

A MESSAGE *From the Director*

Over the past year, I have had the privilege of leading the National Center for Complementary and Alternative Medicine (NCCAM) in a careful assessment of how developments in science, medicine, and health care should shape the Center's strategic directions. The process included scientific workshops, symposia, think tanks, and extensive consultation with our highly diverse stakeholder community.

The result of this year-long dialogue is this, our third strategic plan, which articulates goals and objectives for the coming years and presents a structure for determining priorities for future research. At its core is a vision in which rigorous scientific evidence about complementary and alternative medicine (CAM) informs both the decisions Americans make regarding CAM use and the potential for integration of CAM interventions into health care.

NCCAM's first decade was a period of rapid growth in which we studied a wide array of CAM modalities. As we move into our second decade, we will build on this foundation by focusing a portion of our efforts on study of specific CAM approaches that show the greatest promise to improve upon existing treatment and health promotion strategies.

As in the past, our plan emphasizes the importance of basic and clinical research as the core of building the evidence base for CAM. But in this plan, we give increased emphasis to translational research and bringing the methods of effectiveness and outcomes research to the real world where public use is extensive.

We maintain a strong commitment to providing objective and authoritative evidence-based information to the public and health care professionals. We will continue efforts to build state-of-the-art research capacity through targeted training and career development programs, and through fostering multidisciplinary collaborations.

My experience as a physician who has cared for patients struggling with chronic, painful, and debilitating symptoms greatly informs my perspective on our work. When I began medical school, one of my teachers taught that "the secret of care of the patient is in caring for the patient."* I took these words to heart. Symptoms matter, and few would dispute the fact that modern medicine does not always succeed in alleviating them. Few would also dispute the need for better approaches for encouraging healthy lifestyle choices. These are places in which I believe CAM-inclusive approaches offer promise, and I look forward to exploring the possibilities in the years ahead.

Josephine P. Briggs, M.D.
Director



Josephine P. Briggs, M.D.

* Quote by Herman Blumgart in Bennett MJ. *The Empathic Healer: An Endangered Species?* San Diego, CA: Academic Press; 2001.



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INTRODUCTION

Our Mission

The mission of NCCAM is to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative medicine interventions and their roles in improving health and health care.

Our Vision

Scientific evidence informs decisionmaking by the public, by health care professionals, and by health policymakers regarding use and integration of complementary and alternative medicine.

The National Center for Complementary and Alternative Medicine (NCCAM) is the Federal Government's lead agency for scientific research on complementary and alternative medicine (CAM). There are many definitions of CAM, none of them perfect. NCCAM defines CAM simply as a group of diverse medical and health care interventions, practices, products, or disciplines that are not generally considered part of conventional medicine. Clearly the boundaries between CAM and conventional medicine (also called Western or allopathic medicine) are not absolute. For example, CAM interventions are often incorporated into integrative medicine practices located in conventional medical care settings, and data from national surveys suggest that CAM is most often used by the general public as a complement or adjunct to conventional medical care. In addition, the boundaries are constantly evolving: interventions such as hospice care or relaxation and breathing techniques in childbirth that were once considered unconventional are now widely accepted.

The scope, self-care nature, and associated costs of CAM use in the United States reinforce the need to develop scientific evidence concerning the usefulness and safety—or lack thereof—of CAM interventions.

The most current and comprehensive picture of Americans' use of CAM has been developed under NCCAM leadership through two National Health Interview Surveys (NHIS), conducted by the National Center for Health Statistics at the Centers for Disease Control and Prevention in 2002 and 2007. Both surveys showed that nearly 40 percent of adult Americans reported using some form of CAM. The 2007 survey showed that 12 percent of children are using some form of CAM.

These data also show that Americans spent \$33.9 billion out-of-pocket for CAM in 2007. This accounted for approximately 1.5 percent of total health care expenditures, but more than 11 percent of total out-of-pocket health care expenditures. Moreover, a large fraction of total out-of-pocket spending was self-care—i.e., various products, classes, and materials not specifically recommended by a health care provider or CAM practitioner.

The scope, self-care nature, and associated costs of CAM use in the United States reinforce the need to develop scientific evidence concerning the usefulness and safety—or lack thereof—of CAM interventions, and to ensure the public has access to accurate and timely evidence-based information. Since its creation as an independent Center at the National Institutes of Health (NIH) in 1998, NCCAM has twice developed strategic plans to help guide the implementation of its legislative mandate to address these needs. Building on a decade of scientific progress, a robust research enterprise, and strong collaborations across NIH, NCCAM is now shaping its future through this third comprehensive strategic plan, developed with considerable input from its diverse stakeholder community.



The Use and Cost of CAM in the United States

Use

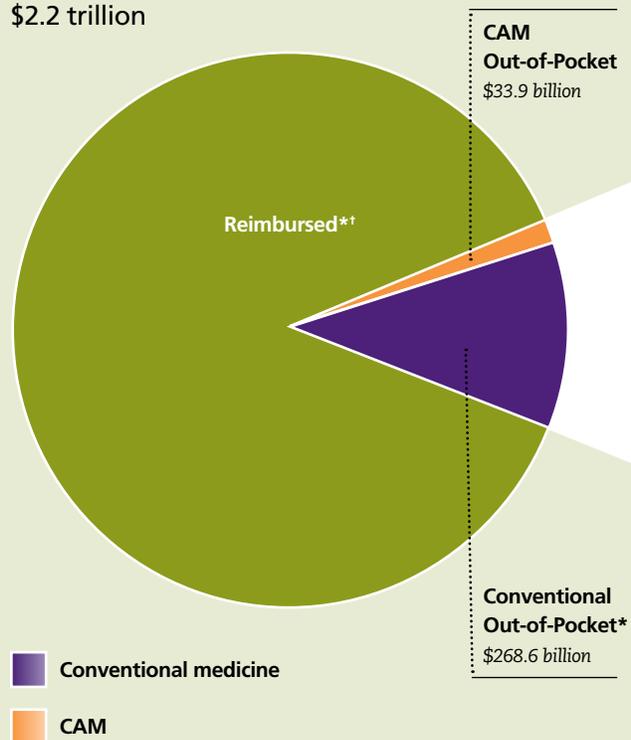
According to the 2007 National Health Interview Survey, which gathered information on more than 32,800 Americans, 38.2 percent of adults in the United States aged 18 years and over and nearly 12 percent of children aged 17 years and under used some form of CAM within the previous 12 months. Use among adults remained relatively constant from previous surveys. The 2007 survey provided the first population-based estimate of children's use of CAM.

Costs

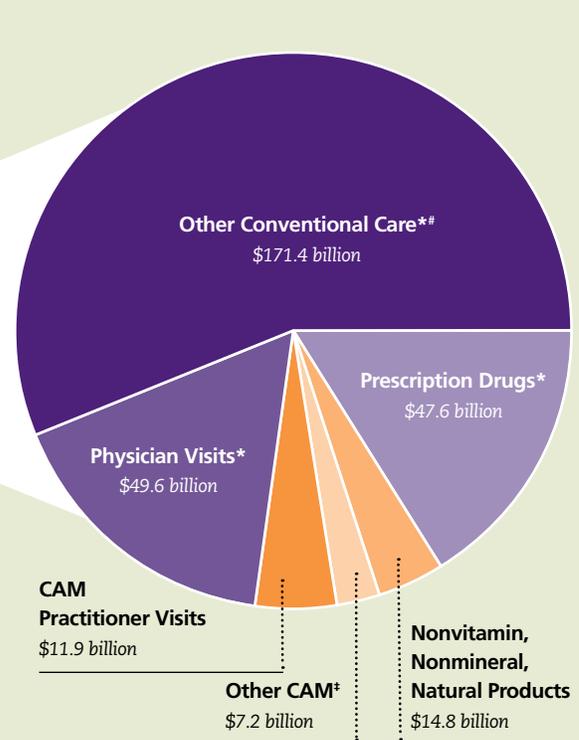
Americans spent \$33.9 billion out-of-pocket on CAM during the 12 months prior to the survey. This accounts for approximately 1.5 percent of total United States health care expenditures, but 11.2 percent of total out-of-pocket expenditures. A substantial portion of this expenditure is self-care (i.e., does not include the guidance of a health care provider or CAM practitioner).

Total Health Care Spending, 2007

\$2.2 trillion



Out-of-Pocket Spending



* National Health Expenditure Data for 2007. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services Web site. Accessed at: http://www.cms.hhs.gov/NationalHealthExpendData/02_NationalHealthAccountsHistorical.asp#TopOfPage on June 25, 2009.

† Reimbursed spending includes all employer and individual private insurance, Medicare, Medicaid, State Children's Health Insurance Program, and other private and public spending.

‡ Other CAM includes, for example, yoga, tai chi, qi gong classes; homeopathic medicine; and relaxation techniques.

Other conventional care includes dental care, nursing homes, home health care, nondrug medical products, hospital care, and other professional services.

Source: Nahin RL, Barnes PM, Stussman BJ, and Bloom B. Costs of Complementary and Alternative Medicine (CAM) and Frequency of Visits to CAM Practitioners: United States, 2007. National Health Statistics Reports; no. 18. Hyattsville, MD: National Center for Health Statistics. 2009.



Goals of the Strategic Plan

NCCAM enters its second decade at a time of both exciting scientific opportunity and heightened potential for making valuable contributions to health care practice and health promotion. This strategic plan is built around three long-range goals aimed at improving the state and use of scientific evidence regarding the two major reasons for use of CAM in the United States—treating health problems and supporting or promoting better health and well-being.

GOAL 1: Advance the science and practice of symptom management.

CAM approaches are most often used to manage symptoms of underlying diseases and conditions, including back or neck pain, arthritic or other musculoskeletal pain, and insomnia, usually in conjunction with conventional medical strategies. Furthermore, evidence suggests that some CAM approaches may be helpful in managing these symptoms and that, in some cases, they engage innate biological processes involved in pain and emotion. Research to understand more clearly whether and how such interventions add value to existing approaches and to identify the biological mechanisms by which they exert beneficial effects will advance the science and practice of symptom management.



GOAL 2: Develop effective, practical, personalized strategies for promoting health and well-being.

It is generally accepted and well established that sustaining healthy behaviors (e.g., good eating habits and regular physical exercise) and modifying unhealthy behaviors (e.g., smoking) reduce risks of major chronic diseases. Many CAM and integrative medicine practitioners and disciplines employ various CAM-based interventions (e.g., meditation or yoga) to help motivate people to adopt and sustain health-seeking behaviors, or they encourage dietary practices (sometimes grounded in traditional medical systems) that incorporate a healthy food philosophy. Newly emerging evidence suggests that CAM use may be associated with greater degrees of health-seeking behavior. While causal relationships between CAM use and healthy behavior have not been established, the claims and preliminary data deserve investigation given the formidable public health challenges in motivating behavior change. Research is needed to explore, clarify, and examine the hypothesis that certain CAM approaches or practices can, in fact, be useful in encouraging better self-care, an improved personal sense of well-being, and a greater commitment to a healthy lifestyle.

GOAL 3: Enable better evidence-based decisionmaking regarding CAM use and its integration into health care and health promotion.

The needs of the public and health care providers (both conventional and CAM) for reliable, objective, evidence-based information regarding CAM remains compelling. Addressing that need remains central to NCCAM's success in fulfilling its legislative mandate. Importantly, evidence gathered during the past several years shows that CAM research findings have influenced CAM use and practice. NCCAM not only will continue to support research that addresses this need but also will continue to provide world-class, evidence-based information on the CAM practices used by millions of Americans.

A Decade of Investment in CAM Research

Growth of the Evidence Base

Two overarching research priorities of NCCAM's first decade addressed (1) the relative paucity of foundational scientific information on the biological properties, safety, and efficacy of most CAM modalities and (2) the need for clinical trials testing the efficacy and safety of selected CAM interventions frequently used by the public. The products of this investment include, first



and foremost, an emerging evidence base—which has grown substantially in both quality and quantity. Basic research and clinical trials, large and small, have yielded results—both “positive” and “negative”—regarding the effects, efficacy, safety, and in some cases, promise regarding CAM. Formal evidence-based analyses and systematic reviews by independent organizations (e.g., the Cochrane Collaboration) point increasingly toward helpful conclusions regarding safety and efficacy—or lack thereof—of specific CAM interventions and practices. These conclusions are influencing the practice guidelines of professional medical societies.

Impact of Research on CAM Natural Product Use and Spending

Major Changes in Frequency of Use Track Research Results

Both the 2002 and the 2007 National Health Interview Surveys examined the use of a number of CAM natural products. Direct comparisons of the extent of use of specific products cannot be made because of differences in the questions asked in the two surveys. However, changes in the relative ranking of the 10 most commonly used products suggest that results from CAM research do influence consumers’ decisions regarding CAM use.

In 2002, fish oils/omega-3 fatty acids ranked eighth, while in 2007 they ranked first. This change correlates with a growing body of evidence suggesting benefit of these products in preventing complications of cardiovascular disease and other significant health problems.

In 2002, the herb St. John’s wort (*Hypericum perforatum*) ranked sixth in use, while in 2007 it ranked twenty-first. This change correlates with publication of research documenting potentially harmful herb-drug interactions involving antidepressants, birth control pills, antiretrovirals used to treat HIV infection, Dilantin or other antiseizure drugs, and warfarin. It also correlates with the publication of several studies that did not find efficacy in major depression or attention deficit hyperactivity disorder (ADHD).

Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

CAM Research Influences Consumer Use and Spending

Two independent lines of evidence—survey data from the NHIS regarding use of dietary supplements and industry sales data—suggest that results of CAM research do influence consumers’ decisions regarding CAM use. Both show changes over time that track with research findings. Specifically, the publication of “negative” results from clinical trials preceded declines in both the frequency of use and the sales of several nonvitamin/nonmineral dietary supplements. Similarly, publication of evidence pointing toward the potential value of omega-3 fatty acids/fish oil preceded increased use and sales. It is also notable that in direct response to the results of NCCAM-funded research, the U.S. Food and Drug Administration has taken action to address concerns about the safety of several specific CAM products.

Basic research and clinical trials, large and small, have yielded results—both “positive” and “negative”—regarding the effects, efficacy, safety, and in some cases, promise regarding CAM.

U.S. Echinacea Sales, 2003–2009

Sales estimates (in millions)



*In a 2003 study, published in the *Journal of the American Medical Association*, researchers evaluated echinacea for efficacy and safety in children with upper respiratory tract infections. In this study, echinacea did not reduce the severity or duration of symptoms.

†In a 2005 study published in *The New England Journal of Medicine*, researchers examined *Echinacea angustifolia* root extracts for effects against rhinovirus (a virus that causes the common cold). None of the echinacea preparations in this study reduced the rate of infection, severity of symptoms, or inflammation. According to the *Nutrition Business Journal*, echinacea sales were negatively affected specifically by the 2005 study.

Source: *Nutrition Business Journal. Supplement Business Report 2010*. Boulder, CO: New Hope Natural Media, Penton Media, Inc. 2010.

Dietary supplement sales data also suggest that new research findings affect use. For example, sales of echinacea have fallen as research findings have indicated that certain preparations do not prevent or reduce the severity of the common cold.



Areas of Scientific Promise

Most importantly, the expanding evidence base includes a large body of intriguing, albeit preliminary, evidence that points toward specific opportunities to improve health care and health promotion using CAM-inclusive strategies. Some examples of these promising leads are included in the table below.

Examples of Important Clinical Research Opportunities and Needs

Mind and Body

- Developing better, comprehensive strategies for management of chronic back pain and defining the roles of acupuncture, spinal manipulation, and massage in those strategies
- Exploring the role of specific promising CAM practices or disciplines (e.g., meditation, yoga, or acupuncture) in developing better strategies for alleviating symptoms (e.g., chronic pain, stress) or in promoting healthier lifestyles
- Exploring the associations between well-characterized pathways of pain processing and acupuncture analgesia or the placebo response
- Exploring the associations of major pathways of cognitive processing and emotion regulation by meditative practices
- Studying the influence of the provider-patient/client interaction, context effects, and the placebo response on outcomes of CAM interventions

Natural Products

- Studying the molecular targets and biological effects of potentially beneficial small molecules that are constituents of natural products or diet (e.g., quercetin, curcumin, or other polyphenols and flavonoids)
- Defining the anti-inflammatory actions of omega-3 fatty acids
- Employing state-of-the-art tools and technologies to study the effects of probiotics on the human microbiome
- Developing evidence regarding the safety profile of certain widely used natural products, including interactions with drugs and other herbals or dietary supplements

Mapping the Path Forward

Over a year-long planning process, NCCAM carefully assessed how recent developments in science, medicine, and health care have affected the Center's strategic approaches in the diverse arena of health care and health promotion interventions. With broad public input, the Center took stock of its existing programs and priorities, the growing evidence base, research capacity, and scientific and public health needs going forward. This assessment led to the following conclusions.

It is important that a portion of the Center's research efforts be specifically targeted toward carefully selected areas of particular public health promise.

Two overarching goals of NCCAM's early history included developing foundational scientific evidence regarding most CAM interventions and building multidisciplinary CAM research capacity where little existed. A relatively broad-based, nontargeted, investigator-initiated research project grant approach was adopted to address these goals. This approach over the past 10 years has served the field very well. Notably, NCCAM's investigator-initiated research project grant stream is increasingly robust. More importantly, it has yielded a substantial body of basic, translational, and clinical research evidence that points toward the potential of a number of CAM interventions to contribute to important public health needs. It is essential that similar opportunities for investigator-initiated research involving less well-studied or -characterized CAM interventions and disciplines be preserved.

At the same time it has become clear that this approach cannot solely be relied upon to ensure that major gaps in knowledge are filled, or that development of a definitive clinical evidence base regarding the most promising research leads are pursued with goal-oriented clarity, timeliness, and efficiency. Therefore, there is a need, particularly given finite resources, to target a portion of NCCAM's investment in research toward development of definitive evidence regarding carefully selected opportunities that offer the most potential for adding significant value to public health.

Framework for Priority Setting. Establishing priorities across the entire field of CAM research is particularly challenging. For a small number of opportunities, available evidence will support a targeted, intensive approach toward development of definitive clinical evidence. For many others, mechanistic or exploratory basic or clinical research data, or the development of translational tools necessary for rigorous clinical investigation, are the most immediate research priorities.

The expanding evidence base includes a large body of intriguing, albeit preliminary, evidence that points toward specific opportunities to improve health care and health promotion using CAM-inclusive strategies.



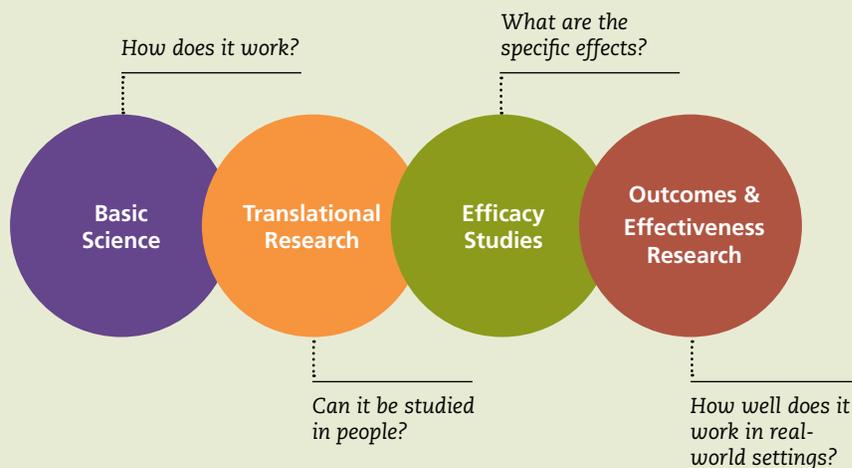


A framework of four factors (as outlined below) will be used by NCCAM in its interactions with investigators and its National Advisory Council to assist in (1) identifying and shaping targeted research initiatives, (2) identifying the most critical knowledge gaps in advancing research on particular CAM interventions, practices, or disciplines, and (3) striking the proper balance between targeted research initiatives and investigator-initiated creativity. The specific weight of these factors will vary, depending on the particular focus of the research.

- **Scientific Promise:** Does a reasonable body of evidence support the potential of the proposed research to lead to improved (1) options or strategies to treat troubling or prevalent health conditions or symptoms or (2) approaches to promote better health and well-being? Is evidence sufficient to support the scope and direction of the proposed research? If not, what research is needed to establish such evidence?
- **Amenability to Rigorous Scientific Inquiry:** Are the key research goals achievable, and are the key research questions amenable to rigorous scientific investigation, given needed and available methods for measurement, translational tools, and technologies? Are potential approaches feasible and scientifically plausible? Do they lend themselves to rigorous quality control? If not, does the proposed research focus appropriately on developing needed methods, tools, and technologies?
- **Potential To Change Health Practices:** Is it reasonably likely that the results of the research or program could lead to changes in the health practices of consumers or health care providers or in the decisions of health policymakers?
- **Relationship to Use and Practice:** Does the proposed project address an important public health concern or scientific information need regarding efficacy, safety, or public use of CAM?

CAM interventions, approaches, and disciplines can and must be studied across the continuum of basic, translational, efficacy, and effectiveness research. Continued emphasis on both *basic research* to understand biological effects and mechanisms of action and on *efficacy studies* to determine specific clinical effects of interventions is essential in developing the scientific evidence base. This plan also articulates the need to strengthen *translational research* required to design and implement definitive clinical research and “real world” *outcomes and effectiveness research* that capitalizes on the reality that many CAM interventions are in widespread public use.

The Range of Research Questions



While the need for clinical research evidence is at the heart of NCCAM’s mission, developing that evidence requires support across the continuum of basic, translational, and clinical research.

- **Basic science:** defining biological effects and mechanisms of action; clarifying scientific hypotheses; supporting development of translational tools
- **Translational research:** identifying and validating biomarkers or other signatures of biological effect; developing and validating measures of outcome; validating treatment algorithms and measures of quality control; developing preliminary clinical evidence regarding efficacy and safety; establishing feasibility or estimates of sample size for future studies
- **Efficacy studies:** determining the specific effects of an intervention under carefully controlled conditions that minimize nonspecific and contextual effects
- **Outcomes and effectiveness research:** studying usefulness and safety in general populations or health care settings

Large clinical trials on the efficacy and effectiveness of CAM interventions require a solid foundation of basic and translational research. Large clinical trials studying efficacy and effectiveness will remain a cornerstone of the CAM clinical research enterprise. Because they are operationally and ethically complex, expensive, and time-consuming, it is imperative that they be designed in ways that maximize the likelihood of clear and unambiguous results (a defining factor of a successful clinical trial). NCCAM's previous strategic plan articulated the importance of understanding mechanisms and biological effects in designing definitive clinical trials. This plan reaffirms that conclusion and further stresses the central importance of translational research in creating a foundation for definitive clinical investigation.

Outcome Measures—Symptoms Matter

Randomized clinical trials are powerful tools for investigating the effects of interventions. The success of a clinical trial in yielding clear and unambiguous evidence depends, among other things, upon the validity and reliability of the techniques used to measure response to the intervention. This presents a particular challenge in designing studies of interventions on troubling symptoms such as pain, nausea, anxiety, or depression, relief of which may be foremost in the minds of patients or clients.



Clinical investigators often rely upon measures of functionality, which can be observed or measured by others, or utilize objective biomarkers that assess physiological variables. While such measures are invaluable and an important part of clinical trial design, they often do not capture the complexity of symptom states or track closely with clinical responses most important to patients. For example, depression may accompany chronic pain, and in some individuals alleviating depression may have a greater impact on overall sense of well-being than pain relief *per se*. In addition, some interventions, particularly mind and body interventions, may affect many aspects of health, so it is often important in a clinical trial to measure the effect of the intervention on a number of health domains and symptoms.

These and similar challenges are the focus of the science of patient-reported outcomes (PROs), a discipline that is critical to NCCAM's research portfolio. New electronic tools are being developed to permit more accurate and frequent assessment of symptoms. NCCAM is taking a leadership role in PROMIS, a trans-NIH Common Fund program that is developing computer-assisted methods to strengthen the assessment of patient-reported outcomes. These issues will continue to be of central importance in designing clinical research studies to test the effects of CAM interventions in alleviating symptoms or improving health and well-being.



Given the widespread use of CAM, opportunities exist to employ clinical outcomes and effectiveness research methodologies in developing useful “real world” evidence about application of specific CAM approaches to health care and health promotion. Most CAM interventions are readily available to the public, and many are used regularly in the health care and health promotion practices of individuals and professions. There are increasingly viable opportunities to take advantage of this fact by employing the methods and tools of clinical outcomes and effectiveness research to develop (1) evidence, based in real-world practices and use, about the potential of CAM interventions, modalities, and disciplines to contribute to better treatment and health promotion and (2) data needed to design maximally informative clinical trials. Pursuing such research will require creative collaboration with experts who confront similar challenges and opportunities in studying outcomes of procedures or multicomponent interventions introduced into and adapted in clinical practice (e.g., surgery, psychotherapy, and behavioral change).

Better strategies for management of chronic pain are an area of public health need and scientific promise in CAM research. National survey data show that the majority of Americans’ use of CAM for treating specific health problems is aimed at ameliorating symptoms, particularly for chronic pain. Furthermore, emerging data from the past 10 years point toward specific scientific opportunities for research with the potential to contribute to better integrative approaches for care and treatment of chronic pain.

Research on the contributions of CAM interventions, practices, and disciplines in promoting or supporting health-seeking behavior is another area of special public health need and scientific opportunity. Although much of CAM use by Americans is aimed at improving general health and well-being, most CAM research to date has focused on the application of CAM practices to the treatment or prevention of various diseases and conditions. While scientific and operational challenges are significant in pursuing a health-promotion research



agenda, compelling opportunities exist to explore the potential role of CAM practices, interventions, and disciplines in promoting or supporting health-seeking behavior.

NCCAM must continue to play a central role in addressing the need for reliable, objective information based on scientific evidence so that consumers and health care providers can make well-informed decisions. Although a vast amount of information about CAM is available in the public domain, much of it is incomplete, misleading, inaccurate, or based on scientifically unproven claims. Much of the public's use of CAM occurs in the absence of advice or guidance from health care providers (conventional or CAM). These facts reinforce the need for reliable, objective, evidence-based information regarding the usefulness and safety—or lack thereof—of CAM.

Strategic Objectives

This plan seeks to address three long-range goals, discussed earlier and summarized here:

GOAL 1: Advance the science and practice of symptom management.

GOAL 2: Develop effective, practical, personalized strategies for promoting health and well-being.

GOAL 3: Enable better evidence-based decisionmaking regarding CAM use and its integration into health care and health promotion.

The plan is organized around the following five strategic objectives, which are summarized below and discussed in greater detail in the ensuing five chapters. Each strategic objective serves, to varying and often overlapping degrees, the above three long-range goals.

Strategic Objective 1: Advance research on mind and body interventions, practices, and disciplines.

Strategic Objective 2: Advance research on CAM natural products.

Strategic Objective 3: Increase understanding of “real world” patterns and outcomes of CAM use and its integration into health care and health promotion.

Strategic Objective 4: Improve the capacity of the field to carry out rigorous research.

Strategic Objective 5: Develop and disseminate objective, evidence-based information on CAM interventions.

STRATEGIC OBJECTIVE 1

ADVANCE RESEARCH ON MIND AND BODY INTERVENTIONS, PRACTICES, AND DISCIPLINES

The term CAM includes a large and diverse group of interventions, practices, and disciplines that are based in physical procedures or techniques administered or taught to others by a trained practitioner or teacher. They are used to improve health and well-being and in the treatment of illness or symptoms such as chronic pain or stress.

These interventions, practices, and disciplines are grouped together in this plan as mind and body* approaches because, from a research perspective, they all share a set of characteristics that create similar challenges in designing rigorous and definitive clinical investigations of their benefit and safety. For example, (1) it is generally difficult or impossible to mask practitioners and/or participants

*Terminology: As used in this plan, *mind and body* encompasses interventions from the three domains of mind/body medicine, manipulative and body-based practices, and energy medicine.

Examples of CAM Mind and Body Interventions

- Acupuncture
- Breath practices
- Meditation
- Guided imagery
- Progressive relaxation
- Tai chi
- Yoga
- Spinal manipulation
- Massage therapy
- Feldenkrais method
- Alexander technique
- Pilates
- Hypnosis
- Trager psychophysical integration
- Reiki
- Healing touch
- Qi gong
- Craniosacral therapy
- Reflexology



involved in clinical research, (2) claims about benefit often relate to subjective clinical outcomes, (3) in practice, the interventions are often individualized, or they are complicated procedures that are difficult to systematize or characterize fully, and (4) means to objectively measure the impact of the interventions on important biological processes are frequently lacking, particularly those that purport to act through processes not understood or well characterized by modern science.

The public's interest in at least some of these approaches is growing. For example, NHIS data show a significant increase between 2002 and 2007 in the use of mind and body approaches such as controlled breathing practices, meditation, massage therapy, and yoga. There is also great interest across many health care disciplines regarding the potential application of some mind and body approaches to a variety of challenging health problems and to health promotion. In large part this interest is based on emerging evidence from research carried out over the past decade. For example, a large body of clinical research evidence now suggests that practices such as meditation and yoga can enhance quality of life, reduce psychological stress, and improve some mental health outcomes. At the same time, a growing body of basic research evidence suggests that mindfulness and other meditation practices engage neurobiological mechanisms known to be involved in cognition, emotion regulation, and behavior. In addition, mainstream clinical practice guidelines include evidence-based recommendations that spinal manipulation, acupuncture, and massage be considered for some patients with chronic back pain.



Specific and Nonspecific Outcomes

Many of the challenges of studying mind and body interventions are illustrated in the current state of research on acupuncture. Centuries of experience suggesting that acupuncture can be helpful in treating pain have stimulated considerable interest in scientific investigation of this ancient treatment, even though traditional teachings based on meridians and the flow of “qi” are difficult to reconcile with contemporary understanding of anatomy and neurophysiology.

The accumulated data from many clinical trials in a variety of pain conditions present a complicated picture. In efficacy-design trials where comparison has been made between “real” acupuncture and a “sham” treatment designed to be subjectively identical, differences have generally been small and not statistically significant. On the other hand, in effectiveness-design trials for a variety of conditions where acupuncture has been compared to standard care, acupuncture generally produces superior pain relief. For example, results from a series of large randomized trials supported by the German government comparing “real” and “sham” acupuncture show minimal differences in relief of pain from osteoarthritis and low-back pain. However, acupuncture plus standard care (following clinical practice guidelines) was found to yield a statistically significant and clinically meaningful superiority to standard care alone.

Thus, the current body of efficacy research provides little clinical evidence for specific effects of “real” acupuncture. At the same time the observation of substantial pain relief in effectiveness-design studies cannot be dismissed.

Research is warranted to better understand (1) the specific and the nonspecific effects involved and (2) whether either or both can be better and more intentionally employed to improve upon current strategies for treating pain. Finally, future clinical research on acupuncture must be carefully designed to ensure that controls are optimally suited for the research question being addressed.



Research Challenges and Needs

Investigators studying mind and body interventions face a number of scientifically interesting and important challenges. Foremost among them is the need to carefully define the most important research questions to be addressed, to choose appropriate experimental controls and study designs to address these questions, and to determine and validate key study design features such as the optimal frequency or duration of the intervention to be studied and measures of effect and outcome.



For example, if the research questions in a clinical trial focus on refining technique or determining a mechanism of action, incorporating a sham intervention in the study may be most appropriate. Alternatively, in cases where the most compelling and clinically relevant questions center on whether or how the intervention adds value to existing approaches (e.g., in managing a chronic symptom), an effectiveness design that entails comparison with a different treatment (rather than with a sham/placebo intervention) may be most appropriate.

Better understanding of the contributions of both specific and nonspecific effects influencing outcomes and the potential for insight into exploitation of either or both to improve symptom management or general health and well-being is needed.

For some mind and body approaches the most pressing research questions require basic or translational research aimed at developing methods or establishing amenability to scientific investigation. For example, traditional explanations for the mechanisms of action of some mind and body approaches involve processes that are not well characterized or even understood from a scientific perspective. In such cases, inability to measure objectively either the intervention itself or its effects on physiological processes is prohibitive to the design of rigorous and reproducible clinical studies. Developing such measures is therefore a more immediate research priority than efficacy studies.

For many mind and body approaches, challenges in designing and executing rigorous studies of mind and body approaches relate to the fact that most involve physical activity or procedures, or they are administered or practiced over extended periods of time, or their use in the real world is highly individualized. It is also often the case that true masking of study participants involved in a procedure (e.g., in a study of massage or meditation) is a practical impossibility. These and other problems have been encountered in other fields of biomedical research, and lessons learned in those contexts can provide important guideposts toward creative clinical research methodology.

Finally, recent research has documented the importance of contextual or nonspecific effects in the encounter between health care practitioners and their patients or clients. For example, communication on the part of the practitioner of empathy or the possibility of a positive outcome and duration of interaction can influence clinical outcomes, independent of the specific effects of interventions that the practitioner may employ. A number of mind and body interventions involve encounters between a health care provider and a patient or client in which these and other nonspecific contextual factors, expectancy, or the placebo response may contribute importantly to outcomes—particularly those involving subjective or patient-oriented benefits. Indeed, many CAM and integrative medicine practitioners intentionally seek to employ these effects to improve outcomes. Better understanding of the contributions of both specific and nonspecific effects influencing outcomes and the potential for insight into exploitation of **either or both** to improve symptom management or general health and well-being is needed.

Strategies

Emerging evidence of promising clinical effects of many mind and body approaches points toward important opportunities to advance the science and practice of symptom management and of health promotion. In many cases the evidence is strengthened by an intriguing and growing body of basic and clinical research employing the tools and technology of the fields of neuroscience, psychoneuroimmunology, psychology, behavioral medicine, physical medicine, and biomechanics. Addressing the scientific and operational challenges confronting the study of promising mind and body interventions requires continued efforts to foster multidisciplinary collaboration that aims to engage the expertise and experience of CAM practitioners and the tools and technologies of a variety of scientific disciplines.

Strategy 1.1: Harness state-of-the-art technologies and approaches of the neurobiological, biomechanical, behavioral, and biological sciences to:

- **Elucidate biological effects and identify mechanisms of action of mind and body interventions, practices, and disciplines**
- **Study the interactions between these interventions and the effects of expectancy, the placebo response, and the provider-patient/client relationship**



Understanding the Engagement of Major Pathways of Emotion Regulation by Meditative Practices



Clinical and laboratory studies of mindfulness meditation are yielding a growing body of evidence that meditation affects the mind, the brain, the body, and behavior in ways that have potential to treat many health problems and to promote healthy behavior.

For example, recent research suggests that systematic mindfulness training and other meditation practices influence areas of the brain involved in regulating awareness, attention, and emotion. Brain-imaging studies suggest that more mindful people may be better able to regulate emotional reactions or have improved self-awareness. Other research suggests that mindfulness training is associated with changes in the physical structure of the brain. Several studies suggest that meditative practices can positively affect immune function. Many of the beneficial physical effects of mindfulness training could be attributable to learning how to cope better with stress.

Ongoing NIH-supported research is investigating the use of mindfulness training in treating specific pain conditions, overeating and obesity, irritable bowel syndrome, insomnia, myocardial ischemia, and substance abuse. Mindfulness meditation is also being explored as a means of facilitating and sustaining healthy behavior change, such as smoking cessation and healthier eating habits.

- **Build a solid biological foundation for translational research needed to carry out clinical studies.**

Developing insight into biological and physiological effects and mechanisms of action of mind and body interventions is critically important in developing translational research tools and designing and executing maximally informative clinical research. It also is a crucial component of the scientific evidence base guiding clinical practice and public use and has significant potential to inform other fields of biomedical research.

Strategy 1.2: Support translational research to build a solid biological foundation for studies of efficacy or effectiveness of mind and body interventions or disciplines.

Rigorous study of all clinical interventions requires well-established methodology that has undergone careful preliminary assessment and feasibility testing. Large clinical studies are an essential component of the evidence base regarding clinical efficacy or effectiveness. To implement such studies, treatment algorithms must be developed and validated and feasibility of accrual must be established. Methods need to be in place to measure consistency and fidelity of protocol implementation, control for practitioner variability, and monitor adherence of participants. In addition, well-characterized and meaningful clinical and laboratory outcome measures are needed to accurately assess the scope and magnitude of effects or to definitively discern a lack thereof.

Rigorous study of all clinical interventions requires well-established methodology that has undergone careful preliminary assessment and feasibility testing.

Investing in development of good translational tools is essential. This investment will increase the quality and quantity of evidence garnered from large-scale clinical research, and it will help ensure that clear conclusions can be drawn from the outcomes observed. It will also augment abilities to compare results across different studies, which is essential in building a clinically useful evidence base.

Mind and Body Translational Research Needs: Selected Examples

- Developing and validating methods to assess and document interactions between providers and patients/clients so consistency can be measured or interventions reproducibly applied to other populations
- Developing and validating better objective outcome measures relevant to particular CAM interventions
- Developing and validating better measures of subjective outcomes
- Studying nonspecific contextual factors important in the interaction between CAM professionals and their patients or clients
- Defining the optimal frequency or duration of a particular CAM intervention for study in subsequent, more definitive clinical trials
- Assessing feasibility and accrual potential—e.g., implementing a particular treatment algorithm; determining the ability to recruit sufficient participants

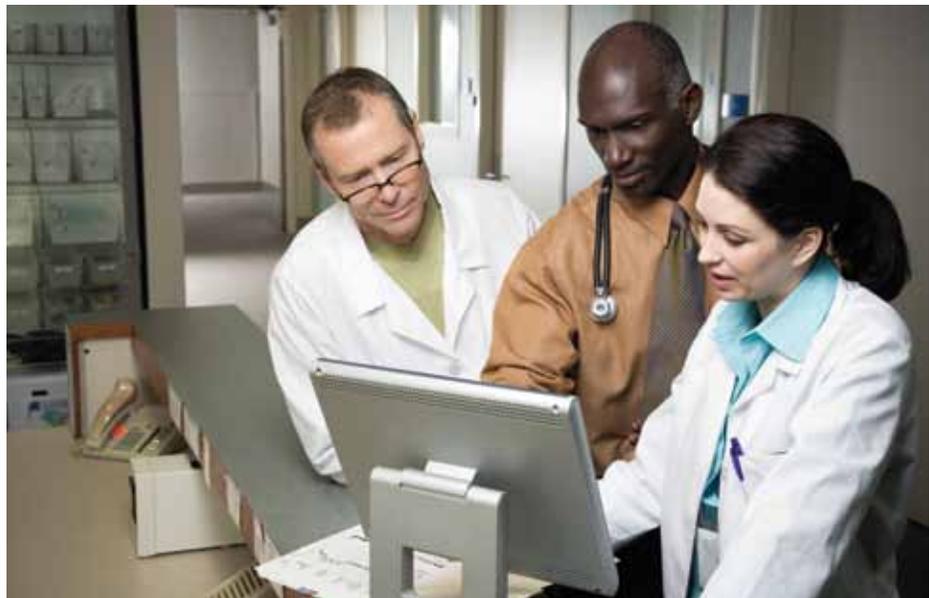
Strategy 1.3: Support clinical evaluation and intervention studies of mind and body interventions.

Decisions regarding clinical research design—for example, whether to use a sham or “other treatment” control—should follow from the research question being addressed.

In studying this set of CAM interventions, it is particularly important that the research questions most relevant to advancing health and well-being are carefully defined and clearly articulated. Major decisions regarding clinical research design—for example, whether to use a sham or “other treatment” control—should follow from this question.

It is also critical to understand a number of considerations related to the specific population under study. Is there a standard of care or an accepted treatment for the disease or condition? What would study participants be willing to accept (e.g., treatment burden, random assignment), and how does that affect the likelihood of completing the study? How might factors such as expectancy influence responsiveness or outcomes to the intervention? Is the CAM use intended to treat conditions (e.g., pain, infection, sleeplessness), change behavior (e.g., support smoking cessation, improve medication adherence), promote overall health (e.g., healthy behavior and lifestyle modification), or a combination of these goals?

Very importantly, this work calls for creative clinical research designs and approaches that draw on the experience of other fields of biomedical and behavioral research studying procedural interventions (e.g., surgery), behavior change (e.g., cognitive-behavioral therapy), or outcomes of health interventions in real world or practice-based populations.



Better Strategies for Managing Back Pain

By any measure, low-back pain is a huge public health problem. It affects approximately 25 percent of adults. While acute back pain usually resolves completely within weeks, pain becomes a chronic problem in 10 to 15 percent of cases. Costs associated with back and neck pain account for a large proportion of, and are increasing more rapidly than, overall health care expenditures.

Individuals searching for relief from chronic back pain pursue many treatment options, including opioids, injections, surgery, physical therapy, spinal manipulation, yoga, exercise therapy, acupuncture, massage, and cognitive-behavioral therapy. Often patients try different approaches, sometimes in consultation with a provider and sometimes on their own, as they search for helpful strategies. Chronic back pain is, by far, the most frequent health problem for which Americans turn to CAM. While data suggest that some interventions, both conventional and CAM, help some individuals, there is broad agreement among health care providers that none are fully satisfactory.

There is an emerging consensus that developing improved strategies for managing chronic back pain will require fresh thinking informed by:

- A better understanding of natural history and prognostic factors
- Improved diagnostic criteria and tools
- Application of state-of-the-art technologies to better elucidate biomechanics, central nervous system responses, emotional and cognitive influences, behavior, and genetics
- Pragmatic trials and outcomes research.



STRATEGIC OBJECTIVE 2

ADVANCE RESEARCH ON CAM NATURAL PRODUCTS

CAM also includes a large and diverse group of orally or topically administered substances such as herbal medicines, botanicals, and probiotics referred to in this plan as CAM natural products.* They are widely marketed and readily available, often sold as dietary supplements. Although research has explored many of these products, in most instances scientific evidence regarding efficacy or safety to support or refute their use is insufficient. Nonetheless, they are used for the treatment of health problems or as a means to improve or maintain general health. Herbal medicines and botanicals are also prominent elements of most systems of traditional medicine, and this vast body of historical experience with them may provide leads for further scientific investigation. These approaches are grouped together in this plan because research on CAM natural products relies heavily on the methods and tools of the scientific disciplines of pharmacology and pharmacognosy.

*Terminology: CAM natural products replaces *biologically based practices* used previously by NCCAM. The term *biologically based* is no longer used because other CAM modalities also exert biologically based effects. *Natural* refers to the source in nature of most CAM natural products. It does not imply safety.





Research Challenges and Needs

In recent years, several issues have emerged that are critical to defining future directions for research on CAM natural products funded by NCCAM.

Need for Mechanistic Research and Signatures of Biological Effect

During NCCAM's first decade, a number of large, randomized efficacy trials of CAM natural products were launched. In most cases, study design was based on a combination of previous clinical experience and preliminary clinical studies. Generally, however, the studies failed to show hypothesized clinical outcomes. As a result, many questions about key aspects of study design (e.g., choice of product, dose, schedule of administration, choice of outcome measures) have been raised, casting uncertainty about the validity of the observed “negative” findings.

Thus it has become clear that maximally informative clinical efficacy studies of CAM natural products should be based on a scientifically sound hypothesis grounded in basic mechanistic research. In addition, the level of mechanistic insight should be sufficient to allow measurement of signatures of biological effect, biomarkers, or surrogate markers relevant to the hypothesis and validated in preliminary translational research, in addition to clinical outcome. This approach will increase greatly the information gleaned from efficacy trials, lessen the likelihood of uncertain “negative” outcomes, and elucidate leads for further research and development.

The Continuum of Exploratory Research and Targeted Development

At one end of the continuum of research aimed at building rigorous evidence regarding CAM natural products are exploratory studies that have the potential to yield new, fundamental, mechanistic, or physiological insight and to identify signals of useful effects in ongoing clinical experience. This work also allows for serendipitous discoveries. The range of CAM natural products appropriate for such exploratory research is extensive and is best supported through investigator-initiated research project grants.

At the other end of the continuum are targeted and goal-directed studies (e.g., large clinical trials) aimed at developing definitive clinical evidence. Given available resources, the expectation is that the number of CAM natural products entering large, advanced clinical trials will be small and that these CAM natural products will have been designated as high priority by NCCAM because of particularly promising preliminary results in smaller studies or because of a compelling public health need (e.g., safety information).

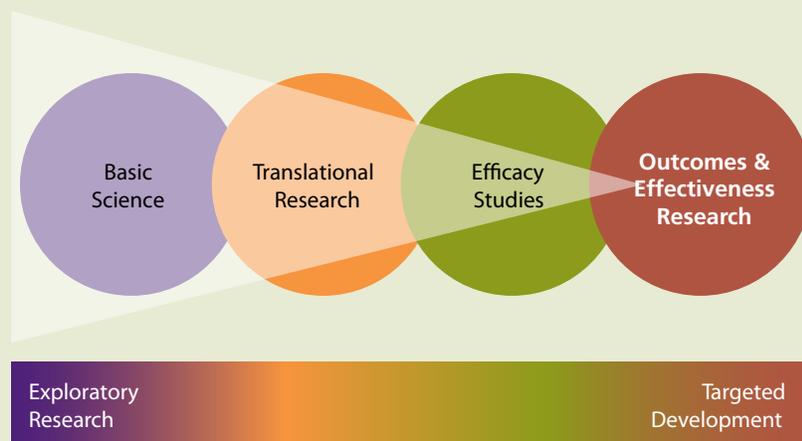


CAM Natural Products Research

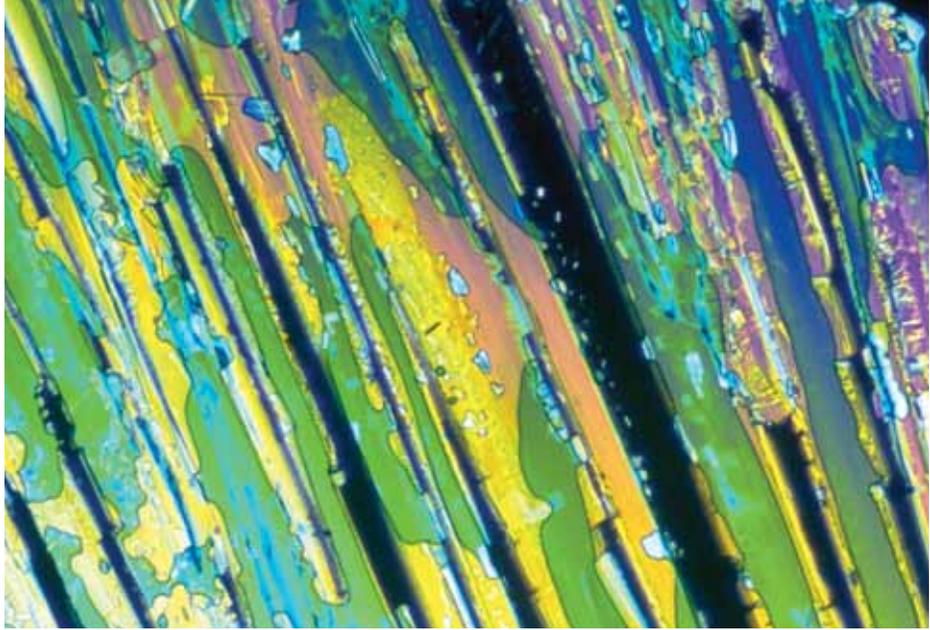
Categories of CAM Natural Products

- Dietary supplements
- Herbal or botanical products
- Traditional medicine formulations
- Folk medicines
- Homeopathic remedies
- Probiotics
- Food-based phytochemicals

The Continuum of CAM Natural Products Research



Although CAM natural products are readily available to consumers, rigorous evidence regarding usefulness and safety of many does not exist. Research priorities for most are at the exploratory end of the research and development continuum. Targeted development and large clinical trials will be warranted only when basic and translational research allows rigorous testing of evidence-based hypotheses. For most natural products, better understanding of safety and interactions with drugs or other natural products is needed.



Historically, NCCAM has supported the vast majority of basic and translational research and development activities relevant to CAM natural products through general solicitations for investigator-initiated research grants. This broad-based approach has yielded a large body of basic mechanistic information and promising leads for future research, and support of similar research in the future remains essential. Going forward, however, it has become clear that a portion of NCCAM's natural product efforts should be targeted to more directed translational and clinical research needed to expedite the development of the evidence base regarding specific, high-priority CAM natural products.

There remain major gaps in knowledge about the adult and pediatric safety profiles of most CAM natural products.

Need for Continued Attention to Product Integrity and Safety

During its first decade, NCCAM led NIH in establishing rigorous standards and policies regarding the quality and integrity of CAM natural products used in both mechanistic and clinical research supported by the Center. The overarching goal of these efforts has been to increase the likelihood that the research will yield both definitive and reproducible results. NCCAM's Natural Product Integrity Policy (<http://nccam.nih.gov/research/policies/naturalproduct.htm>) has been updated to better link the stringency of requirements for informational detail with the stage of a natural product's investigation along the continuum of exploratory research and targeted development.

Nonetheless, there remain major needs for improved methodology for characterizing and analyzing natural products. Furthermore, it remains true that information about the adult and pediatric safety profiles of most CAM natural products, including their interactions with drugs or other natural products, is limited. Claims that these products have fewer side effects or are "safer" than conventional pharmaceutical alternatives are generally unproven and sometimes erroneous, as well documented by reports of adverse herb-drug or herb-herb interactions, product contamination, or product adulteration.

Strategies

The primary scientific challenge in studying CAM natural products is bringing the available and emerging tools, technologies, and approaches of the sciences of pharmacology and pharmacognosy to bear on the study of chemically and biologically complicated interventions and approaches. Increasingly, however, researchers are taking advantage of state-of-the-art technologies and systems biology approaches to better understand the biological effects of these products and to more effectively study their potential to contribute to health and well-being.

Strategy 2.1: Harness state-of-the-art “omics” and other high-throughput technologies and systems biology approaches of the sciences of pharmacology and pharmacognosy to:

- Elucidate biological effects, mechanisms of action, and safety profiles of CAM natural products
- Study interactions of components with each other and with host biology
- Build a solid biological foundation for translational research needed to carry out clinical studies.



These tools and technologies offer considerable promise in addressing the need for better methods to qualitatively, quantitatively, and comprehensively capture the chemical diversity of complex CAM natural products. “Omics” and other high-throughput technologies also offer promise for investigating the validity and potential of hypothesized but largely unsubstantiated additive or synergistic effects at the core of many herbal medicine traditions. Greater clarity about the biological activities of individual components should facilitate study of possible synergistic effects. For example, most techniques for standardization and characterization of herbal medicines currently in use focus on the analysis of a limited number of abundant or easily detected and measured “marker” compounds, which may or may not be relevant to biological or clinical effects.

Studying the Effects of Probiotics on the Human Microbiome



Probiotics, as defined by the World Health Organization, are “live microorganisms which, when administered in adequate amount, confer a health benefit.” They are available to consumers in foods (e.g., yogurt) and as dietary supplements. In theory they introduce deficient or absent microbes (usually bacteria) that are normally present and believed to be beneficial. There is scientific evidence that probiotics are useful in treating some forms of diarrhea, and emerging evidence that they may be helpful in treating a number of other conditions. NCCAM supports a large portfolio of research on probiotics.

At the same time, the trans-NIH Human Microbiome Project is exploring the complex microbial ecology of the body, using new technologies such as high-throughput sequencing and comparative and functional genomics. This work is yielding important insights into the functional significance of many normally present microbial species, including their roles in human health and disease.

NCCAM is closely aligning its probiotic research with the work of the NIH Human Microbiome Project. This collaboration seeks to provide additional insights into the potential applications of probiotics and to provide additional platforms for advancing understanding of the human microbiome. NCCAM is also working closely with other NIH institutes and centers, the Food and Drug Administration, and the U.S. Department of Agriculture to share resources and expertise, harmonize technology standards and translational tools, develop biomarkers, and facilitate progress in research and regulatory policy.



Strategy 2.2: Support translational research to build a solid biological foundation for research on CAM natural products to:

- **Develop and validate sensitive and reliable translational tools to detect and measure mechanistically relevant signatures of biological effect and to measure efficacy and other outcomes**
- **Conduct preliminary/early phase studies of safety, toxicity, dosing, adherence, control validation, effect/sample sizes, ADME (absorption, distribution, metabolism, and excretion), and pharmacokinetics**
- **Build upon established and proven product integrity policies and processes.**

Clinical intervention studies must be grounded on a solid foundation of information derived from basic and clinical translational research. This work requires multidisciplinary research collaborations between basic and clinical scientists.

Maximally informative studies require careful characterization of the intervention, determination of suitable outcome measures, validation of laboratory measures of biological effect, an understanding of pharmacokinetics and pharmacodynamics, rigorous attention to product integrity, and other steps necessary to ensure that later research is as informative and definitive as it can be.

Specific efforts are needed to explore the adult and pediatric safety profiles of CAM natural products—including their interactions with pharmaceuticals and with other CAM natural products—in widespread, self-care use by the public.

Clinical intervention studies must be grounded on a solid foundation of information derived from basic and clinical translational research. This work requires multidisciplinary research collaborations between basic and clinical scientists.

Basic Research on CAM Natural Products

For centuries, plant-derived medicines have been a cornerstone of most folk medicine and traditional medical systems. This use is sustained by perceptions of effectiveness, although the benefits and risks of many of these traditional remedies are poorly documented. This experience does, however, provide fertile ground for identifying new treatments for many health problems. Indeed, many of the most important modern drugs have deep roots in traditional medicine.

Curcumin provides a good example. It is a component of turmeric, the spice that gives a golden yellow color to curries, and has been used in Chinese and Ayurvedic medicine to treat a host of health problems, including rheumatism, fever, intestinal disorders, amenorrhea, and topical treatment of wounds. Recent research supported by NCCAM and others has revealed significant effects of curcumin on a number of cell-signaling pathways relevant to disease processes: *in vitro* curcumin can be shown to inhibit NF-K activity, COX-2 and 5-LOX expression, and to reduce the formation of cytokines.

This body of basic research provides information critical to the formulation of hypotheses for disease treatment. It also allows the design of better clinical research since changes in gene expression may provide a biological signature of the effects of this promising compound. It also points toward leads for research to deal with the problem that curcumin, as an isolated compound, has limited bioavailability.

Sorting through the vast global experience to identify other promising compounds for targeted research and development is an enormous strategic challenge. Recent advances in metabolomics, genomics, chemical separation, molecular characterization, and high-throughput screening provide new tools to address this challenge. These state-of-the-art methodologies should also prove helpful in characterizing chemical and biological properties and ultimately in designing better and more informative clinical studies.



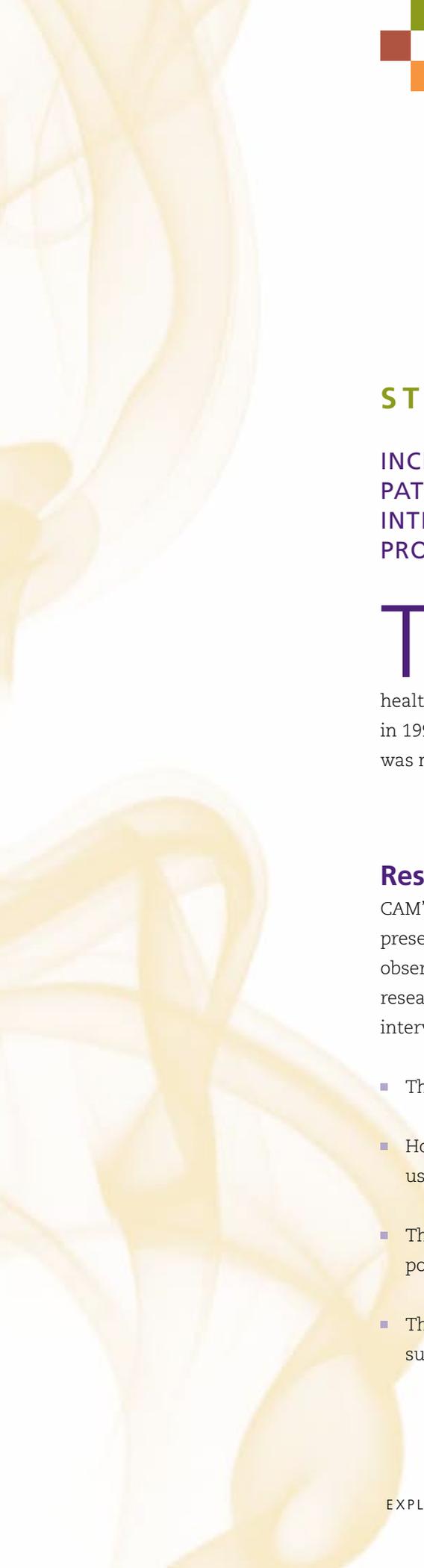


Strategy 2.3: Support targeted large-scale clinical evaluation and intervention studies of carefully selected CAM natural products.

A successful clinical trial is definitive in addressing its primary goals and also yields as much information as possible, whether or not the hypothesized clinical benefit is observed. This measure of success is especially important for large clinical trials, given their inherent complexity, expense, and risks. To help ensure success, large clinical trials should be based on a strong mechanistic hypothesis supported by basic research and exploratory clinical studies; a sound body of pharmacokinetic/ADME information; and the translational tools (e.g., laboratory measures of biological effect) needed to maximize knowledge gained, including measurement of ancillary biomarkers or other signatures of biological effect. Clinical and laboratory measures of effect must be sensitive enough to detect reasonable and realistic clinical effects or to determine with a high degree of certainty that a negative result is truly negative.

NCCAM’s investment in large clinical trials of CAM natural products should be highly selective and only made when there is ample scientific and public health justification (see Framework for Priority Setting in the Introduction). This work requires a well-defined and transparent process for priority setting and a milestone-driven and transparent approach to oversight of progress in the various steps of clinical evaluation.

NCCAM’s investment in large clinical trials of CAM natural products should be highly selective and only made when there is ample scientific and public health justification.



STRATEGIC OBJECTIVE 3

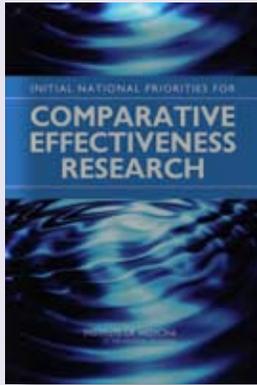
INCREASE UNDERSTANDING OF “REAL WORLD” PATTERNS AND OUTCOMES OF CAM USE AND ITS INTEGRATION INTO HEALTH CARE AND HEALTH PROMOTION

Two defining features of CAM in the United States are its widespread use by the public and a relative paucity of research evidence regarding efficacy or safety to guide decisionmaking about that use by individuals, health care providers, and health policymakers. Indeed, NCCAM was established in 1998 because Congress believed that a concerted research effort at the NIH was needed to address these gaps in scientific evidence and public information.

Research Opportunities and Needs

CAM’s extensive use by both adults and children in the general population presents opportunities to use tools and methods of the disciplines of observational, survey, epidemiology, outcomes, health services, and effectiveness research to help address a number of information needs about CAM interventions, practices, and disciplines, including:

- The frequency and characteristics of CAM use
- How and why individuals and health care providers decide whether or not to use CAM approaches
- The benefits, risks, and cost-effectiveness of CAM use in the general population
- The potential role of CAM interventions, practices, or disciplines in supporting healthy lifestyles and well-being.



IOM* Priorities for Comparative Effectiveness Research Involving CAM Approaches

- Compare the effectiveness of mindfulness-based interventions (e.g., yoga, meditation, deep-breathing training) and usual care in treating anxiety and depression, pain, cardiovascular risk factors, and chronic diseases
- Compare the effectiveness of acupuncture for various indications using a cluster-randomized trial
- Compare the effectiveness of dietary supplements and usual care in the treatment of selected high-prevalence conditions
- Establish a prospective registry to compare the effectiveness of treatment strategies for low-back pain without neurological deficit or spinal deformity

*Institute of Medicine (part of the National Academies)

Information about these and related matters derived from rigorous population-based research has significant potential to help in (1) identifying and shaping research priorities and initiatives, (2) building evidence needed to advance research on specific promising interventions, practices, or disciplines, and (3) informing and shaping health care policy. With respect to health policy, it is noteworthy that 4 of the top 100 topics identified by the Institute of Medicine as priorities for comparative effectiveness research involve CAM approaches.

Strategies

Strategy 3.1: Support survey and epidemiological research to:

- Better understand patterns of adult and pediatric CAM use both at the national level and within specific demographic subpopulations
- Better understand decision-making processes of individuals and practitioners regarding CAM use
- Study the safety and risks of adult and pediatric CAM use
- Develop data needed to inform future research hypotheses or studies.

Since its inception NCCAM has supported a variety of epidemiological studies of CAM use. Most prominent have been the population-based NHIS surveys, carried out in 2002 and 2007, and many secondary analyses of the public-use data sets derived from them. This body of work has been extremely important in shaping understanding of CAM use at both the national level and within specific populations. That understanding has, in turn, been instrumental in shaping NCCAM's strategic thinking and research priorities. For example, NHIS data regarding CAM use have pointed toward the first two overarching goals of this strategic plan (better strategies for symptom management and better strategies for healthier lifestyles). And together with clinical trial data and evidence-based recommendations suggesting the potential usefulness of several specific CAM practices (spinal manipulation, acupuncture, and massage), NCCAM is targeting research on chronic back pain as a high priority for future investment.

Observational data are instrumental in identifying research priorities, informing the hypotheses and designs of intervention studies, and shaping public information activities.

Observational data inform both the hypotheses and the designs of specific CAM research projects. For example, they help justify the need for a particular study, establish feasibility and accrual potential, or permit evidence-based estimates of sample size.

Understanding the scope and nature of public use of CAM and the decision-making processes behind that use is critically important in shaping the communication and public information activities of NCCAM and other organizations. For example, they help define priorities across a spectrum of health conditions and CAM approaches. They also shape content so that it best addresses the questions and needs of the end users.



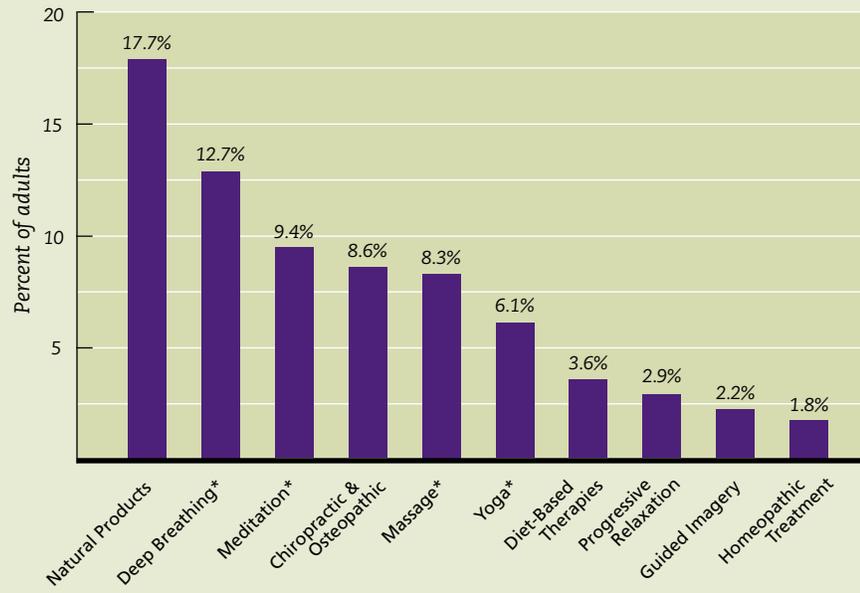
Specific Use of CAM in the United States, 2007

***Therapies with significant increases between 2002 and 2007**

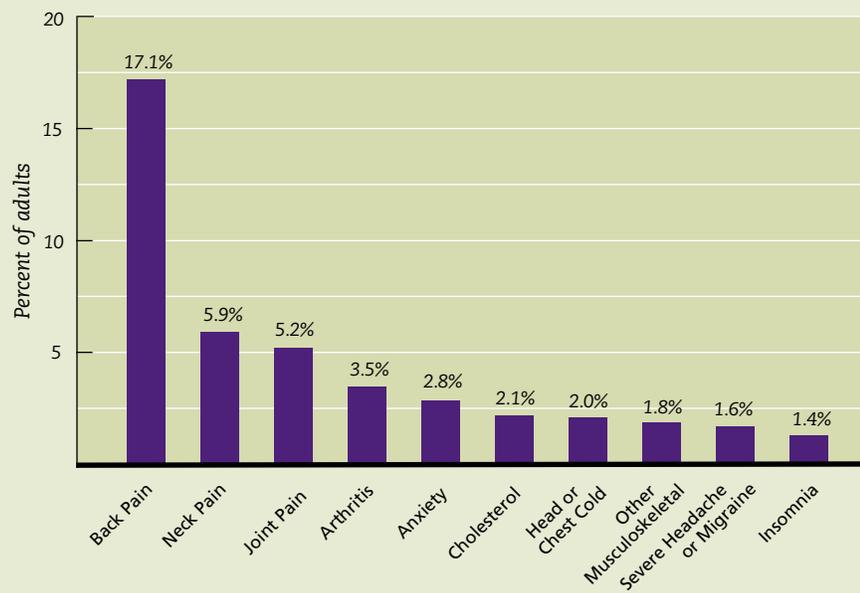
	2002	2007
Deep breathing	11.6%	12.7%
Meditation	7.6%	9.4%
Massage	5.0%	8.3%
Yoga	5.1%	6.1%

Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

10 Most Common CAM Therapies Among Adults

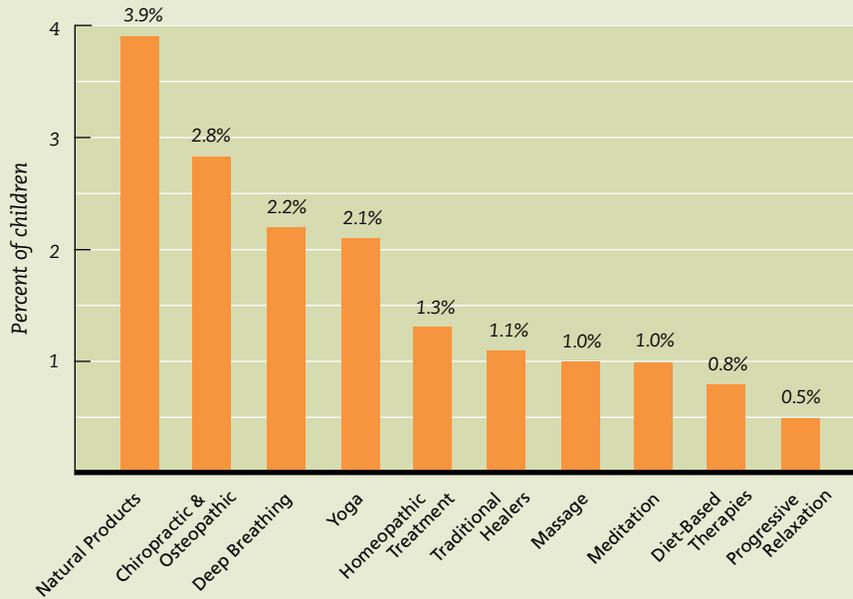


Diseases/Conditions for Which CAM Is Most Frequently Used Among Adults



Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

10 Most Common CAM Therapies Among Children



Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.

Diseases/Conditions for Which CAM Is Most Frequently Used Among Children



Source: Barnes PM, Bloom B, Nahin R. CDC National Health Statistics Reports #12. *Complementary and Alternative Medicine Use Among Adults and Children: United States, 2007*. December 2008.



Going forward, NCCAM will continue to build upon the body of both directed and investigator-initiated observational research that addresses the need for better understanding of (1) patterns of CAM use and the decision-making processes that drive this use and (2) the safety of CAM interventions, in both adults and children.

Strategy 3.2: Develop research examining the contributions of specific promising CAM approaches to better treatment and health promotion using the real-world methods and tools of the disciplines of observational, outcomes, health services, and effectiveness research.

It is important to seek out opportunities to take scientific advantage of the extensive use of CAM in the general population to help address the gaps in evidence that confront the public and health care providers. The disciplines of observational, outcomes, health services, and effectiveness research offer a number of tools, methods, and pragmatic study designs for gathering useful evidence regarding CAM interventions and disciplines on a larger scale than typical clinical trials.

For example, some specific CAM interventions or disciplines are covered by some health insurance providers and not covered by others. It should be possible to take scientific advantage of this natural experiment to develop insight into the safety, effectiveness, and cost-effectiveness of these approaches.

Health provider networks, practice-based clinical research networks, and integrative medicine practices provide important venues in which to develop real-world evidence across a broad array of outcome measures regarding the effects and effectiveness of CAM approaches and their integration into strategies for treatment and health promotion. Practice-based research provides an important setting in which to study the complex interplay of intervention, the patient-provider relationship, and other important contextual and environmental factors involved in health care and health promotion. Indeed, many CAM and integrative care practices actively seek to employ these factors. Population-based and practice-based research strategies also offer great potential for developing evidence regarding the effectiveness of CAM-related interventions in engaging individuals in health-promoting behaviors and practices (see strategy 3.3, below).

The methods and approaches of observational, outcomes, and effectiveness research also offer potential to address the concern that CAM research often fails to reflect practice in the real world. For example, studies are sometimes criticized because clinical trial protocols do not allow for the kind of individualization of treatment that a typical CAM practitioner might employ or because the experimental design focuses on a specific aspect of a multifaceted approach to care. Similar challenges confront other disciplines of health care research that employ individualized interventions or complicated and multifaceted systems of care. There is broad interest within the biomedical and behavioral research communities in applying effectiveness and outcomes approaches, including comparative effectiveness and pragmatic trial designs, to such questions. There is also broad interest in developing and validating better patient-oriented outcome measures for such research.

Pursuing these approaches in the context of CAM and integrative medicine practice will require collaboration with experts who confront similar challenges and opportunities in studying outcomes of procedures or multicomponent interventions introduced into and adapted in clinical practice (e.g., surgery, psychotherapy, and behavioral change). This research will also require creative leveraging of the capacities and resources of insurers and health care and clinical research networks.

It is important to seek out opportunities to take scientific advantage of the extensive use of CAM in the general population to help address the gaps in evidence that confront the public and health care providers.



Strategy 3.3: Conduct research on the potential of CAM interventions, practices, or disciplines to support healthy lifestyle behaviors and behavior change.

Many CAM disciplines, systems of traditional medicine, and integrative medicine practices place a strong emphasis on preventive health strategies, including better dietary practices and regular physical exercise. In addition, CAM and integrative medicine practitioners often claim a high degree of success in supporting healthy behavior, using CAM-inclusive interventions and practices to facilitate behavior change and support sustained motivation.

Although limited in scope, an emerging body of interesting data suggests that users of CAM have a greater degree of health consciousness, in that they are more likely to engage in activities widely accepted as health promoting. For example, preliminary data suggest that CAM users are more likely to exercise regularly than non-CAM users. Other data suggest that individuals who see both CAM and conventional medical providers are more proactive about their health than are those who see only CAM or only conventional medicine providers.

These claims and preliminary findings are noteworthy because of the widely recognized need for better or more individualized strategies for promoting healthy behavior and positive health behavior change. They merit further investigation initially aimed at verifying this preliminary evidence and exploring the observed associations. If confirmed, translational research toward subsequent intervention trials testing evidence-based hypotheses would be warranted.

Going forward, NCCAM will work with its stakeholder communities to develop initiatives for research exploring these associations and, if appropriate, designing the methods and translational tools needed to develop this area of investigation further.

Can Yoga or Mindfulness Meditation Assist in Promoting Weight Loss and Healthier Eating Habits?

Obesity is epidemic: 65 percent of Americans are overweight or obese. Overeating often reflects dysregulation of physiological, emotional, and behavioral systems. Chronic stress responses may drive eating patterns that lead to obesity and appear to favor central fat deposition, which is closely linked to the metabolic syndrome and complications such as increased cholesterol, hypertension, and insulin resistance.

Most weight-loss programs focus heavily on diet, but do little to address the impact of stress on food intake and metabolism, and most individuals gradually return to former patterns of overeating. Recent research suggests that the addition of yoga or mindfulness meditation practices may be associated with greater psychological well-being, less disordered eating, greater weight loss, and improved metabolic function.

These preliminary results warrant further investigation into the short- and long-term effectiveness of meditative practices in enhancing weight-loss programs and maintaining healthier eating habits. An important element of this research direction is translational research to validate a panel of outcome measures and to define the frequency, duration, and other characteristics of the intervention. This work is needed to prepare for larger clinical trials and to facilitate comparison of the results of different studies.





STRATEGIC OBJECTIVE 4

IMPROVE THE CAPACITY OF THE FIELD TO CARRY OUT RIGOROUS RESEARCH

When Congress established NCCAM, it recognized the need to build research capacity in the field and authorized NCCAM to undertake various steps to bring together qualified experts from various CAM disciplines and the biomedical sciences to carry out NCCAM's research mission. These efforts have been successful in training and creating a cadre of CAM research scientists from biomedical, behavioral, and CAM backgrounds. A robust and highly collaborative interdisciplinary community of investigators, based in both conventional biomedical and CAM institutions, now employs and develops state-of-the-art research methods and tools in studying the safety and potential application of CAM interventions.

Challenges and Needs

Significant growth in the quality and quantity of the evidence base regarding CAM reflects this growth in CAM research capacity. In the past 10 years, NCCAM has funded more than 2,500 research projects resulting in more than 3,300 scientific articles in peer-reviewed journals. Nonetheless, as described in the first three strategic objectives of this plan, numerous challenges remain that must be addressed to support rigorous research on the role of CAM interventions in treating health problems and improving health and well-being.

To pursue these questions successfully, NCCAM must continue to ensure that the human talent, resources, and infrastructure needed to design and carry out the highest quality basic, translational, and clinical research are in place; that they involve collaborative, interdisciplinary research partnerships across a spectrum of scientific and health practice disciplines and experiences; and that the Center takes advantage of opportunities to leverage national and international scientific resources and experience.



Strategies

Strategy 4.1: Support a variety of high-quality research training and career development opportunities to increase the number, quality, and diversity of CAM researchers.

A successful and robust CAM research enterprise must include CAM practitioners expert in their respective disciplines and biomedical/behavioral scientists expert in cutting-edge scientific methods.

A successful and robust CAM research enterprise must draw from two sources of well-trained, skilled, and experienced talent: CAM practitioners expert in their respective disciplines and biomedical/behavioral scientists expert in cutting-edge scientific methods. CAM practitioners are the key holders of knowledge related to the potential application of CAM interventions and disciplines. NCCAM has always recognized the need for research training and career development efforts targeted specifically toward this diverse community. Over the years the Center has developed a number of programs aimed at enhancing CAM practitioners' abilities to critically evaluate biomedical literature, participate in clinical research, and, in some cases, seek advanced training and career development opportunities for careers in the field of CAM and integrative medicine research.

Researchers from many different biomedical and behavioral disciplines are the key holders of scientific knowledge and technologies required for in-depth investigation of the basic biological, physiological, and clinical effects and safety of CAM interventions. Over the years, NCCAM has also targeted resources aimed

at attracting well-trained and experienced scientists into CAM research and in supporting their development as scientific leaders in the field.

Going forward, NCCAM will continue to support a variety of high-quality research training and career development opportunities aimed at building and maintaining a vibrant, productive, multidisciplinary, and diverse research enterprise and addressing the unique needs for research training in this field. In particular, the Center will focus on:

- CAM practitioners who wish to gain the knowledge and experience needed to engage in rigorous, collaborative, multidisciplinary research in their field
- Scientists trained in key biomedical and behavioral research disciplines necessary for rigorous, state-of-the-art scientific investigation of CAM interventions, practices, and disciplines
- Members of populations who are underrepresented in scientific research and are interested in careers in CAM and integrative medicine research.

Research Training and Career Development Opportunities— Areas of Emphasis

Experts in CAM clinical practice	Biomedical and behavioral research scientists
<p>Goal: Gain knowledge and experience in rigorous, collaborative, multidisciplinary research in their field of CAM expertise</p> <ul style="list-style-type: none"> ■ Doctoral degree holders ■ Early and mid-career professionals ■ Members of populations underrepresented in scientific research 	<p>Goal: Gain knowledge and experience in applying scientific expertise to collaborative, multidisciplinary CAM research</p> <ul style="list-style-type: none"> ■ Doctoral degree holders ■ Mid-career and senior investigators ■ Members of populations underrepresented in scientific research



Interdisciplinary Collaboration and Partnerships

The success of the CAM research enterprise depends upon multidisciplinary partnerships and collaboration between CAM practitioners and biomedical/behavioral research scientists.

Expert practitioners in CAM disciplines and interventions	Biomedical and behavioral research scientists
Key holders of knowledge regarding the history, use, application, and practice of CAM interventions and disciplines	Key holders of the scientific knowledge and technologies required for rigorous investigation of the effects and safety of CAM interventions

Clinical investigation aimed at providing scientific evidence useful to the public, health care providers, and health policymakers is an inherently interdisciplinary enterprise.

Strategy 4.2: Foster interdisciplinary collaboration and partnerships.

Across the fields of biomedical and behavioral research it has become clear that clinical investigation aimed at providing scientific evidence useful to the public, health care providers, and health policymakers is an inherently interdisciplinary enterprise. This is particularly true of the field of CAM research. Rigorous investigation in this field requires cross-disciplinary and multidisciplinary teams, both within and across institutions and health care settings.

For example, the development of effective translational research tools for CAM research requires in-depth understanding of the interventions, the health conditions under study, and the tools and technologies of relevant basic and clinical research disciplines. This can only be achieved through partnerships involving institutions and practitioners with particular expertise in CAM or integrative medicine together with institutions and individuals with relevant biomedical or behavioral research expertise and experience. Promoting and fostering such collaborative and strategic partnerships has been and will remain a cornerstone of NCCAM’s approach to capacity building.

Strategy 4.3: Collaborate with and leverage the scientific and information resources and activities of other fields, organizations, and countries.

Incentives for private-sector investment in CAM research are few. As a consequence, NCCAM's investments in investigating CAM safety and usefulness and increasing capacity for CAM research are particularly important. Although the Center continues to take the lead among Federal agencies in CAM research, it cannot pursue its mission in isolation.

For example, given the breadth of NCCAM's mission, the Center frequently enlists the help and collaboration of other institutes and centers (ICs) of NIH. Examples range from joint sponsorship of large clinical trials to trans-NIH workshops or research initiatives. These collaborations with other NIH ICs have yielded significant payoffs in advancing knowledge of CAM and disseminating the research results. NCCAM will continue to leverage its privileged position as a component of NIH and actively seek opportunities and partners in areas of shared interest. In addition, NCCAM is now poised to serve as a focal point for specific trans-NIH activities important to public health, such as chronic back pain.

In addition, CAM, integrative medicine, and traditional medicine are focal points of interest of many national and international scientific and professional organizations, national governments, and the World Health Organization. NCCAM's decade of effort aimed at building scientific evidence about these practices is a rich resource of experience and information for these activities. In turn, the efforts and initiatives of these other organizations and countries provide numerous opportunities for collaborative and mutually beneficial research, training, and information-sharing activities.



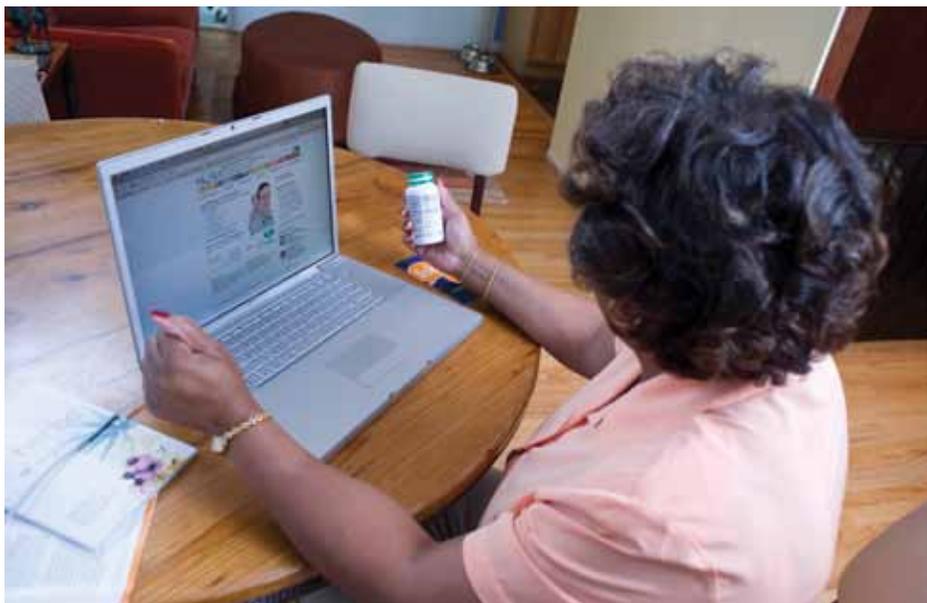
STRATEGIC OBJECTIVE 5

DEVELOP AND DISSEMINATE OBJECTIVE, EVIDENCE-BASED INFORMATION ON CAM INTERVENTIONS

Public interest in CAM remains strong. Helping the public and health care providers to be better informed about the safety and usefulness (or lack thereof) of CAM interventions, practices, and disciplines is the overarching communication goal of NCCAM.

The translation and dissemination of evidence-based health information to the public and health care providers is a key component of the mission of NIH. Thus, it is essential that the public have ready access to the authoritative, unbiased health and medical information that NIH produces every day.

As a component of NIH, NCCAM shares in the mandate to communicate regularly about research advances and present the most current health and science information on CAM and integrative medicine. Two facts underscore the central importance of NCCAM's information activities. First, they usually concern evidence regarding products or practices that are readily available and widely used by the general public; second, many are used as self-care interventions, without the advice or guidance of a health care provider—whether conventional or CAM.





Challenges and Needs

NCCAM shares with its sister NIH ICs many of the challenges of translating and delivering complex scientific information to an interested public. In this regard, two features of the landscape of complementary and alternative medicine in the United States are noteworthy.

First, the public domain is deluged with information about CAM, some of it overtly promotional and much of it either not based on evidence or of questionable quality and reliability. Second, NCCAM's constituencies include consumers who are curious about what the science says, as well as individuals with strong, often polar-opposite beliefs or biases regarding the state of evidence about particular CAM interventions—or even the need for CAM research. Thus, the same evidence-based information can appear to some as promoting unproven or dangerous practices and to others as discrediting practices with proven safety and value.

In this context, NCCAM must ensure that its presentation of the evidence is scientifically objective and appropriately balances what is known about risk and benefit. Most importantly, it must provide information that is of value to the public and health care providers given the reality of widespread and frequent self-care use of CAM.

Strategies

Strategy 5.1: Provide reliable, objective, and evidence-based information to help the public make informed decisions about CAM.

NCCAM seeks to provide an objective voice to help the public and providers make informed decisions about CAM use.

Given the quantity of information available to the public about CAM, NCCAM seeks to provide an objective voice to help the public and providers make informed health care decisions. NCCAM uses a variety of communication techniques and technologies to explain to the public what is known about the science of CAM without bias or preconceived ideas and to provide an accurate and balanced perspective on the promise, as well as the concerns, of using CAM. The Center also collaborates with both domestic and international agencies and organizations to share information and leverage communication resources.

The field of communications evolves rapidly. NCCAM will continue to provide information in a variety of formats to its audiences through multiple channels, including the Web, broadcast and print media, its clearinghouse and exhibit program, and social media. The Internet is a key source of information, with 8 in 10 Internet users (or two-thirds of U.S. adults) looking online for health

Information—An Evolving Landscape

To ensure that authoritative and evidence-based CAM information is reaching the public, NCCAM employs emerging technologies and platforms including video, social media, and mobile applications.

Conveying information about the safety of CAM therapies is vital to NCCAM's goal of improving health and health care. Thus, NCCAM conveys FDA safety alerts through its Web site, e-mail newsletters, and social media profiles.



information. Online communities are continuously springing up, bringing together groups of people who share information and resources with each other. Social networking sites are replacing the standard search engines as the most frequent destinations for online users. Mobile phones and other devices are fast replacing personal computers. To ensure that those interested in CAM research find NCCAM's information, it is incumbent on the Center to use these emerging technologies.

Importantly, as the evidence base continues to evolve, NCCAM will be able to draw more and more on the evidence-based interpretations or conclusions of independent organizations and professional societies. NCCAM will collaborate with these and other third-party organizations and other Government

Outreach to Health Care Providers

The Internet has become an indispensable information tool for health care providers. According to a recent study, providers turn to online resources for health information above any other source, and physicians spend an average of 8 hours online each week for professional purposes. For information on CAM practices, health care providers need reliable, evidence-based information about safety and effectiveness so they can help manage patient care and promote health

and well-being. In response to this need, NCCAM has designed a portal on its Web site specifically for health care providers. This Web portal provides links to scientific literature on CAM, including reviews from the Cochrane Collaboration, as well as clinical practice guidelines issued by third-party organizations and online continuing education modules.



NCCAM's Web portal for health care providers (nccam.nih.gov/health/providers/)

agencies to improve the quality and depth of information that reaches its many stakeholder audiences and to maximize opportunities to leverage communication resources.

Finally, NCCAM will strive to address its information and resources primarily to the large majority of consumers and health care providers who are curious about what the science says, even when the evidence is inconclusive or does not lead to clear guidance. To accomplish this, NCCAM will continue to work actively with its diverse community of stakeholders to identify, understand, and address the CAM information needs of consumers and health care providers and their concerns about accuracy or interpretation of research results and health messages.

Strategy 5.2: Provide reliable, objective, and evidence-based information about CAM to help health care providers manage care and provide advice.

Health care professionals—both conventional and CAM—also confront many challenges in accessing current scientific information about CAM. Recognizing

these challenges, NCCAM has developed information resources targeted toward the needs of this important audience. These resources include specialized communications, an exhibit program, outreach to professional societies, and online tools, including a dedicated Web portal that summarizes research findings and provides links to relevant clinical practice guidelines. These communication efforts will help ensure that health care providers have reliable information and authoritative resources on CAM. Ultimately, these efforts will also facilitate evidence-based integration of CAM practices shown to be useful and safe into comprehensive programs of health care and health promotion.

Strategy 5.3: Enable informed and integrative dialogue between consumers and health care providers about CAM use and the support of healthier lifestyles.

A 2006 NCCAM/AARP survey of individuals age 50 or older revealed that while more than two-thirds of respondents used some form of CAM, less than one-third of CAM users had talked to their physicians about CAM. The main reasons given for not talking about CAM use were that respondents did not know they should discuss CAM and that their physicians never asked.

Safe and well-integrated health care requires partnership involving the person and all of his or her health care providers—whether conventional or CAM. In an effective partnership, communication is clear and open among the various parties about the full range of health care interventions and the health practices the individual is using.

NCCAM’s Time to Talk campaign provides tools to facilitate conversation about CAM use between health care providers and patients. NCCAM will explore expansion of this program to additional audiences—including CAM providers and a more diverse community of consumers—as well as harnessing new communication channels and technologies to enhance this important dialogue.

Safe and well-integrated health care requires partnership involving the person and all of his or her health care providers—whether conventional or CAM.





Appendix: NCCAM Strategic Planning Process

The year-long process of developing this strategic plan was carried out under the auspices of the National Advisory Council for Complementary and Alternative Medicine. Throughout the process, NCCAM also sought guidance and input from its diverse community of scientific and practitioner stakeholders, experts in health communications, and members of the general public through a series of workshops and symposia and several opportunities to provide comment through the NCCAM Web site.

NCCAM is grateful to its Advisory Council members, stakeholder organizations, members of the public, and individual experts who contributed their time and thoughtful input into the development of this plan.

Major events in the strategic planning process include the following:

September 10, 2009: A strategic planning workshop, convened in conjunction with a meeting of the NCCAM Advisory Council, considered: (1) NCCAM mandate and mission, (2) NCCAM priority setting, and (3) information and communication about CAM research and decisionmaking about CAM use.

September 25, 2009: A wellness workshop considered the state of the science with regard to measures of psychological, physical, social, and global components of wellness.

October–November 2009: Three draft position papers resulting from the September strategic planning workshop were posted on the NCCAM Web site for public comment.

March 26, 2010: A meeting of the Think Tank on Natural Products focused on the state of the science and future directions for research in this area.

April 26–27, 2010: A workshop on control/comparison groups focused on the design of clinical trials of nonpharmacological interventions.

May 10–11, 2010: A workshop on back pain considered the current status of the science and future needs for research on better strategies for diagnosis and treatment.

May 10–28, 2010: Background papers on back pain and natural products were posted on the NCCAM Web site for public comment.

June 3, 2010: A strategic planning meeting on gaps and opportunities in health behavior research was convened in conjunction with a meeting of the NCCAM Advisory Council.

August 30–September 30, 2010: The draft strategic plan was posted on the NCCAM Web site for public comment.

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