire of conventional medicine–particularly with respect to managing chronic illness and associated symptoms, enhancing resilience and coping to prevent illness, slow or reverse disease progression, and foster wellness. nccam aims to play a prominent role in this important area and is assigning it a high priority. We encourage researchers to pursue new knowledge and understanding of mind-body medicine, using all the high-tech tools and techniques available to elucidate the underlying mechanisms at the cellular, molecular, and genetic levels.

Resources Needed

- Rigorous measures of key individual differences and genetic variability in psychosocial and cultural characteristics, environmental context, emotional and psychological states, and spirituality
- Standardized protocols for brain imaging and validated and more reliable surrogate markers of brain states, correlated with brain imaging
- A research community that includes geneticists, immunologists, endocrinologists, neuroscientists, psychologists, social scientists, brain imaging specialists, cell biologists, physiologists, clinicians, and specialists in the diseases and modalities under study

Goal 1 Identify the common and specific features of widely used mind-body medicine practices.

Objectives

- Explore mind-body interventions such as relaxation, meditation, tai chi, and yoga looking for specific commonalities in the procedures and in associated changes in the brain and in emotional, psychological, and physiological measures insofar as these are related to positive health outcomes.
- Elucidate the neurological, endocrine, and immunological mechanisms that link the most efficacious features common to these modalities with meaningful clinical and physiological outcomes.
- Elucidate the emotional, behavioral, and psychological mechanisms responsible for linking the most efficacious features common to these modalities with meaningful clinical and physiological outcomes.
- Optimize the timing, components, duration, and level of various mind-body interventions to achieve health benefits.

12 *Lazar SW, Bush G, Gollub RL, et al. Functional brain mapping of the relaxation response and meditation. Neuroreport. 2000;11(7):1581-1585.*

13 *Davidson RJ, Kabat-Zinn J, Schumacher J, et al. Alterations in brain and immune function produced by mindfulness meditation. Psychosomatic Medicine. 2003;65(4):564-570.*

14 *Danner DD, Snowdon DA, Friesen WV. Positive emotions in early life and longevity: findings from the nun study. Journal of Personality and Social Psychology. 2001;80(5): 804-813.*

15 *Scheier MF, Matthews KA, Owens JF, et al. Optimism and rehospitalization after coronary artery bypass graft surgery. Archives of Internal Medicine. 1999;159(8):829-835.*

16 *Benedetti F, Arduino C, Amanzio M. Somatotopic activation of opioid systems by target-directed expectations of analgesia. Journal of Neuroscience. 1999;19(9):3639-3648.*

17 *de la Fuente-Fernández R, Ruth TJ, Sossi V, et al. Expectation and dopamine release: mechanism of the placebo effect in Parkinson's disease. Science. 2001;293 (5532);1164-1166.*

Goal 2 Discover means of enhancing and accelerating the healing process beyond the effects provided by conventional medicine.

Objectives

- Investigate the complementary use of mind-body interventions to enhance the efficacy of mainstream therapeutic interventions.
- Test interventions of the built environment (e.g., the use of light, music, color, architectural modifications) that complement the positive effects of conventional interventions on healing and recovery times, with the important additional aim of understanding how these environmental enhancements may accelerate the healing process, slow or reverse pathology, and promote wellness.
- Determine the nature of the mind-body phenomena underlying the placebo effect and characterize the regimen parameters as well as features of the health care provider and patient encounter that are associated with the placebo effect.

Goal 3 Explore the value of cam therapies to reduce the burden of stress-related chronic illnesses.

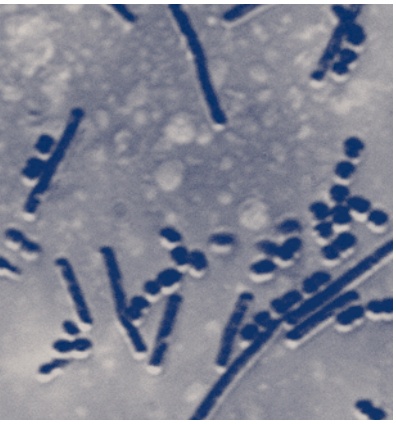
Objectives

- Study the effects of various cam therapies and their mechanisms of action on the state of the nervous, endocrine, and immune systems of individuals experiencing prolonged negative states (e.g., stress, depression, and anxiety).
- Determine, among the range of mind-body practices, which, if any, practices can be individualized to slow or reverse stress-related chronic diseases, such as gastrointestinal disorders, autoimmune diseases, asthma, hiv infection, cardiovascular disease, diabetes, and sleep disorders.

Goal 4 Explore the ability of cam therapies to enhance resilience, positive affect, and coping in order to improve health and well-being, prevent or slow disease progression, and treat diseases and disorders and their symptoms.

Objectives

- Explore commonalities and physiological correlates of personal characteristics, such as spirituality, resilience, altruism, and forgiveness that are associated with enhanced health and the amelioration of disease processes.
- Explore the effects of cam therapies on these characteristics and how they relate to health outcomes.
- Characterize the specific biological mechanisms that link these characteristics with improvements in wellness and in the prevention, mitigation, and treatment of diseases and disorders and their symptoms.



Biologically Based Practices

The use of substances from the natural world as a source of healing remedies–as well as a means of altering moods or mental states or simply to feel good–is as old as humanity. Indeed, there is evidence that our close kin among the primates also use materials from their natural environment in self-treatment. Today, what are called biologically based practices encompass the use of a wide range of products, including complex herbs and botanicals, animal extracts, selected bacteria used in probiotic formulations, whole diets reputed to be healthful, and functional foods that may provide a health benefit beyond basic nutrition, such as soy. Other biologically based practices include use of bioactive compounds (e.g., flavonoids, carotenoids, lutein) or of vitamins and minerals, fatty acids, and amino acids, which have been purified or synthesized as simpler compounds.

Botanical substances, most notably herbal products marketed as dietary supplements, are among the most popular cam therapies in the United States. Many people believe that because these products are "natural," or have been in use in some parts of the world for generations, they must be safe. In fact, few have been subject to large-scale studies of safety and efficacy. Indeed, because of their widespread use, the Center felt obliged to move quickly to multicenter phase iii clinical trials to gather data on the safety and efficacy of popular herbal remedies, basing the tests initially on the products commercially available and the dosages recommended for the intended population of consumers. As it turned out, conducting research to determine the true value of any of these products in terms of their intended purposes and audiences has proven challenging.

It is the reality of the regulations under which dietary supplements are marketed in the United States[18] that some products are used virtually unprocessed; and others are extracts, perhaps mixed with other chemicals, or in other ways represent varying degrees of complexity in the formulation. Given their intrinsic complexity and the added variability due to formulation, it is especially difficult to determine the nature of the active ingredient(s) of these products, establish dosage levels, determine mechanisms of action, and weigh risks against benefits. Until the fda finalizes its guidance on good manufacturing practices for dietary supplements, manufacturers are required only to follow the good manufacturing practices regulations for foods. Thus, many products on the market vary widely in the actual contents of the product on the label. Many even fail to meet standards of purity and could be contaminated or adulterated with prescription drugs or toxic substances. Further, even with well-characterized products and quality control production standards in place, it is evident that care must be taken to establish dosages and appropriate populations to avoid the risk of false-negative findings.

18 *Dietary Supplement Health and Education Act of 1994. Public Law 103-417. Accessed at http://www.fda.gov/opacom/laws/dshea.html on December 10, 2004.*

A Balanced Portfolio

Based on our experience, as well as what we have learned from listening to experts, nccam has determined a course to follow for future studies of biologically based products. Our goal is to achieve a balanced portfolio that will include research on products at all levels of complexity. We will implement an orderly procedure for progressing from smaller to larger studies and ultimately to multicenter controlled clinical trials. The cam product in question must be well characterized and meet reasonable standards of uniformity and purity before proceeding to phase i trials (to establish safety and dosage levels) and phase ii trials (for efficacy). Studies of simpler single-chemical products may progress through the phases of clinical studies more rapidly than investigations of complex botanical mixtures. Preclinical *in vitro* and animal studies will assume growing importance to define the products, their pharmacological properties, their biological targets, and mechanisms of action. In some cases, based on historical evidence, phase ii dose-ranging studies of products may be conducted in parallel with studies of their underlying mechanisms. Large phase iii randomized controlled clinical trials will only be undertaken following a consideration of formal preclinical and earlier phase clinical study results, the public health significance of the approach, and feasibility.

nccam's investment in a number of other biologically based practices, such as probiotics and popular cam diets, has been less substantial than for dietary supplements but remains important. The inherent complexity of diets, many of which are embedded in cultural approaches and individualized, makes their study a challenge. But here again, we will adhere to rigorous standards.

Resources Needed

- Resources to analyze and standardize products and ensure they are contaminant-free. When feasible, products should be standardized on more than one marker.
- Publicly available databases on product quality and of translated texts and ancient manuscripts.
- A repository of selected research reference materials (e.g., test compounds, serum, tissue) to be analyzed in the future when more sophisticated methods become available and active markers are identified.
- Access to resources to enable application of state-of-the-art technologies and approaches (e.g., metabolomics, proteomics, genomics, microarrays, mass spectrometry, nuclear magnetic resonance).
- Interdisciplinary teams of researchers with a broad range of relevant expertise that include biochemists, pharmacologists, pharmacognosists, toxicologists, cell and molecular biologists, geneticists, genomicists, nutritionists, and cam and conventional clinical researchers.

Goal 1 Verify and define the composition of botanicals.

Objectives
- Use state-of-the-art analytic tools and methods to identify key ingredients of selected products and their concentrations and verify that they meet acceptable analytical profile criteria.
- Use state-of-the-art analytic tools and methods to verify that products are not contaminated or adulterated.

Goal 2 Determine the mechanisms underlying the biological actions of selected cam products and diets.

Objectives
- Employ rigorous molecular, cellular, and biochemical techniques and approaches, including dna microarray, proteomic, and other cutting-edge approaches, in studies to determine mechanisms of action of cam products.
- Quantify biochemical and physiological changes induced by cam products and popular cam diets in animals and human subjects.
- Examine whether complex chemical mixtures such as herbal products or combinations of herbal products provide greater safety and benefits in preclinical and early phase studies than single herbs or single chemical constituents of herbs.
- Identify immunological and microflora changes associated with use of probiotics.

Goal 3 Determine the pharmaceutical and pharmacokinetic properties of selected cam products.

Objectives
- Study the stability, dissolution, absorption, and metabolism of cam products.
- Define potential contributions of pharmacogenomics to variability in pharmacokinetics and drug interactions with botanical products.

Goal 4 Ensure the safety of selected cam products and practices.

Objectives
- Measure safety and toxicity in all clinical studies by monitoring relevant parameters.
- Define the optimal dose and schedule for cam products through appropriate preclinical and early phase clinical studies. Exploit existing data sources for information relevant to adverse effects of biologically based practices.
- Where appropriate, use placebo controls to verify which, if any, adverse reactions could be attributable to the cam products and diets.
- Characterize interactions between herbal products and conventional drugs and biologicals.

Goal 5 Establish the efficacy of selected biologically based practices to maintain health, prevent disease, and treat conditions of public health importance.

Objectives
- Using well-validated qualitative and quantitative methods–including randomized, placebo-controlled trials of herbal/botanical products, other compounds, probiotics, and diets, for which there is sufficient evidence to select optimal regimens, appropriate study populations, and clinical endpoints–determine whether the given practice is effective and safe.

Manipulative and Body-Based Practices

Perhaps the best-known manipulative therapy in the United States is provided by Doctors of Chiropractic, who apply force to the joints of the spine (and other joints and muscles) as input to the nervous system to mediate beneficial changes to the body. According to the most recent national survey,[19] 7.5 percent of Americans had chiropractic treatment in 2002. Chiropractic adjustment, as well as massage (reported to have been used by 5 percent of the population in the same survey), osteopathic manipulation, and other manipulative and body-based practices are used primarily to relieve musculoskeletal problems–commonly low-back and neck pain. These literally hands-on treatments ("chiro" is from the Greek word for hand) are also used to manage other conditions–including other musculoskeletal pain conditions, asthma, stress, and mental health problems–and to enhance the function of other body systems. Common to these approaches to healing is the belief that reducing stresses and improving alignment of the skeleton and its associated soft tissues will, because of the interrelatedness of all the body parts, enhance the body's innate ability to heal.

Some forms of massage are ancient and were incorporated into the traditional medical systems of Egypt, China, India, and other countries. Other manipulative approaches are more recent. Chiropractic and osteopathic medical systems were developed in the United States during the 19th century. Still other body-based practices gained popularity in mid-to-late 20th century America, including several named for their founding practitioners: Alexander technique, Feldenkrais method, Trager bodywork, and rolfing. The techniques and application sites of these and other manipulation and massage practices vary widely. For example, craniosacral therapy works on the plates of the skull; reflexology uses foot and sometimes hand massage applied to "reflex zones." (See Appendix v for descriptions of these therapies.)

The evidence that these approaches are efficacious, as determined by well-designed, randomized controlled clinical trials is incomplete. Reports in the literature primarily relate to chiropractic manipulation. Collectively, reports of animal studies, case studies, and numerous clinical trials of chiropractic manipulation suggest that spinal manipulation can alter the activity of nearby nerve cells that sense body position and muscle movements. In turn, these alterations may ultimately lead to observed changes in circulating levels of various neurochemicals and proteins that affect nervous system function. Whether this cascade is responsible for the reported clinical efficacy of chiropractic manipulation for back and neck pain is unknown.

Studies of massage-like stimulation in animals indicate that the treatment can stimulate the nervous system release of morphine-like chemicals (opioids) for the relief of pain.[20] These studies clearly invite further investigation, replication, and expansion for clues as to what may be happening physiologically, and–along with phase i trials for safety and establishment of optimal regimens, and phase ii trials for efficacy–should precede and provide the rational basis for full-scale phase iii clinical trials.

Resources Needed

- Application of advanced imaging techniques, such as positron emission tomography (pet) and functional magnetic resonance imaging (fmri)
- Development and exploitation of better biomarkers and instruments to quantify disease symptoms and disability
- Development of *in vitro* and animal models to study manipulative techniques
- Use of biomechanical principles, tools, and techniques to better measure forces on the body's soft and hard tissues
- Expertise from other fields to work in interdisciplinary teams, including biomechanical and tissue engineers, computer scientists, pain neuroscientists, imaging experts, geneticists, neuroendocrinologists, neurophysiologists, immunologists, manipulative and body-based practitioners, physical therapists, muscle physiologists, rheumatologists, and orthopedists

19 *Barnes PM, Powell-Griner E, McFann K, Nahin RL. Complementary and alternative medicine use among adults: United States, 2002. CDC Advance Data Report Number 343. 2004.*

20 *Lund I, Yu LC, Uvnas-Moberg K, et al. Repeated massage-like stimulation induces long-term effect of nociception; contribution of oxytocinergic mechanisms. European Journal of Neuroscience. 2002;16(2):330-338.*

Goal 1 Elucidate mechanisms of action operative in manipulative and body-based practices.

Objectives

- Use the resources outlined to facilitate the design of research to determine the effects of manipulative and body-based practices. Begin with tissue studies and animal models and proceed to clinical research, using objective outcome measures (e.g., biomarkers of pain) as well as subjective measures (patient ratings).
- Conduct comparative studies of manipulative and body-based practices to determine commonalities and differences at the molecular, biomechanical, neurological, and clinical levels.
- Characterize the biomechanics of manipulative and manual procedures.

Goal 2 Determine the disorders and states of wellness for which selected manipulative and body-based practices may offer meaningful benefits and specify the optimal circumstances under which the chosen manipulative and body-based practices are performed.

Objectives

- Use the findings from studies of the biomechanical and biological features of manipulative and body-based practices, and the existing body of clinical evidence to formulate optimal regimens (i.e., number, intensity, duration, and frequency of treatments) for each approach found to offer therapeutic or wellness benefits.
- Use biomarkers and other tools to measure tissue strain and neurological, immunological, and endocrine responses to manipulative and body-based interventions to identify patient populations who would be most responsive to manipulative and body-based practices, noting diagnostic and genetic variability.

Goal 3 Study manipulative and body-based practices to determine their potential therapeutic or wellness benefits.

Objectives

- Conduct larger phase ii and phase iii trials if preliminary preclinical and small clinical studies of selected manipulative and body-based practices indicate significant benefits.
- Incorporate into large trials measures of the costs and benefits of manipulative and body-based approaches relative to more conventional practices.

Goal 4 Determine the extent to which patient expectations prior to treatment and satisfaction following manipulative and body-based practices are related to objectively measured biological endpoints.

Objective

- Compare outcomes of treatment on subjective reports (wellness, improved function) with validated physiological and psychosocial measures.

Energy Medicine

Energy medicine is based on the belief that all living things possess and emit energies, and can be affected by external energies. This is certainly true for a number of forms of energy–and verifiable by the various instruments that record electrocardiograms, electroencephalograms, and infrared (thermal) emissions. Indeed, a number of external and verifiable sources of energy that are in use now are known to aid diagnosis and treatment, including radiation therapy, magnetic resonance imaging, and cardiac pacemakers. Other external energies are reported to have therapeutic benefits, including electromagnetic fields and light therapy. However, the field of energy medicine also encompasses much more than these verifiable energies. There is an underlying belief in certain healing systems of a potent "life force" present in all living individuals, whose imbalance or attenuation leads to disease. This theory has led to the belief that vital energies can be reoriented or strengthened to promote or restore health. Examples of therapeutic modalities using life force energies are qi gong, Therapeutic Touch, Reiki, polarity, Healing Touch, and Johrei.

What makes the field of "energy medicine" problematic to study is the lack of measurability of these latter healing energies by the instruments and devices available in the physical sciences. Further, it is believed that such energies can operate both locally and nonlocally–over long distances in some cases. Thus, an individual deemed able to transmit energies to a patient–a healer–may not necessarily have to be in close proximity to the patient to restore health.

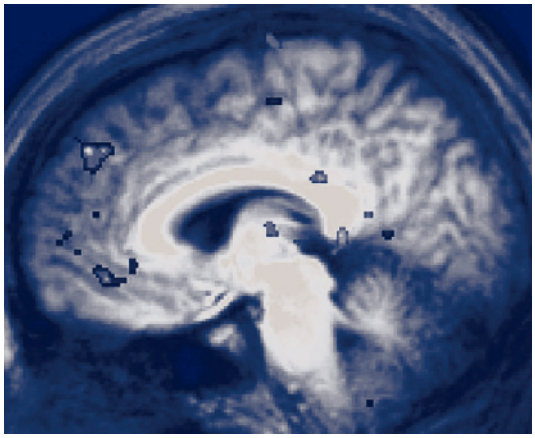
The use of the common term "energy medicine" to apply to the therapeutic use of both verifiable and nonverifiable forms of energy has contributed to some misunderstanding and lack of acceptance of the whole field by the scientific community. We will continue to use the traditional term "energy medicine" for this domain of cam, with the understanding that alternative terms such as "information medicine" or "biofield medicine" may be preferred by some practitioners to describe certain of its approaches.

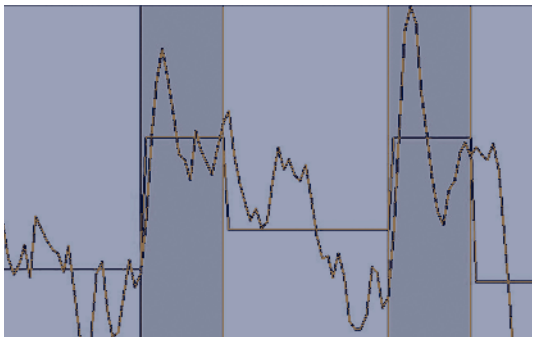
Resources Needed

The field of energy medicine research is in its infancy and is challenged by a major impediment to research: the inability to characterize–detect, describe, store, measure–the purported healing energies or life forces. Failure of science to characterize such energies does not, of course, confirm that they do not exist. Indeed, the history of physics provides examples of successive discoveries of sources of energy and their "taming"–through the development of mathematical models for the laws that govern them and through instrumentation to detect them. Accordingly, it is imperative to:

- Recruit multidisciplinary teams to investigate energy medicine: physicists, biophysicists, physical chemists, engineers, cell biologists, and both cam and non-cam clinicians and investigators

Goal	**1**	Apply in studies of energy medicine the same standards used in designing experiments in physics, chemistry, and other scientific disciplines.
Objectives	•	Develop preclinical models–cell, tissue, animal–to validate measuring devices and test the effects of verifiable energy sources.
	•	Ensure that the methodology of clinical studies of energy medicine using verifiable sources conforms to standard procedures/protocols used in other clinical studies.
Goal	**2**	Accelerate progress in understanding the source and biological effects of putative energy fields.
Objectives	•	Investigate currently available devices purported to detect and quantify energy fields.
	•	Study the biological effects of putative healing energy sources, with rigorous attention to regimen, dosages, controls, and objective outcome measures in cells, organ systems, and animals before undertaking clinical studies.
Goal	**3**	Enhance understanding of what transpires in the course of energy healer-patient interactions.
Objectives	•	Study characteristics of practitioners as clues to the nature of the putative healing energies they may be transmitting to a subject.
	•	Study the psychosocial aspects of healer-patient relationships to determine to what extent aspects of the placebo effect–expectation, belief, desire to please–contribute to outcomes.





Whole Medical Systems

Throughout the world many people rely for their health care on traditional or alternative whole medical systems that are based on precepts and principles distinctly different from the conventional (allopathic) system that is standard in the United States and other developed countries. For example, according to the World Health Organization,[21] up to 80 percent of people living in Africa use traditional whole medical systems, while in China between 30 and 50 percent of all medicines consumed are traditional herbal preparations.

Many of these alternative systems have ancient roots, schools of learning, and extensive scholarly documentation. Traditional Chinese medicine (tcm) in written form dates back to the third century b.c., and variations of it have spread to Korea, Southeast Asian countries, and Japan.[22] However, these and other Asian countries have incorporated their own traditional diagnostics, disease categories, and treatments, so as to constitute independent whole medical systems.

In tcm, health is seen to be a balance between two opposing forces: yin, the cold, slow, or passive principle;[23] and yang, the hot, excited, and active principle. Disease is the result of an imbalance between the forces that leads to the blocking of blood flow and "vital energy" (qi) along prescribed pathways in the body called meridians. Interventions, such as herbal medicines and acupuncture, in which needles are inserted and agitated at specified points along the meridians, are designed to restore the balance and flow of qi. (Qi gong, a cam procedure that uses movement, meditation, and breath control to enhance the flow of qi, is practiced by some religious groups in China, including Daoists and Buddhists; it overlaps with, and is considered a component of, secular tcm.[24])

Similarly, Indian Ayurvedic ("the science of life") medicine[25] is based on ancient Hindu concepts of the composition of human beings and involves practices of meditation and yoga that invoke body, mind, and spirit as well as the use of herbal preparations, cleansing procedures, and physical manipulations. Like traditional Chinese medicine, Ayurveda sees disease as a disturbance in the natural harmony of body, mind, and spirit; and interventions are designed to restore that harmony. Unani[26] and Siddha[27] represent two other distinct examples of ancient and established systems still used in the Indian subcontinent. Siddha is a Tamil language variant of Ayurveda with its own unique therapeutics, and Unani is derived from ancient Greco-Muslim medicine and is still commonly used by Indians and Pakistanis. The medicine of Tibet also represents a distinct Asian tradition that fuses aspects of Ayurvedic, Chinese, and Greco-Muslim medicine with indigenous Tibetan shamanism and practices.

Other traditional medical systems can be found among indigenous communities around the world. Often these indigenous systems are less well documented and the underlying principles are conveyed in narrative form from teacher to apprentice. There is rich ground for exploration of the health practices of these relatively isolated groups–especially gleaning information on their use of natural products to enhance or restore health–as well as for exploring the major alternative medical systems more extensively practiced in the world today.

Two examples of more recent cam medical systems have their roots in Germany. Homeopathy is a system of medicine developed by Samuel Hahnemann in the 18th century. It is based on treating disease with extremely high dilutions of agents that in larger amounts would cause symptoms similar to those associated with the disease being treated.[28] Using an elaborate set of questions and clues, homeopathic physicians pay close attention to the individual characteristics of their patients, including their mental and emotional states, to identify the appropriate treatment.

Naturopathy is a system of medicine based on the principle that the body has innate healing powers. It is derived from many sources but most directly from hydrotherapy (the use of water to treat illness). In parallel with Chinese and Indian medicine, remedies are chosen to restore the body's natural balance or harmony. Early naturopaths in Germany predominantly proposed water cures and herbal remedies. Naturopathy today is considerably more eclectic, adding homeopathic medicine, chiropractic manipulation, diet, massage, and other interventions, as long as they are deemed "natural," as opposed to, for example, potent drugs.

Conducting research on these systems is challenging for a number of reasons. In general they are not rooted in, nor have they adopted a scientific, evidence-based approach. More importantly, they are complex whole systems, which often employ individualized approaches that are tailored to the practitioner's perceived needs of each patient. Furthermore, they are often multimodal and may employ various combinations of medicines (plant-, animal-, or mineral-based), physical manipulation, exercise, diet, and assorted mind-body practices, along with modalities unique to the system, such as Chinese acupuncture and moxibustion, or techniques of breathing and meditation. Thus, research on whole medical systems overlaps all four domains in nccam's research portfolio. Finally, they are not static. Some cam whole medical systems, such as naturopathy, have incorporated conventional Western medical treatments, including drugs and vaccines. Thus, just as many Americans use cam to complement, rather than as an alternative to, mainstream medicine, many people using cam systems as their primary source for health care may find that their providers complement the traditional healing approaches with conventional interventions.

To date, research on practices that are prevalent in these whole medical systems has tended to single out particular interventions for study. This has led to some interesting and important findings. For example, studies of *Artemisia annua*, a traditional Chinese herb used to treat fevers, has led over the past two decades to the development of semisynthetic artemisinin drugs for malaria based on an extract of the herb.

Similarly, acupuncture has been studied outside the context of tcm. Popular interest and a growing Western research emphasis on acupuncture began in the early 1970s with preparation for President Nixon's visit to China. *New York Times* reporter James Reston's story of how he underwent emergency appendectomy surgery there recounts his relief of postsurgical pain and discomfort as a result of the acupuncture needling treatment. A growing body of evidence suggests that acupuncture treatment effects changes in the peripheral and/or central nervous system that influence pain pathways and perhaps regulatory control over temperature and other involuntary functions. Moreover, there is reasonable evidence that acupuncture ameliorates nausea, dental pain, and pain associated with osteoarthritis of the knee. There is more equivocal and contradictory evidence for efficacy in other types of pain, numbness, paralysis, movement disorders, and psychiatric conditions.

21 *World Health Organization. Traditional Medicine. World Health Organization Web site. Accessed at http://www.who.int/mediacentre/factsheets/fs134/en on December 10, 2004.*

22 *Unschuld PU. Medicine in China: A History of Ideas. Berkeley, CA: University of California Press; 1988.*

23 *Kaptchuk TJ. Acupuncture: theory, efficacy, and practice. Annals of Internal Medicine. 2002;136(5):374-383.*

24 *Miura K. The revival of qi: qigong in contemporary China. In: Kohn L. Taoist Meditation and Longevity Techniques. Ann Arbor, MI: University of Michigan Press; 1989:331-362.*

25 *Basham AL. The practice of medicine in ancient and medieval India. In: Leslie C., ed. Asian Medical Systems: A Comparative Study. Rev ed. Berkeley, CA: University of California Press; 1998.*

26 *Iaggi OP. Medicine in Ancient India. Delhi: Atama Tam; 1981.*

27 *Subramanian SV and Madhavan VR., eds. Siddha Medicine. Madras: International Institute of Tamil Studies; 1983.*

28 *Jonas WB, Kaptchuk TJ, Linde K. A critical overview of homeopathy. Annals of Internal Medicine. 2003;138(5):393-399.*

How To Study Whole Systems

While there have been other research studies exploring the efficacy of selected modalities of whole medical systems to treat health problems, such as the utility of yoga to treat insomnia or of practicing Chinese exercises (tai chi) to benefit Parkinson's disease, there has been a growing sense that whole medical systems merit study in their totality. Clearly this is not an easy matter. Conducting research on whole medical systems has been likened to comprehending an opera: it cannot be teased apart into this or that melodic line, chorus, plot progression, or climax, but must be seen as a whole, working synergistically together–orchestral harmonies, mythic plot, majestic chorus, heroic characters–interacting seamlessly to create an esthetically rich and intellectually satisfying musical experience. Applying the same sweeping approach to the study of whole medical systems means, at the very least, engaging members of a multidisciplinary team. It may also mean observing the operations of a traditional system in the field–in India or China or other countries where the system is the standard for health care.

Resources Needed

The study of whole systems requires multidisciplinary collaboration and methodological innovation involving scientists from a number of fields who can apply high-tech resources and analytic tools as well as those who have skills in the conduct of clinical trials. In addition, research on whole medical systems needs to enlist scholars from other fields, including cell and molecular biologists, geneticists, cam and conventional practitioners, behavioral and social scientists (including ethnographers and medical anthropologists), epidemiologists, and biostatisticians, systems biologists, and clinical trialists.

Goal 1 Acquire a richer understanding of cam whole medical systems and how they operate within their indigenous and dispersed settings.

Objective
- Characterize the ways in which patients and providers using cam whole medical systems define health and illness, and how they diagnose, treat, or prevent diseases. This will entail studying the basic precepts and philosophy underlying the system.

Goal 2 Document the benefits of some cam whole medical system treatments for selected health conditions.

Objectives
- Conduct outcome studies of multimodal treatments, using both subjective and objective outcome measures, and determine benefits, risks, and cost-effectiveness of the treatment or prevention strategies for selected disorders.
- Conduct randomized controlled clinical trials of multimodal therapies where there is evidence of efficacy from observational and earlier phase clinical studies.

Goal 3 Elucidate mechanisms underlying successful multimodal treatments used in cam whole medical systems.

Objective
- Undertake mechanistic studies of individual modalities used as parts of whole medical systems, and apply appropriate analyses to data from studies of multimodal treatments, to estimate the relative contributions each makes to the overall changes in health.

International Health Research

The Center's first strategic plan included a goal to "establish a global nccam research enterprise." This goal was further developed in a strategic planning document drawn up in 2002, *Expanding Global Horizons of Healthcare*.[29] The intent was to increase understanding of complementary and alternative medical systems throughout the world, study how certain practices may have evolved after introduction in the United States by successive waves of immigrants, and consider the potential of adopting those practices shown to be beneficial. Accordingly, a number of research and training programs were launched to foster international collaborative research, build research capacity at foreign sites, and enhance understanding of, and sensitivity to, the many ethical and social issues involved in conducting cam research across diverse cultures.

These remain laudable goals. But the intervening years have heightened awareness of the important role nccam can play in advancing global health. As with many u.s. Government agencies, this awareness has grown from an appreciation of the global impact of emerging and re-emerging diseases (e.g., hiv/aids, drug-resistant tuberculosis, and more recently, sars) and of the scientific and humanitarian efforts to combat them.

Other factors more specific to nccam's support of international efforts are also important. First, data from the World Health Organization and others indicate that the most serious threats to future generations worldwide will include diabetes, hypertension and vascular disease, and depression. These are conditions for which traditional medical practices and systems claim an important role. Second, there is considerable interest and political support in a number of foreign countries for promoting traditional medicine around the world. Much of this interest is driven by the perception of a potentially large market for cam. It is vital that an ethos of scientific rigor be established in the context of this global expansion, and nccam is ideally positioned to play a role in this regard. A third factor is the inexorable disappearance of potentially important indigenous knowledge or the extinction of natural sources of some traditional medicines. Finally, other countries have addressed the integration of cam with Western medicine in their own way. It is probable that there are important lessons to be learned from their successes or failures.

Accordingly, nccam's plans for international health research include study of key cam whole medical systems where they may best be observed–in their countries of origin–and determining the extent to which some of these systems and their discrete practices may add to the armamentarium of interventions to combat global health problems.

Resources Needed

- Increased global capacity for international cam research (e.g., modern facilities, well-trained researchers, and the ability to secure research funding)
- An international network of cam research institutions in developed and developing countries that can collaborate to share knowledge and resources, advance cam research methodology, and carry out specific studies

29 *Visit http://nccam.nih.gov/about/plans/oihr/index.htm.*

Goal	**1**	Advance understanding of traditional/indigenous medical systems through international collaborative studies.
Objectives	•	Increase global cam research and research capacity, emphasizing research and training collaborations that link established, funded research-intensive institutions with cam institutions in other countries.
	•	Enhance training in the conduct (design, methodology, implementation, analysis, and ethics) of cam basic and clinical research for investigators and practitioners at foreign study sites, and enhance knowledge of international cam practices by u.s. investigators and practitioners.
	•	Conduct basic and clinical studies of promising cam interventions for global health problems.
	•	Conduct qualitative and quantitative studies using interviews, survey instruments, and ethnographic/anthropological observations to probe how individuals (and families) in a given culture define and respond to illness and make decisions on treatment.
Goal	**2**	Contribute to the preservation of irreplaceable and valuable traditional/indigenous cam knowledge and resources.
Objectives	•	Foster international efforts to sustain biodiversity and protect the sources of natural products used in research, wherever it is conducted or wherever the interventions are used, through accepted principles of conservation and protection.
	•	Enhance efforts to characterize and protect indigenous and traditional knowledge.
	•	Foster fair sharing of the benefits of research through appropriate and creative approaches to the protection of intellectual property and benefit-sharing agreements.
Goal	**3**	Enhance understanding of how safe and effective cam interventions are integrated with non-cam interventions abroad and in the United States.
Objective	•	Study the ways in which other countries have successfully integrated Western practices with those of cam whole medical systems.

Health Services Research

With the rise of consumer interest in–and spending for–cam products and services over the past few decades, investigators have been intrigued to discover the who, what, and why of cam use. Such questions fall into the broad category of health services research, which explores the factors that influence people's access to and utilization of health care services; the nature, costs, and quality of that care; and ultimately the effects on their health and well-being. While surveys have been of varying size, scope, and methodology, they have been consistent in charting growth in the use of cam by the American public over the past decade. The most recent and comprehensive survey was one in which nccam collaborated with the National Center for Health Statistics of the Centers for Disease Control and Prevention in developing a questionnaire to supplement the 2002 National Health Interview Survey.[30]

The Who

The survey, based on interviews with over 31,000 adults, indicated that 36 percent of Americans had used some form of cam in the previous 12 months. The figure jumps to 62 percent if the definition of cam includes the use of prayer specifically for health.

The What

Of the 27 different cam therapies listed in the questionnaire, mind-body interventions[31] were the most commonly used. Leading cam interventions used included prayer for one's own health (43 percent), prayer by others for the respondent's health (24 percent), natural products (19 percent), deep breathing exercises (12 percent), meditation or chiropractic care (about 8 percent each), yoga (5 percent), and massage (5 percent). The five leading health problems for which respondents chose a cam therapy were a back pain or problem, head or chest colds, a neck pain or problem, joint pain or stiffness, and anxiety or depression.

And the Why

When asked why they used cam, the majority said they thought that it would help in combination with conventional care. About a quarter used cam because their regular health care provider had recommended it–while another fourth of users did so because they didn't think conventional treatments would help. Thirteen percent said that they used cam because they thought conventional medicine was too expensive. In fact, many cam therapies are paid for out-of-pocket. A 1997 study[32] estimated that between $36 billion and $47 billion was spent on cam therapies, of which somewhere between $12.2 billion and $19.6 billion represented out-of-pocket expenses paid to cam providers–fees that exceeded the sums the public paid out-of-pocket for all hospitalizations that year, and that amounted to half of what people paid out-of-pocket for regular physician services.

Gaps To Be Filled

Data from the survey released in May 2004 will continue to be mined to provide further "big picture" details of cam use. But there remain many health services research questions that will not be answered by large surveys and need to be addressed in specific studies. One would like to know, for example, for a proven cam intervention, whether it is truly cost-effective compared with conventional treatments; what degree of risk may be involved; and whether there are long-term benefits for quality of life and well-being. Government agencies, such as the Centers for Medicare and Medicaid Services and the Agency for Healthcare Research and Quality, have an interest in these questions as well, providing additional resources for health services research independently or in partnership with nccam. Should research findings favor the use of the cam intervention, they could be instrumental in policy changes leading to insurance coverage as well as encouraging steps to integrate the cam practice with mainstream medicine.

30 *Barnes PM, Powell-Griner E, McFann K, Nahin RL. Complementary and alternative medicine use among adults: United States, 2002. CDC Advance Data Report Number 343. 2004.*

31 *The following practices were listed under mind-body therapies: biofeedback, meditation, guided imagery, progressive relaxation, deep-breathing exercises, hypnosis, yoga, tai chi, qi gong, prayer (prayed for own health, others ever prayed for your health, participation in a prayer group, healing ritual for own health).*

32 *Eisenberg DM, Davis RB, Ettner SL, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. Journal of the American Medical Association. 1998;280(18):1569-1575.*

So far, rigorous cam health services research in any of these areas has been sparse and at times has yielded contradictory results. For example, retrospective studies suggested that chiropractic therapies could reduce referral and treatment costs for low-back pain, while prospective studies suggested that cam was an additional expense that did not substitute for conventional care.[33] cam health services research in other areas–detailing which procedures are covered by third-party payers and why,[34,35,36] establishing whether cam therapies truly enhance quality of life[37,38] learning in general what cam patients believe about cam[39.40.41.42] and if they are satisfied with treatments[43,44,45]–have all been subject to study, but variations in the methods and instruments used, as well as how cam and quality of life were defined in them, make it difficult to generalize and indeed dictate that future nccam-supported health services research should be specific with respect to service and disease. Different services for different conditions may have varying implications for quality, cost, patients and populations, access, and organization of care.

Resources Needed

- Improved survey instruments (along with their performance characteristics) to measure quality of life, patient satisfaction, health care quality, and value of delivery of effective care in health care organizations
- Interdisciplinary teams that include health economists, epidemiologists, computer scientists and statisticians, social and behavioral scientists, cam and conventional care providers, and clinical trialists

Goal 1 Determine how cam services affect the health care marketplace.

Objective
- Conduct studies to discover if proven cam services add to or replace the costs of conventional treatments; determine what effect integrating the cam service with conventional care has on health care costs, and how patient cost-sharing affects utilization of cam.

Goal 2 Enhance the design of cam clinical studies and trials by adding instruments to collect health services research data.

Objectives
- Add validated quality-of-life components to large clinical studies of selected cam therapies.
- Use a variety of qualitative and quantitative methods, including randomized clinical trials, as a vehicle for collecting data on costs, cost offsets, and cost effectiveness.
- Provide for careful monitoring and reporting of adverse effects within effectiveness trials.

Goal 3 Explore models of organized health care delivery that integrate cam with conventional care.

Objective
- Measure outcomes of integrated health care delivery models with respect to quality of care, cost, and access.

33 *White AR, Ernst, E. Economic analysis of complementary medicine: a systematic review. Complementary Therapies in Medicine. 2000;8(2):111-118.*

34 *Pelletier KR, Astin JA. Integration and reimbursement of complementary and alternative medicine by managed care and insurance providers: 2000 update and cohort analysis. Alternative Therapies in Health and Medicine. 2002;8(1):38-39, 42, 44.*

35 *Pelletier KR, Astin JA, Haskell WL. Current trends in the integration and reimbursement of complementary and alternative medicine by managed care organizations (MCOs) and insurance providers: 1998 update and cohort analysis. American Journal of Health Promotion. 1999;14(2):125-133.*

36 *Pelletier KR, Marie A, Krasner M, et al. Current trends in the integration and reimbursement of complementary and alternative medicine by managed care, insurance carriers, and hospital providers. American Journal of Health Promotion. 1997;12(2):112-122.*

37 *Jacobsen PB, Meade CD, Stein KD, et al. Efficacy and costs of two forms of stress management training for cancer patients undergoing chemotherapy. Journal of Clinical Oncology. 2002;20(12):2851-2862.*

38 *Targ EF, Levine EG. The efficacy of a mind-body-spirit group for women with breast cancer: a randomized controlled trial. General Hospital Psychiatry. 2002;24(4):238-248.*

39 *Henderson JW, Donatelle RJ. Complementary and alternative medicine use by women after completion of allopathic treatment for breast cancer. Alternative Therapies in Health and Medicine. 2004;10(1):52-57.*

40 *Williamson AT, Fletcher PC, Dawson KA. Complementary and alternative medicine: use in an older population. Journal of Gerontological Nursing. 2003;29(5):20-28.*

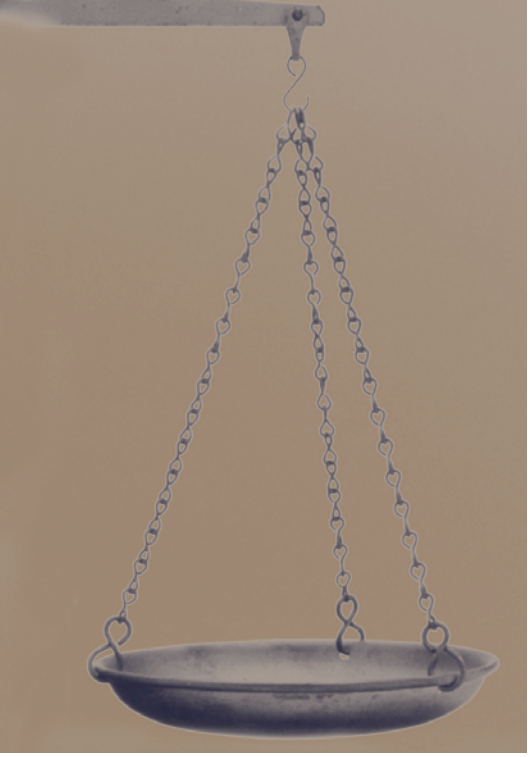
41 *Duggan J, Peterson WS, Schutz J, et al. Use of complementary and alternative therapies in HIV-infected patients. AIDS Patient Care and STDs. 2001;15(3):159-167.*

42 *Astin JA. Why patients use alternative medicine: results of a national study. Journal of the American Medical Association. 1998;279(19):1548-1553.*

43 *Rao JK, Mihaliak K, Kroenke K, et al. Use of complementary therapies for arthritis among patients of rheumatologists. Annals of Internal Medicine. 1999;131(6):409-416.*

44 *Coulter ID, Hurwitz EL, Adams AH, et al. Patients using chiropractors in North America: who are they, and why are they in chiropractic care? Spine. 2002;27(3):291-296.*

45 *Baldwin ML, Cote P, Frank JW, et al. Cost-effectiveness studies of medical and chiropractic care for occupational low back pain; a critical review of the literature. Spine Journal. 2001;1(2):138-147.*



Ethical, Legal, and Social Implications of CAM Research and Integrated Medicine

A number of social, legal, and ethical issues impede a smooth pathway to conducting cam research, training cam investigators, expanding outreach, and facilitating integration. Indeed, these concerns pose sufficient challenges that nccam is augmenting its research portfolio by the addition of a research agenda specifically addressing the ethical, legal, and social implications of cam research and integrated medicine. Examples of these issues have been raised elsewhere in the plan; they are briefly recapitulated here.

Social Issues

nccam was established after Americans began to spend billions of dollars every year for products and procedures marketed as natural and safe complements or alternatives to scientifically proven modalities–albeit with little research to support their use. nccam assumed the responsibility of doing studies needed to assure the public that the cam therapies they were using were acceptable, or else to alert them to potential harm. Communicating this information effectively, without unduly alarming or antagonizing the public, demands an understanding and sensitivity to social and cultural variables. Yet, despite the abundance of survey data on cam, information regarding who uses cam and for what purposes, when, and why, is incomplete, as is information on the knowledge and attitudes of mainstream practitioners, educators, and others in a position to effect social and policy changes. In this regard, it is of interest to note that surveys indicate that upwards of 70 percent of cam users do not disclose their use of cam therapies to their physicians.[46] This lack of communication, for whatever reason, can have serious consequences resulting from interactions of cam products and prescription drugs.

Studies of how and why the use of cam has come into such prominence today are also limited. In 19th century America, a variety of alternative practices flourished in competition with what constituted orthodox (and often toxic) medicine, especially in its pre-germ theory, preantiseptic heyday. In 1910, the publication of the Flexner report[47] changed all that, all but eliminating alternative schools and ushering in an era of professional medical education and practice in America based on an ever-evolving medical *science*–which came to dominate and continues to define mainstream medicine.

Subsequent gains in health and average lifespan in the 20th century from advances in medicine, as well as in sanitation and public health, have altered the patterns of health and disease in the United States. Growing numbers of mature adults in good health expect to live long and stay well. Many other Americans, in spite of suffering from chronic diseases not easily treated by conventional medicine, also want to lead a good life with relief of symptoms. If a conventional cure or help with symptoms is not at hand, many may opt for alternative approaches, seeking comfort in the kinds of compassionate care in the individualized, less technological settings characteristic of many cam therapies and therapists. Again the questions arise: Who chooses (or rejects) cam? Do parents choose cam for their children? Do people choose cam as a complement? Or as an alternative? For what reasons? What kinds of cam? For what conditions? Answering these questions will not only advance understanding of the dynamics of social change in the United States, but also point the way to more effective means of presenting scientific findings from nccam research to guide decisionmaking by the public and professional communities nccam serves.

46 *Eisenberg DM, Kessler RC, Van Rompay MI, et al. Perceptions about complementary therapies relative to conventional therapies among adults who use both: results from a national survey. Annals of Internal Medicine. 2001;135(5):344-351.*

47 *Flexner A. Medical Education in the United States and Canada. New York, NY: Carnegie Foundation for the Advancement of Teaching; 1910. Flexner's study accelerated reforms in the standards, organization, and curriculums of U.S. medical schools.*

Legal and Ethical Issues in CAM Practice

As the United States comes to grips with social and cultural changes that affect health care, a number of legal issues have emerged. cam practitioners and practices span a range of disciplines for which training, credentialing, and licensure vary from state to state, with few national credentialing and licensing bodies to determine qualifications for a particular cam practice. There is further variability with respect to access to and reimbursement for cam procedures by third-party payers. Until each of the professions has established clear standards of practice, it will be hard for many cam practitioners to be credentialed and reimbursed.

Legal and Ethical Issues in CAM Research

Nor will it be possible for cam practitioners, without credentialing, to participate as coinvestigators in nccam-supported research studies. This is one of several legal and ethical issues that have arisen with regard to conducting cam research and clinical trials, both domestically and internationally. Another issue, encountered in connection with biologically based practices, concerns products sold as dietary supplements. Under the Dietary Supplement Health and Education Act of 1994,[48] such products are subject to less stringent regulation than prescription drugs. This has led to problems in research with regard to their characterization, standardization, and stability, including the potential for contamination with harmful substances. To counter these problems, nccam has taken steps to assure quality control of products used in research.

cam clinical studies have also been subject to ethical questions and concerns that are impeding research. For example, irb members who may be unfamiliar with cam modalities may reject studies of products that lack formal analysis of their composition, mechanisms of action, and safety in humans, and question the ethical validity of testing any cam procedure in the absence of known benefits or risks. More generally, ethical issues have been raised about the design of cam clinical trials in terms of the adequacy of consent forms, use of placebo controls (here a major cam issue is the difficulty in devising "sham" procedures for modalities such as mind-body interventions and manipulative procedures), potential for bias, and so on. These issues have been addressed in an article by Miller et al.,[49] which concluded that cam clinical trials can and should be conducted with the same degree of rigor as conventional clinical trials.

Given the international scope of complementary and alternative medicine, nccam must also address ethical issues that have emerged when industrialized countries conduct clinical trials in the developing world (home to many cam whole medical systems). One concern focuses on what some believe to be an absolute requirement of uniform care–assuring that trial subjects in developing countries receive care equivalent to what would be received in the industrialized world. One could ask, for example, if it would be ethical for nccam to support a study in China of an unproven traditional Chinese medicine intervention that is widely accepted as "standard care" there, if there is an accepted mainstream standard of care in the United States.

nccam recognizes the importance of airing these collective ethical, legal, and social concerns and values the advice and guidance from experts. Toward that end, in 2002 nccam, joined by 16 nih institutes and ahrq, commissioned a study by the Institute of Medicine of the National Academies[50] to address research and policy issues with regard to the ethical, legal, and social implications of cam research and practice. The recommendations of the Institute of Medicine report will inform the Center's approaches to studies of the ethical, legal, and social implications of cam that affect both its study and the potential for cam approaches to be meaningfully integrated with mainstream health care practices in the United States.

48 *Public Law 103-417. Accessed at www.fda.gov/opacom/laws/dshea.html on December 10, 2004.*

49 *Miller FG, Emanuel EJ, Rosenstein DL, Straus SE. Ethical issues concerning research in complementary and alternative medicine. Journal of the American Medical Association. 2004;291(5):599-604.*

50 *Institute of Medicine. Complementary and Alternative Medicine in the United States. January 12, 2005.*

Resources Needed

- Guidelines to assist irbs in reviewing cam clinical trial proposals
- Data on the training, licensing, accrediting, and credentialing of cam practitioners state by state
- Strong professional guidelines for training and credentialing of cam practitioners, and clear and consistent laws defining their scope of practice
- Input and participation from a diverse group of scholars, including ethicists, clinical trial researchers, biostatisticians, cam and conventional researchers and practitioners, lawyers, insurers, representatives from other Government agencies, credentialing and licensing authorities, social and behavioral scientists, anthropologists, and cultural historians

Goal 1 Enhance understanding of the social, cultural, and economic factors relating to the use of cam.

Objectives

- Use well-validated qualitative and quantitative social science instruments for assessing knowledge, attitudes, and beliefs held by the public and cam and conventional practitioners with respect to the use of cam products and practices.
- Determine whether and how conventional practitioners introduce new cam interventions into their practices, and examine the variables that affect their decisions.
- Investigate how the knowledge, attitudes, and beliefs of consumers and health care providers (cam and conventional) affect the nature, cost, and outcomes of health care services in the United States.
- Develop a consensus definition of cam for use in the design of survey instruments to enable comparisons of data among individual surveys.

Goal 2 Describe the framework needed to enable the creation of integrated, multidisciplinary research teams.

Objectives

- Study historical models to learn how academic health care and practice communities successfully integrated new disciplines such as psychology, social work, and other health professions into the research and health care delivery system.
- Assess the barriers that prevent cam and conventional practitioners from working together in practice.

Goal 3 Encourage the creation of integrated research environments and practice communities.

Objectives

- Identify the requirements needed to create and sustain academic medical institutions committed to integrated research, using the experience of institutions that have successfully forged multidisciplinary teams of researchers and allied health professionals.
- Study how allied health professionals achieved credibility and acceptance as meritorious researchers and practitioners among their peers, and how institutions subsequently incorporated these members into multidisciplinary teams.
- Use the knowledge obtained from studies of barriers to integration, as well as features of successful models, to develop demonstration projects of integration.

Goal 4 Define and address ethical and legal issues related to the conduct of cam clinical trials domestically and internationally.

Objectives

- Examine ethical issues in the conduct of research in settings that rely heavily on traditional, indigenous health practices.
- Develop model designs and protocols adhering to the highest standards of ethical criteria for cam clinical trials conducted in the United States or abroad. Identify barriers that impede irb approval of cam clinical trials.

Strategic Area 2

Training CAM Investigators

The focus of Strategic Area 2 in nccam's first strategic plan was on research training, with the goal of increasing the number, quality, and diversity of cam investigators–both conventional and cam-trained professionals–able to conduct cam research. Mindful of the diversity of the individuals attracted to cam research, nccam chose to implement a variety of research training opportunities at predoctoral, postdoctoral, and faculty levels, through both individual and institutional awards. nccam also committed to a research training component when it established its intramural research program.

Five years' experience has yielded some successes: as nccam has grown, so too has the pool of established, conventional researchers–m.d., ph.d., and m.d.-ph.d.–who were drawn to and now conduct basic and clinical cam research. At the same time, students, postdoctoral fellows, and junior faculty have received training in cam research at sites around the country and in nccam's intramural laboratories. nccam's research training and career development programs have attracted both cam practitioners and those from conventional backgrounds.

Still, cam research could benefit from a more diverse workforce: relatively few of nccam's investigators hold cam degrees or are from racial and ethnic groups underrepresented in medical research. Currently, nccam is striving to foster the long-term success of cam practitioners undergoing research training and to improve recruiting of underrepresented minorities to cam research.

These are among the issues addressed by a panel of experts convened to conduct a formal review of nccam's training and career development programs as part of the Center's ongoing evaluation activities. Their full report was released in early 2005.[51] But because the evaluation process was coincident with plans to develop the second strategic plan, the panel of reviewers joined with the other experts convened into working groups to draft goals and priority recommendations for the Center in the next 5 years, and many of their findings and recommendations are included here.

Resources Needed

The absence of an established research infrastructure and of an adequate supply of mentors–and in some sites, the lack of an institutional culture recognizing the value and rewards of cam research–are currently leading barriers to developing a strong cadre of cam-trained investigators. Just as in other fields of science, adequate resources are a prerequisite to successful research training in cam, whether it takes place in a cam or conventional institution.

51 *NCCAM. Research Training and Career Development Programs: An Early Assessment. January 2005 nccam.nih.gov/training/assessment.htm*

Goal 1 Tailor a portfolio of research training programs reflective of the evolving needs of cam research.

Objectives

- Offer research training and career development opportunities for those from both cam and conventional backgrounds and encourage skilled investigators to enter the field of cam research.
- Provide research training opportunities for individuals ranging in experience from predoctoral students to junior faculty, maintaining an emphasis on training at the postdoctoral level and beyond.
- Invest in research training and career development in cam-specific areas that other nih institutes and centers are unlikely to support, as well as in conventional areas that are particularly relevant to cam research.

Goal 2 Continue to foster a research culture and the necessary resources to enable both cam-trained and conventionally trained individuals to build successful careers in cam research.

Objectives

- Ensure that cam research training and career development take place in settings where there is a critical mass of ongoing related research, infrastructure, and research mentors.
- Foster cam practitioners' exposure to, and understanding of, the biomedical research literature and evidence-based approaches to advancing science and health care.
- Target selected research training awards for cam practitioners.
- Support career development awards for promising postdoctoral fellows to ease the transition from postdoctoral training in cam research to independent research careers.
- Capitalize on opportunities to draw underrepresented minorities into cam research training.
- Reinforce the importance of experienced mentors in cam research training, by emphasizing programs that support midcareer investigators in research and mentorship roles.

Strategic Area 3

Expanding Outreach

The Center recognized early on the importance of informing the public about cam research results so they could make informed health care decisions. The subject matter of cam presents unique challenges and opportunities. Unlike other areas of research, large segments of the American public are already using various complementary and alternative healing practices in the absence of rigorous scientific evidence of their safety and effectiveness. Further, there are very strong feelings about the study of cam.

Among nccam's many publics are cam proponents who may regard nccam's research activities as an effort to disprove cam; another group includes cam opponents who consider nccam's research endeavors an endorsement of unproven medicine; and a vast general public who hear many conflicting messages about cam, including the assumption that any product labeled as "natural" must be safe. Thus, the topic of cam presents an environment of uncertainty for the public. Where can the public turn for reliable and accurate information? Whom can they trust?

In communicating its messages, nccam applies the same rigor in reporting and responsiveness to the public as nccam does in its very support and conduct of cam research: It presents the facts–and acknowledges the limitations on what is known–about particular cam procedures and products. nccam recognizes the power of collaboration in communication to the public and has begun partnering with like-minded consumer advocacy and health professional organizations to disseminate cam information.

In outreach to the scientific community, the Center has recognized the necessity of recruiting seasoned conventional researchers who could bring their expertise and experience to address cam-related research questions. Also key to the research process is outreach to cam practitioners, who can lend their subject-matter expertise to enrich the research process. In addition, nccam reaches out to health professionals and students at conventional and cam institutions, informing them of opportunities for funding of research, research training, and career development.

These measures have done much to establish nccam as the national voice for complementary and alternative medicine–among those who are aware of the Center–earning the respect of both cam and conventional practitioners and the public. Nevertheless, many Americans are unaware of nccam and the research it supports. Because cam practices are so diverse and used for so many conditions, nccam has strived to identify natural communications partners to enhance its outreach efforts.

Resources Needed

Organizations with whom nccam can partner to extend its reach to wider audiences. Partnerships should be sought among patient and professional associations, nih components and other Federal agencies, private foundations, community organizations, and other interested parties.

Goal 1 Help the public and health care professionals make informed health care decisions about cam.

Objectives

- Conduct consumer research to assess stakeholder perceptions, barriers, opportunities, and unmet needs, using surveys, interviews, focus groups, and other means as appropriate and to evaluate the effectiveness of nccam communications.
- Position nccam as an authoritative, trusted source of cam information.
- Continue to develop a coalition of outreach partners to expand the reach of critical cam health information. Meet with key stakeholder groups to maintain a dialogue and solicit feedback on nccam's communication activities.
- Communicate state-of-the-science cam information through a multifaceted communications program that includes the media, public forums, the continued development of culturally sensitive health information materials, and an enhanced Internet presence.
- Provide the public with critical assessment skills so they are better able to discern conflicting messages about cam.

Goal 2 Enrich the pool of multidisciplinary cam researchers.

Objectives

- Engage and recruit multidisciplinary researchers in the study of cam by informing the research community of opportunities, publicizing research advances, attending and providing lectures at scientific meetings, and developing informational tools for prospective grantees.
- Develop and implement an outreach strategy to attract minority researchers.
- Work to facilitate research partnerships domestically and internationally.

Strategic Area 4

Advancing Our Organization

Since nccam's founding in 1999, our staff has grown severalfold, and with that growth have come new challenges. With 5 years of experience, we learned many lessons and are examining how we have evolved, what our organizational culture is, and how we conduct our work. As a result, we are now poised to further advance the Center's goals and mission through better management of the public's investment in cam research.

The goals and objectives described below outline ways in which nccam can build upon the strong foundation laid during its formative years.

Goal 1 Promote organizational growth.

Objectives

- Develop an organizational culture that values integrity and practices respect, teamwork, and open communications.
- Clearly define the roles and responsibilities of each division and office.
- Encourage dialogue among nccam staff members at all levels and across all organizational units; actively solicit, respond to, and reward staff input, as appropriate.
- Enhance working relationships and develop trans-nccam work teams that value and utilize the perspectives and expertise of all staff members.
- Promote diversity among nccam employees and enhance understanding and appreciation of cultural differences.
- Share decisionmaking processes and knowledge at all levels of the organization.

Goal 2 Encourage and empower nccam's staff.

Objectives

- Clearly define the roles, responsibilities, and accountability of each staff member.
- Entrust staff members with the authority and autonomy to fulfill their responsibilities effectively.
- Clarify performance expectations, refine metrics for success, encourage creativity, and reward achievements.
- Further develop staff expertise and encourage career development through mentoring, practical experience, and training.
- Support quality-of-worklife programs and initiatives.

Goal 3 Optimize effective management of the public's investment in cam research.

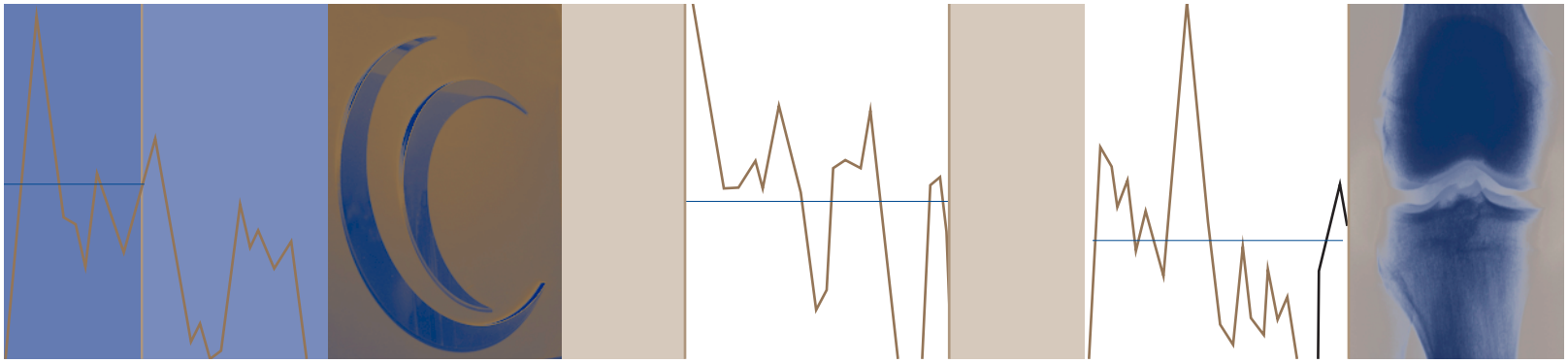
Objectives

- Evaluate our programs and operations to further incorporate best practices and solidify management controls.
- Develop standard operating procedures with input from all relevant staff members and widely communicate them to all those affected.
- Seek opportunities to further leverage our resources through partnerships and collaborations to maximize the return on research investment.
- Provide effective management tools, capitalizing on information technology.

Appendix I

Important Events in NCCAM's History

November 1991	Public Law 102-170 provides $2 million to the National Institutes of Health to establish an office and advisory panel to recommend a research program that would investigate promising unconventional medical practices.
June 1993	Public Law 103-43, the nih Revitalization Act of 1993, establishes the Office of Alternative Medicine within the Office of the Director of nih. The purpose of oam is to facilitate the evaluation of alternative medical treatment modalities and to disseminate information to the public via an information clearinghouse.
October 1995	A research centers program is established to provide a nationwide focus for interdisciplinary cam research in academic institutions.
October 1996	A public information clearinghouse is established.
November 1996	oam is designated a World Health Organization Collaborating Center in Traditional Medicine.
September 1997	The first phase iii clinical trial is funded, a study of St. John's wort for major depression. The trial is cosponsored by oam, the National Institute of Mental Health, and the nih Office of Dietary Supplements.
October 1998	Public Law 105-277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, elevates the status and expands the mandate of oam by authorizing the establishment of nccam. This act amends Title iv of the Public Health Service Act.
January 1999	William R. Harlan, m.d., is appointed Acting Director of nccam.
February 1999	The Secretary of Health and Human Services signs the organizational change memorandum creating nccam and making it the 25th independent component of nih. The nccam Director is vested with broad decisionmaking authority, especially concerning financial and administrative management, and fiscal and review responsibility for grants and contracts.
May 1999	nccam independently awards its first research project grant. The nccam Trans-Agency cam Coordinating Committee is established to foster the Center's collaboration across nih, hhs, and other Federal agencies.
June 1999	A Special Emphasis Panel is chartered to enable nccam to conduct peer review of mission-specific cam applications.
August 1999	The National Advisory Council for Complementary and Alternative Medicine is chartered.



September 1999	nccam funds its first research training, fellowship, and career development awards.
October 1999	The Secretary of Health and Human Services appoints Stephen E. Straus, m.d., as the first Director of nccam (see Appendix ii). nccam and the nih Office of Dietary Supplements establish the first dietary supplements research centers with an emphasis on botanicals.
September 2000	nccam 's first strategic plan is published, *Expanding Horizons of Healthcare: Five-Year Strategic Plan, 2001–2005.*
February 2001	nccam and the National Library of Medicine launch cam on PubMed, a comprehensive Internet source of research-based information on cam.
April 2001	The Division of Intramural Research is established.
April 2002	Results of nccam's first phase iii clinical trial, of St. John's wort for major depression, are published.
June 2002	nccam's first intramural study, of electroacupuncture to treat chemotherapy-induced nausea, is launched.
July 2002	nccam initiates a new lecture series, "Distinguished Lectures in the Science of Complementary and Alternative Medicine."
October 2002	nccam and 16 Federal cosponsors launch an Institute of Medicine study of the scientific and policy implications of the use of cam by the American public.
January 2003	Margaret A. Chesney, ph.d., is appointed as nccam's first Deputy Director (see Appendix ii).
September 2003	As part of its restructured research centers program, nccam funds centers of excellence to support established researchers and developmental centers to partner cam institutions and major research universities. In addition, planning grants for international centers were awarded to partner u.s. and international research teams.
February 2004	nccam establishes an analytical resource center to assay and characterize dietary supplements.
December 2004	nccam-funded researchers complete the longest, largest controlled phase iii clinical trial of acupuncture ever conducted, demonstrating that acupuncture, when used as an adjunctive treatment for osteoarthritis of the knee, significantly reduces pain and improves function.

Appendix II

Biosketches

Stephen E. Straus, M.D.

Stephen E. Straus, m.d., was appointed the first Director of the National Center for Complementary and Alternative Medicine in October 1999. An internationally recognized expert in clinical research and clinical trials, Dr. Straus is also Senior Investigator in the Laboratory of Clinical Investigation at the National Institute of Allergy and Infectious Diseases (niaid). He has extensive basic and clinical research experience related to many conditions for which there are alternative or complementary remedies, including chronic fatigue syndrome, Lyme disease, hiv/aids, chronic hepatitis b virus, genital herpes infections, and chronic post-herpetic pain. Dr. Straus also has extensive background in investigations of the molecular biology, pathogenesis, treatment, and prevention of human viral infections and immunologic diseases. Among his accomplishments in these areas are demonstration that acyclovir suppresses recurrent genital and oral herpes and his characterization of a previously unrecognized genetically determined disease, the autoimmune lymphoproliferative syndrome.

Dr. Straus began his academic training at the Massachusetts Institute of Technology, where in 1968 he obtained his Bachelor of Science degree in life sciences. In 1972, he received his medical degree from the Columbia University College of Physicians and Surgeons. Dr. Straus's career at the National Institutes of Health began in 1979, when he joined niaid as a Senior Investigator. He is board-certified in internal medicine and infectious diseases.

His professional achievements have been recognized by many prestigious professional societies, including the Association of American Physicians and the American Society for Clinical Investigation, and by appointment to the editorial boards of several scholarly journals. He is the recipient of five medals and other commendations from the u.s. Public Health Service, including the Distinguished Service Medal for innovative clinical research and the hhs Secretary's Distinguished Service Award for drafting the blueprint to reinvigorate clinical research at nih. Dr. Straus was a member of the Clinical Research Roundtable of the National Academies' Institute of Medicine and he continues to serve on the National Institutes of Health Steering Committee. He has published more than 400 research articles and edited several books.

Margaret A. Chesney, Ph.D.

Margaret A. Chesney, ph.d., is Deputy Director of the National Center for Complementary and Alternative Medicine. She also serves as the Center's Director of the Division of Extramural Research and Training. While engaged in clinical research in behavioral medicine and health psychology, Dr. Chesney focused on the relationship between behavior and chronic illness; behavioral factors in clinical trials, including issues of recruitment, adherence, and retention; and the development and evaluation of behavioral treatments of health problems. Her research primarily targeted women's health concerns, cardiovascular disease, and hiv/aids.

Dr. Chesney received her undergraduate degree from Whitman College, Walla Walla, Washington. She obtained her master's and doctoral degrees in clinical psychology and counseling from Colorado State University, Fort Collins. Dr. Chesney completed postdoctoral fellowship training in the Department of Psychiatry at Temple University's School of Medicine, Philadelphia.

Before joining nccam in February 2003, Dr. Chesney was Professor of Medicine at the School of Medicine, University of California, San Francisco (ucsf). While at ucsf, she served as Co-Director of the Center for aids Prevention Studies; Associate Director of the California aids Research Center at ucsf; and Director of the Behavioral Medicine and Epidemiology Core of the ucsf Center for aids Research. In 2001 and 2002, Dr. Chesney also was a Visiting Scientist with the Office of Research on Women's Health in the Office of the Director of nih.

Dr. Chesney is a past President of the Academy of Behavioral Medicine Research and of the American Psychosomatic Society, and President of the Division of Health Psychology of the American Psychological Association (apa). Her awards include the Annual Award for Outstanding Contributions to the apa Division of Health Psychology in 1982 and 1986, the President's Award from the Academy of Behavioral Medicine Research in 1987, and the Charles C. Shepard Science Award from the Centers for Disease Control and Prevention in 1999. In 2000, Dr. Chesney was a Senior Fellow at the Center for the Advancement of Health in Washington, d.c., supported by the Robert Wood Johnson and John D. and Catherine T. MacArthur Foundations. In 2001, she was elected to the Institute of Medicine of the National Academies. She has published more than 240 research articles and edited several books.

Appendix III

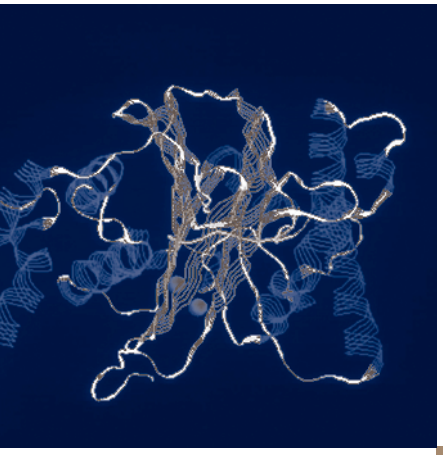
The Strategic Planning Process

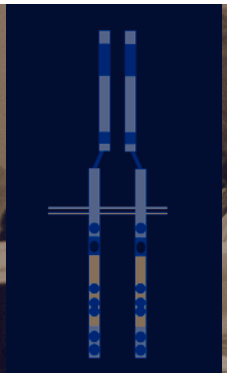
The strategic planning process proceeded in two phases. In phase i, nccam solicited advice and comments on its future activities from a broad range of stakeholders, each acting independently. The exercise began with insiders' views: an nccam staff retreat held on February 11, 2004. The Strategic Plan Advisory Panel met 2 days later and consisted of highly regarded cam and conventional scientists, clinicians, public health advocates, academicians, editors, and administrators. (See Appendix iv.) The third and fourth groups included representatives of cam disciplines, investigators, and members of the public who were invited to testify at two regional stakeholder forums. They spoke before listening panels composed of nccam senior staff and nccam Advisory Council members. The East Coast forum was held in Bethesda, Maryland, on March 22, followed on April 19 by a West Coast forum in Seattle. Additional public comments were elicited via nccam's Web site.

Based on the various priority listings of research topics from the phase i meetings, we developed a list of master health goals (see page 17) that address key issues–such as the seriousness of the health problems, needs of special populations, and use of cam practices to prevent disease and promote health and wellness.

These were incorporated into the charge to the 10 working groups (see Appendix iv) constituting phase ii of the strategic planning process. These groups were defined by the themes repeatedly emphasized by phase i participants.

- nccam was advised to dedicate five working groups to parallel the four principal cam domains and whole medical systems, while the recognition that cam is a global enterprise dictated a need for a working group on international health research. The admonition from advisors to study in more detail who uses cam and how, when, and why, as well as to evaluate the cost-effectiveness of cam practices, spurred the conviction that nccam should have a working group on health services research.





- Outreach and research training as subjects for working groups were obvious, since they were strategic areas in our first plan. Moreover, there was some urgency in the concerns voiced by many stakeholders about who is best able to conduct cam research–and where. These concerns meshed with plans already in place to evaluate nccam research training and career development programs, and led to integrating evaluation into the charge of the Research Training Working Group.
- Issues raised by the phase i advisors also inspired the creation of a working group on the ethical, legal, and social implications of cam research and integrated medicine.

Approximately 80 individuals participated as members of one or more of the 10 working groups. To ensure a broad perspective, each group was co-chaired by an outside expert and an nccam staff member. Members included representatives of cam and conventional research and practitioner communities, members of the National Advisory Council for Complementary and Alternative Medicine, and members of the phase i Strategic Plan Advisory Panel. Included were many distinguished researchers, new to cam, who lent their expertise and experience in other areas toward solving problems related to cam research, using the range of state-of-the-art approaches from molecular and cellular biology through population-based studies.

In addition to these 10 working groups, an internal working group on stewardship, with broad representation of nccam staff and an expert consultant, provided recommendations for advancing the nccam organization. (See Appendix iv.)

The plan benefited from extensive preliminary review by working group members. It was discussed at the meeting of the National Advisory Council for Complementary and Alternative Medicine on September 10, 2004, and members of the public at large were offered the opportunity to provide comments via the nccam Web site. In addition, comments were specifically solicited from individuals instrumental in the initial formation and development of the Office of Alternative Medicine and nccam.

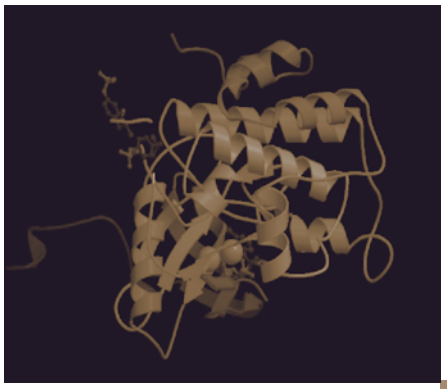
Appendix IV

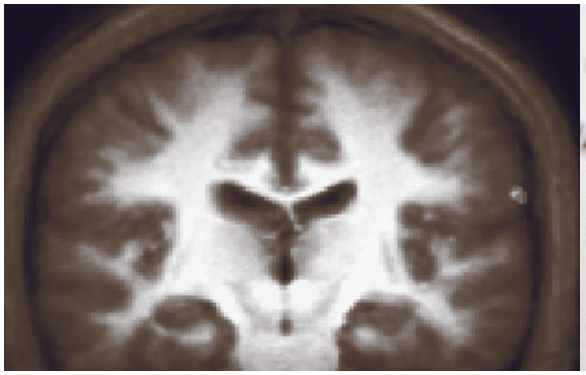
NCCAM Advisors

Strategic Plan Advisory Panel
Natcher Conference Center, NIH
February 13, 2004

Chairperson

Arthur Kleinman, m.d., m.a.
Chairperson
Department of Anthropology
Esther and Sidney Rabb Professor of Anthropology
Harvard University
Professor of Medical Anthropology and Professor of Psychiatry
Department of Social Medicine
Harvard Medical School
Cambridge, ma





Members

Shu Chien, m.d., ph.d.
University Professor of Bioengineering and Medicine
Chairperson
Department of Bioengineering
University of California, San Diego
La Jolla, ca

Haile Debas, m.d.
Executive Director
Global Health Services
University of California, San Francisco
San Francisco, ca

Balz Frei, ph.d.
Professor and Director
Department of Biochemistry and Biophysics
Linus Pauling Institute
Oregon State University
Corvallis, or

Peggy Hamburg, m.d.
Vice President for Biological Programs
Nuclear Threat Initiative
Washington, dc

Ted J. Kaptchuk, o.m.d.
Assistant Professor of Medicine
Department of Medicine
Beth Israel-Deaconess Medical Center
Harvard Medical School
Boston, ma

Tieraona Low Dog, m.d.
Clinical Assistant Professor
Department of Family and Community Medicine
University of New Mexico
School of Medicine
Albuquerque, nm

George D. Lundberg, m.d.
Editor in Chief
Medscape General Medicine
Adjunct Professor of Health Policy
Harvard School of Public Health
Los Gatos, ca

William Meeker, d.c., m.p.h.
Vice President for Research
Palmer Chiropractic University
Director
Palmer Center for Chiropractic Research
Davenport, ia

William J. Mulvihill, m.ed.
Senior Associate Athletic Director
University of Cincinnati
Cincinnati, oh

Herbert Pardes, m.d.
President and ceo
New York-Presbyterian Hospital
New York, ny

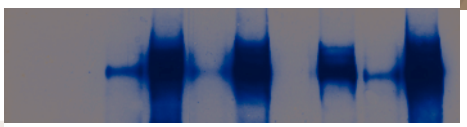
Robert Park, ph.d.
Director of Public Information
American Physical Society
Washington, dc

Ralph Snyderman, m.d.
Chancellor for Health Affairs
President/ceo
Duke University Health System
Duke University
Durham, nc

Allen M. Spiegel, m.d.
Director
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, md

Nora D. Volkow, m.d.
Director
National Institute on Drug Abuse
National Institutes of Health
Bethesda, md

Robert E. Wittes, m.d.
Physician-in-Chief
Memorial Sloan-Kettering Cancer Center
New York, ny



Strategic Planning Workshop
Mind-Body Medicine Working Group
Hunt Valley, Maryland
May 23–25, 2004

Co-Chairs

Margaret Chesney, ph.d.
Deputy Director
Director
Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, md

Anne Harrington, ph.d.
Professor for the History of Science
Harvard University
Cambridge, ma

Reporter

Dale Birkle, ph.d.
Scientific Review Administrator
Office of Scientific Review
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, md

Members

Vania Apkarian, ph.d.
Associate Professor
Department of Physiology
Northwestern University
Medical School
Chicago, il

Fabrizio Benedetti, m.d.
Professor
Department of Neuroscience
University of Turin Medical School
Turin, Italy

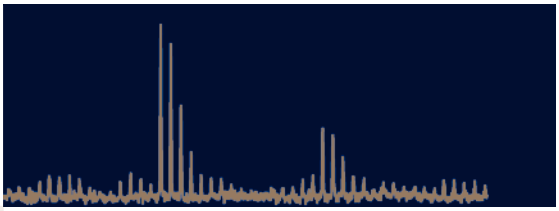
Richard Lane, m.d., ph.d.
Professor of Psychiatry, Psychology, and Neuroscience
University of Arizona
Tucson, az

Robert Nussenblatt, m.d.
Chief
Laboratory of Immunology
National Eye Institute
National Institutes of Health
Bethesda, md

Thomas Pickering, m.d., d. Phil.
Professor of Medicine
Director, Behavioral Cardiovascular Health and Hypertension Program
Columbia Presbyterian Medical Center
New York, ny

Bruce Rabin, m.d., ph.d.
Professor of Pathology and Psychiatry
University of Pittsburgh
Medical Center
Medical Director
upmc Healthy Lifestyle Program
Pittsburgh, pa

Bruce Rosen, m.d., ph.d.
Director
Martinos Center for Biomedical Imaging
Massachusetts General Hospital
Charlestown, ma



Strategic Planning Workshop
Biologically Based Practices Working Group
Hunt Valley, Maryland
May 23–25, 2004

Co-Chairs

Marguerite Klein, m.s.
Program Officer
Division of Extramural Research and Training
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, md

Irwin Rosenberg, m.d.
Dean
Friedman School of Nutrition Science and Policy
Tufts University
Boston, ma

Reporter

Jeanette Hosseini, ph.d.
Scientific Review Administrator
Office of Scientific Review
National Center for Complementary and Alternative Medicine
National Institutes of Health
Bethesda, md

Members

Andrew Avins, m.d., m.p.h.
Research Scientist
Northern California Kaiser-Permanente
Associate Professor
Departments of Medicine and Epidemiology and Biostatistics
University of California, San Francisco
Kentfield, ca

Yung-Chi (Tommy) Cheng, ph.d.
Professor
Department of Pharmacology
Yale University School of Medicine
New Haven, ct

Paul Coates, ph.d.
Director
Office of Dietary Supplements
National Institutes of Health
Bethesda, md

Gordon Cragg, ph.d.
Chief
Natural Products Branch
National Cancer Institute
National Institutes of Health
Frederick, md

Adrian Dobs, m.d., m.h.s.
Professor
Department of Medicine
The Johns Hopkins School of Medicine
Baltimore, md

Steven Kliewer, ph.d.
Professor
Department of Molecular Biology and Pharmacology
University of Texas
Southwestern Medical Center at Dallas
Dallas, tx

Eric Lien, ph.d.
Professor Emeritus
Department of Pharmaceutical Sciences
University of Southern California
Los Angeles, ca

Tieraona Low Dog, m.d.
Clinical Assistant Professor
Department of Family and Community Medicine
University of New Mexico
School of Medicine
Albuquerque, nm

Steven Zeisel, m.d., ph.d.
Professor and Chairman
Department of Nutrition
School of Medicine
Associate Dean for Research
School of Public Health
University of North Carolina
Chapel Hill, nc

Strategic Planning Workshop
Manipulative and Body-Based Practices Working Group
Hunt Valley, Maryland
May 23–25, 2004

Co-Chairs

Richard Nahin, ph.d., m.p.h.
Senior Advisor for
Scientific Coordination and Outreach
National Center for Complementary
and Alternative Medicine
National Institutes of Health
Bethesda, md

Daniel Cherkin, ph.d.
Associate Director
and Scientific Investigator
Group Health Cooperative Center
for Health Studies
Professor of Family Medicine
and Health Services
University of Washington
Seattle, wa

Reporter

Christine Goertz, d.c., ph.d.
Director of Clinical Research
Samueli Institute
for Information Biology
Alexandria, va

Members

Boyd Bowden, d.o.
Orthopedic Surgeon
Member, Board of Directors
American Osteopathic Association
Columbus, oh

Vince Caiozzo, ph.d.
Associate Professor
Departments of Orthopedics
and Physiology and Biophysics
College of Medicine
University of California, Irvine
Irvine, ca

Leslie Crofford, m.d.
Associate Professor
Department of
Internal Medicine-Rheumatology
University of Michigan Medical School
Ann Arbor, mi

Mark Grabiner, ph.d.
Professor and Head
Department of Movement Sciences
University of Illinois at Chicago
Chicago, il

Joel Greenspan, ph.d.
Associate Professor
Department of Biomedical Sciences
Director
Research Center for
Neuroendocrine Influences on Pain
University of Maryland at Baltimore
Baltimore College of Dental Surgery
Baltimore, md

Janet Kahn, ph.d., n.c.t.m.b.
Research Assistant Professor
Department of Psychiatry
University of Vermont
Burlington, vt

William Meeker, d.c., m.p.h.
Vice President for Research
Palmer Chiropractic University
Director
Palmer Center
for Chiropractic Research
Davenport, ia

William J. Mulvihill, m.ed.
Senior Associate Athletic Director
University of Cincinnati
Cincinnati, oh

John Triano, d.c., ph.d.
Co-Director of Conservative Care
Director
Chiropractic Division
Texas Back Institute
Research Professor
Department of Engineering
University of Texas, Arlington
Plano, tx

Strategic Planning Workshop
Energy Medicine Working Group
Hunt Valley, Maryland
May 23–25, 2004

Co-Chairs

Morgan Jackson, m.d., m.p.h.
Director
Office of Special Populations
Division of Extramural Research
and Training
National Center for Complementary
and Alternative Medicine
National Institutes of Health
Bethesda, md

Shan Wong, ph.d.
Program Officer
Division of Extramural Research
and Training
National Center for Complementary
and Alternative Medicine
National Institutes of Health
Bethesda, md

Joan eb Fox, ph.d.
Research Scientist
Department of
Molecular Cardiology
Director
Center for Integrative Medicine
The Cleveland Clinic Foundatioin
Cleveland, oh

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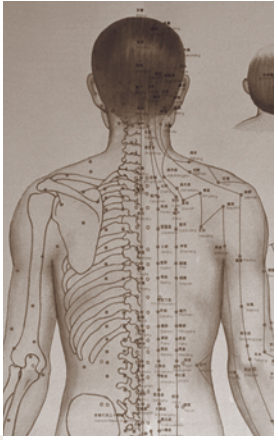

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Barbara Sorkin, ph.d.
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Mikel Aickin, ph.d.
Senior Investigator
Helfgott Research Institute
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Professor of Anthropology and Religion
Chair
Department of Anthropology
Case Western Reserve University
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National Institutes of Health
Bethesda, md

Wayne Jonas, m.d.
Director
Samueli Institute for Information Biology
Alexandria, va

Ted J. Kaptchuk, o.m.d.
Assistant Professor of Medicine
Department of Medicine
Beth Israel-Deaconess Medical Center
Harvard Medical School
Boston, ma

Bala Manyam, m.d.
Director
Plummer Movement Disorders Center
Professor
Department of Neurology
Scott and White Memorial Hospital and Clinic
Texas a&m College of Medicine
Temple, tx

Stephen Myers, ph.d., b.med., n.d.
Director
Australian Centre for Complementary Medicine Education and Research
Lismore, Australia

Jeff Sloan, ph.d.
Director
Quality of Life Program
Department of Biostatistics
Mayo Clinic College of Medicine
Rochester, mn

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Community and Minority Affairs
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Global Development
Amgen, Inc.
Thousand Oaks, ca

Charles Henderson, d.c., ph.d.
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Neuroscience
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Davenport, ia

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Senior Fellow
Fogarty International Center
National Institutes of Health
Bethesda, md

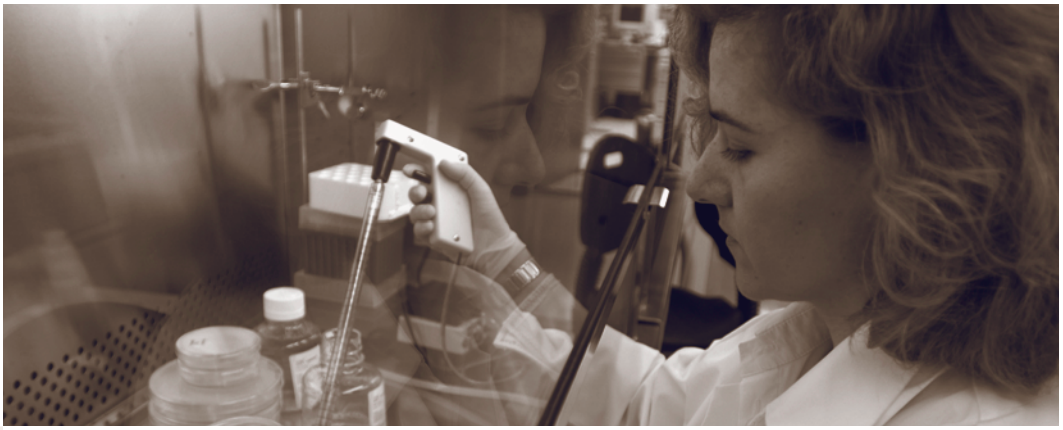
William Lafferty, m.d.
Associate Professor
Department of Health Services
School of Public Health and Community Medicine
University of Washington
Seattle, wa

Debra Lappin, j.d.
Senior Advisor
b&d Sagamore
Englewood, co

George D. Lundberg, m.d.
Editor in Chief
Medscape General Medicine
Adjunct Professor of Health Policy
Harvard School of Public Health
Los Gatos, ca

Laura Patton, m.d.
Clinical Director
cam Services
Group Health Cooperative
Seattle, wa

Mary Ruggie, ph.d.
Adjunct Professor of Public Policy
Kennedy School of Government
Harvard University
Cambridge, ma



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Senior Investigator
Human Genetics
and Integrative Medicine Section
Laboratory of Genetics
National Institute on Aging
National Institutes of Health
Baltimore, md

Heather Greenlee, n.d., m.p.h.
Postdoctoral Research Fellow
Department of Epidemiology
Mailman School of Public Health
Columbia University
New York, ny

Barbara Hamkalo, ph.d.
Professor
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Irvine, ca

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Neuroscience
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Editor in Chief
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Adjunct Professor of Health Policy
Harvard School of Public Health
Los Gatos, ca

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Vice President for Research
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Davenport, ia

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Professor
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Ogilvy Public Relations
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Program Analyst
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National Center for Complementary
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Program Analyst
Office of Science Policy and Operations

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Program Analyst
Office of Administrative Operations

Shirley Villone
Program Advisor
Office of Administrative Operations

Appendix V

Glossary

Definitions are intended to clarify the strategic plan by giving brief snapshots of the terms defined; the intent is not to provide comprehensive or definitive overviews of often-complex topics. Within definitions, terms that are highlighted are defined elsewhere in this glossary.

Acupuncture: A method of healing developed as part of traditional Chinese medicine. Today, acupuncture describes a family of procedures involving stimulation of anatomical points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea, and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.

Alexander technique: A body-based practice that focuses on patient education and guidance in ways to improve posture and movement, and to use muscles efficiently.

Allopathic medicine: A synonym for conventional medicine. Also called allopathy.

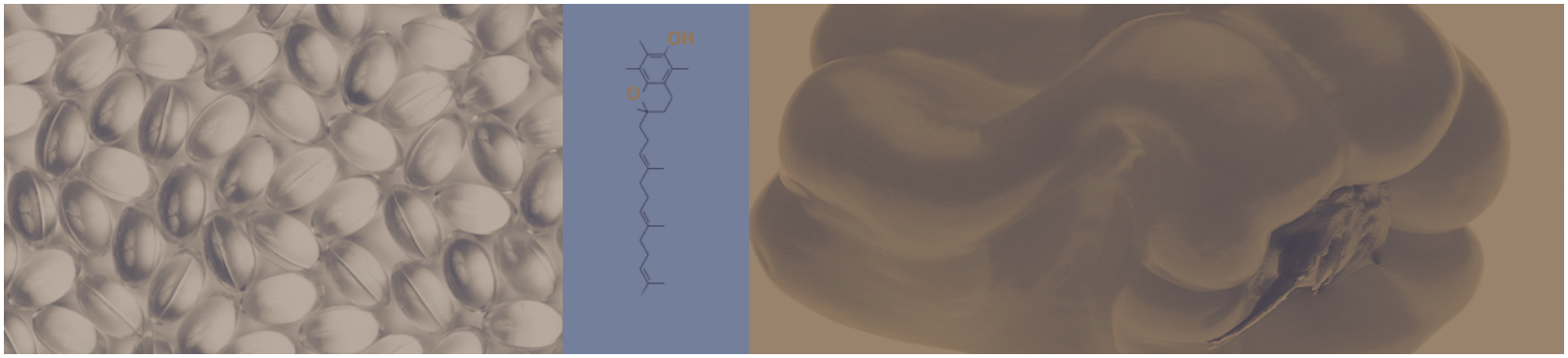
Ayurvedic medicine: A whole medical system that has been practiced primarily on the Indian subcontinent for 5,000 years. It includes diet and herbal remedies, and emphasizes the use of body, mind, and spirit in disease prevention and treatment. Also called Ayurveda.

Biofeedback: A mind-body therapy. The patient learns, through the use of simple electronic devices, how to consciously regulate body functions that are normally unconscious (such as breathing or heart rate). This is done to help treat certain conditions and improve overall health.

Biofield: A vital energy or life force that is believed by many energy medicine practitioners to flow throughout the body. The existence of biofields has not been scientifically proven, and they have not been measured by conventional instruments.

Biologically based practices: A domain of practices that employ substances found in nature, such as herbal or botanical products; selected compounds such as vitamins, minerals, and other molecules assumed to have therapeutic value; probiotics; and selected dietary regimens purported to improve health and well-being.

Biomedicine: A synonym for conventional medicine.



Botanical: A plant or plant part that is used for its flavor, scent, and/or therapeutic properties. Examples include flowers, leaves, bark, fruits, seeds, stems, and roots; substances emitted by plants; and algae.

Chiropractic medicine: A system of health care that focuses on the relationship between the body's structure, primarily of the spine, and function. Practitioners use a type of hands-on therapy called manipulation (or adjustment) as their core clinical procedure. Most use other treatments in addition to manipulation.

Complementary and alternative medicine (cam): A group of diverse medical and health care systems, practices, and products that are not presently considered an integral part of conventional medicine. Complementary medicine is used together with conventional medicine, and alternative medicine is used in place of conventional medicine. Some health care providers practice both cam and conventional medicine.

Conventional medicine: A whole medical system practiced by holders of m.d. (medical doctor) or d.o. (doctor of osteopathy) degrees and by their allied health professionals, such as physical therapists, psychologists, and registered nurses. Other terms for conventional medicine include allopathy; Western, mainstream, and orthodox medicine; and biomedicine.

Craniosacral therapy: A body-based practice. Practitioners use light touch and manipulation focused on the skull and spine, with the intent of sensing and removing what they refer to as blockages or imbalances that may be contributing to a health condition.

Dietary supplement: Congress defined the term "dietary supplement" in the Dietary Supplement Health and Education Act (dshea) of 1994 as a product (other than tobacco), taken by mouth, that contains a "dietary ingredient" intended to supplement the diet. Dietary ingredients may include vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, and metabolites. Dietary supplements come in many forms, including extracts, concentrates, tablets, capsules, gel caps, liquids, and powders. They have special requirements for labeling. Under dshea, dietary supplements are considered foods, not drugs.

Dietary Supplement Health and Education Act (dshea) of 1994: This law defines a new category of food for regulatory purposes–dietary supplements–and stipulates how the products should be labeled and which health claims are permitted. Under dshea, dietary supplements are subject to different quality, safety, and efficacy requirements than drugs. Among the most important differences: The Food and Drug Administration must approve drugs before marketing, based on proof of safety and efficacy. No such requirement exists for dietary supplements, leaving supplement manufacturers responsible for ensuring the quality of their products, that they are safe, and that health claims for them are accurate.

Effectiveness: The ability of a treatment to produce an effect on a disease or condition when it is used in usual practice.

Efficacy: The ability of a treatment to produce an effect on a disease or condition in a research study.

Energy medicine: A domain of practices that involve the therapeutic use of forms of energy, including those that can be measured, such as electromagnetic radiation and sound, as well as those that are yet to be measured but are believed to exist. Energy medicine is based on the belief that all living things possess and emit energies and can be affected by external energies.

Feldenkrais method: Group classes and hands-on lessons designed to improve the coordination of the whole person in comfortable, effective, and intelligent movement.

Functional food: A food that has biologically active components (such as fish oils or plant estrogens) that may provide health benefits beyond basic nutrition.

Guided imagery: A mind-body therapy. The person uses relaxation techniques followed by mental images produced by the imagination–for example, that one's body is healthy, strong, and free of a specific disease. Guided imagery is used in helping patients cope with diseases and in treating mental disorders.

Healing Touch: A variation of Therapeutic Touch (a term that is sometimes used interchangeably). Healing Touch incorporates techniques targeted to specific health problems, with the practitioner using the hands (often through gentle touch) to work with what is proposed to be an energy system inside and outside the patient's body. The intent is to enhance well-being and support healing.

Health services research: The study of factors that influence people's access to and utilization of health care services; the nature, costs, and quality of that care; and ultimately its effects on people's health and well-being.

Herb: A flowering plant whose leaves, or leaves and stems, are used for food or medicine or for their scent or flavor.

Homeopathy: A whole medical system developed in Germany in the 18th century. Homeopathy seeks to stimulate the body's defense mechanisms and processes so as to prevent or treat illness. A core practice is giving very small doses of highly diluted substances that, it is believed, would produce the same or similar symptoms of illness in healthy people if given in larger doses (a principle called "like cures like"). Also called homeopathic medicine.

Indian Ayurvedic medicine: See Ayurvedic medicine.

Institutional Review Board (irb): An independent group of health care providers, other experts, and laypeople from the community who make sure that a clinical trial is set up and run safely and fairly. irbs review protocols and the consent documents that people must sign in order to participate in a clinical trial.

Integrated medicine: An approach to medicine that combines mainstream medical therapies and cam therapies for which there is high-quality scientific evidence of safety and efficacy. Also called integrative medicine.

Johrei: An energy medicine therapy where the practitioner seeks to transmit energy by moving his or her hands near the patient, in the belief that this can help physical and mental conditions.

Light therapy: The use of intensive levels of light under controlled conditions to treat a health condition.

Mainstream medicine: A synonym for conventional medicine.

Manipulation: A manual therapy (i.e., one delivered by the hands) in which the practitioner applies controlled force to a joint, moving it beyond its normal range of motion. This is done to increase the range and quality of motion and to aid in restoring health. In chiropractic medicine, the preferred term is "adjustment."

Manipulative and body-based practices: A domain of practices that involve the use of manipulation or movement of one or more parts of the body. Some examples include massage, chiropractic manipulation, and osteopathic manipulation.

Massage: A body-based therapy that involves pressing, rubbing, and otherwise manipulating muscles and other soft tissues of the body, causing them to relax and lengthen and allowing pain-relieving oxygen and blood to flow to the affected area.

Meditation: A mind-body practice used to achieve mental calmness and physical relaxation by suspending the stream of thoughts that normally occupy the mind.

Mind-body medicine: A domain of practices that involve the use of a variety of techniques to enhance mental and physical functioning and to prevent, mitigate, or treat diseases and disorders and/or their symptoms. Examples include forms of meditation and yoga.

Mindfulness meditation: A type of meditation based on the concept of being mindful, or having increased awareness, of the present. It uses breathing methods, guided imagery, and other practices to relax the body and mind and help reduce stress. Also known as mindfulness relaxation and mindfulness-based stress reduction.

Moxibustion: The application of heat from the burning of an herb called moxa at an acupuncture point.

Naturopathy: A whole medical system that originated in Europe in the 19th century. Naturopathy proposes that a healing power in the body establishes, maintains, and restores health. Practitioners work with the patient with a goal of supporting this power, through treatments such as nutrition and lifestyle counseling, dietary supplements, exercise, and others. Also called naturopathic medicine.

Osteopathic medicine: A form of conventional medicine founded in the United States in the late 19th century. Osteopathic medicine, in part, emphasizes diseases arising in the musculoskeletal system. There is an underlying belief that all of the body's systems work together, and disturbances in one system may affect function elsewhere in the body. Some osteopathic physicians use osteopathic manipulation. Also called osteopathy.

Phase i–iii clinical trials: Clinical trials take place in phases. In each phase, different research questions are answered. A phase i trial seeks to find out the safest dose of the treatment, how the treatment should be given, and how it affects the human body. A phase ii trial studies whether the treatment shows promise to treat a specific condition. A phase iii trial studies whether the treatment is better than, the same as, or worse than the standard (or most widely accepted) treatment or a placebo.

Placebo: An inert or sham treatment, such as a sugar pill.

Placebo effect: The physical or psychological benefits that can occur with the use of an inert or sham treatment (a placebo), such as a sugar pill.

Polarity therapy: An energy medicine practice based in part on the principles of Ayurvedic medicine. Among the techniques used are pressure point and joint manipulation, massage, yoga, and dietary changes.

Probiotic: Any one of a number of bacterial species that may have healthful effects, such as defending the body against viral and bacterial infections and maintaining a healthy digestive system. An example of a source of probiotics is yogurt.

Qi: A Chinese term for vital energy or life force. In traditional Chinese medicine, qi (pronounced "chee") is believed to regulate a person's spiritual, emotional, mental, and physical balance, and to be influenced by the opposing forces of yin and

Qi gong: A component of traditional Chinese medicine that combines movement, meditation, and regulation of breathing, in the belief that this can enhance the flow of qi in the body, improve blood circulation, and enhance immune function.

Randomized controlled trial (rct): A research study in which the participants are assigned by chance to separate groups: a group that will receive the treatment being studied or a group (called the control group) that will receive either the standard treatment (if there is one) for their disease or condition, or a placebo. This approach gives the best chance for the groups to be similar and the treatments to be compared objectively. In some complex trials, there are more than two groups. Also called a randomized clinical trial; randomized, placebo-controlled trial; or randomized, controlled clinical trial.

Reflexology: A body-based practice that uses a form of foot (and sometimes hand) massage in which pressure is applied to "reflex zones," with the intent of promoting relaxation or healing in other parts of the body.

Reiki: An energy medicine therapy in which the practitioner seeks to transmit purported energy, either from a distance or by placing his or her hands on or near the patient. This is done with the intent to heal the spirit and thus the body.

Relaxation: A mind-body strategy that uses various techniques (such as guided imagery) to calm the mind and release the muscles. The intent is to reduce physical tension and promote emotional well-being.

Rolfing: A body-based practice that uses deep tissue massage and movement education. The goal is to encourage health and relieve stress by bringing the body into proper alignment with gravity.

Spirituality: An individual's sense of purpose and meaning to life beyond material values. Spirituality may be practiced in many ways, including through religion.

Tai chi: An exercise program that is part of traditional Chinese medicine. The exercises consist of a series of slow movements coordinated with deep breathing and mental focus.

Therapeutic Touch: An energy medicine practice derived from an ancient technique called the laying-on of hands. It is based on the premise that it is the healing force of the practitioner that affects the patient's recovery; healing is promoted when the body's energies are in balance; and by passing their hands over the patient, practitioners can identify energy imbalances.

Traditional Chinese medicine (tcm): A whole medical system that was documented in China by the 3rd century b.c. tcm is based on a concept of vital energy, or qi that is believed to flow throughout the body. It is proposed to regulate a person's spiritual, emotional, mental, and physical balance and to be influenced by the opposing forces of yin (negative energy) and (positive energy). Disease is proposed to result from the flow of qi being disrupted and yin and yang becoming unbalanced. Among the components of tcm are herbal and nutritional therapy, restorative physical exercises, meditation, acupuncture, and remedial massage.

Trager bodywork: A body-based practice that involves light massage combined with slight rocking and shaking of the patient's limbs in a rhythmic fashion. The intent is to release physical tensions and promote health.

Whole medical systems: A general term for medical and health care systems that employ practices from among the four domains of mind-body medicine, biologically based practices, manipulative and body-based practices, and energy medicine. Conventional medicine is a whole medical system employing practices within these domains, such as psychotherapy in mind-body medicine, pharmaceuticals in biologically based practices, physical therapy in manipulative and body-based practices, and radiation therapy in energy medicine. Examples of cam whole systems of medicine include traditional Chinese medicine, Ayurvedic medicine, homeopathy, and naturopathy.

Yin/yang: The concept of opposing forces in traditional Chinese medicine. Yin represents the cold, slow, or passive principle, while yang represents the hot, excited, or active principle. Among the major assumptions in tcm are that health is achieved by maintaining the body in a balanced state and that disease is due to an internal imbalance of yin and yang.

Yoga: A mind-body practice that combines breathing exercises, physical postures, and meditation. Originating in yoga is intended to calm the nervous system and balance the body, mind, and spirit.

Appendix VI

Acronyms and Abbreviations

ahrq	Agency for Healthcare Research and Quality
cam	Complementary and Alternative Medicine
d.c.	Doctor of Chiropractic
edta	Ethylene Diamine Tetra-Acetic Acid
fda	U.S. Food and Drug Administration
fmri	Functional Magnetic Resonance Imaging
fy	Fiscal Year
hhs	U.S. Department of Health and Human Services
ics	Institutes and Centers (within nih)
irb	Institutional Review Board
nccam	National Center for Complementary and Alternative Medicine
nci	National Cancer Institute
n.d.	Doctor of Naturopathic Medicine
nhlbi	National Heart, Lung, and Blood Institute
nia	National Institute on Aging
niaid	National Institute of Allergy and Infectious Diseases
niams	National Institute of Arthritis and Musculoskeletal and Skin Diseases
nichd	National Institute of Child Health and Human Development
niddk	National Institute of Diabetes and Digestive and Kidney Diseases
nih	National Institutes of Health
nimh	National Institute of Mental Health
ninds	National Institute of Neurological Disorders and Stroke
oam	Office of Alternative Medicine (within nih; nccam's predecessor)
ods	Office of Dietary Supplements, nih
o.m.d.	Doctor of Oriental Medicine
pet	Positron-Emission Tomography
PubMed	Online searchable databse of journal citations and abstracts, a service of the National Library of Medicine (within nih)
tcm	Traditional Chinese Medicine

Photos

Cover *Photomicrograph of St. John's wort*
Dennis Kunkel/Phototake

III *Molecular structures of insulin and glucose*

IV *Shitake mushrooms (Lentinus edodes)*

8 *(top) Chemical structure of hyperforin, a component of St. John's wort*
(bottom) St. John's wort (Hypericum perforatum)

13 *Echinacea purpurea*

14 *Chemical structure of tamoxifen, a PXR receptor ligand*
Cranberries
Ginkgo biloba

16 *(right) Time course of brain activity during acupuncture*

19 *Meditation research with Buddhist monk. Courtesy of Richard Davidson, University of Wisconsin-Madison.*

22 *Photomicrograph of Lactobacillus bulgaricus and Streptococcus thermophilus, bacterial flora of yogurt, mag. 1000x.*
J.C. Revy/Phototake

29 *(top) Effects of acupuncture on brain activity as measured by fMRI*
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Courtesy of Kathleen Hui, Massachusetts General Hospital

47 *Structure of enzyme protein phosphatase 2C alpha (PP2C)*
Courtesy of Michael Quon, NCCAM

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Courtesy of Michael Quon, NCCAM

50 *(left) Baseline fMRI*
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Yoav Levy/Phototake

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