

Chapter 3: Coordination of Research

The public's increased use of complementary and alternative medicine has added urgency to the need to examine the safety, efficacy, and cost effectiveness of complementary and alternative medicine (CAM) practices and products and to discover the basic mechanisms underlying them. Basic, clinical, and health services research in CAM are all essential to the inclusion of CAM in the health care system. Public and private funding for this research should be increased and the paucity of private investment in research on herbal and other CAM products popular with the public should be addressed.

Rigorous research provides the information needed to increase the public's knowledge about CAM and to educate and train CAM and conventional health care professionals. It also provides a basis for regulating the quality and use of CAM products and devices as well as improving access to safe and effective CAM practices and products and health insurance coverage for them. In addition to questions of safety and efficacy, further studies should be undertaken to determine why people use CAM, how lifestyle and self-care affect health and disease, and how practitioner-patient interactions affect treatment outcomes. Research is also needed to pursue answers to questions posed by CAM that lie outside the conventional medical paradigm.

Establishing a strong scientific base in CAM is necessary for acceptance and inclusion of safe and effective CAM therapies in health care. In conventional medical practice, professional judgments are based on practitioners' training and experience and an accepted and expanding body of knowledge based on research findings published in peer-reviewed journals. Professional judgments in the practice of CAM are often not viewed in a similar light because of the lack of a sufficient body of evidence-based knowledge on which to form them. As the body of research literature in CAM expands, the professional judgments of trained and experienced CAM practitioners will be accepted more readily.

An important milestone toward the goal of increasing the body of evidence-based knowledge in CAM occurred in 1992 with the establishment of the Office of Alternative Medicine at the National Institutes of Health (NIH). The mandate of this office was to facilitate and coordinate CAM research and related projects with other NIH institutes, centers and offices, and to provide information to the public. In 1998, research in CAM took another major step forward when the Office of Alternative Medicine became, through congressional mandate, the National Center for Complementary and Alternative Medicine (NCCAM). The expanded resources available to NCCAM enhanced its ability both to continue and build upon the work of the earlier office to provide the public with evidence on the safety and efficacy of CAM practices and products.

Research Support and Scope

Current CAM Research Activities

The Commission commends NCCAM for its leadership and contributions to CAM research, methodology, training, and infrastructure development and supports increasing the center's crucial activities in these areas, including its database development and information dissemination responsibilities. NCCAM collaborates with NIH components, as well as other government agencies and non-government organizations. It initiates and funds research projects and establishes research centers at conventional medical institutions and CAM institutions. It also supports the training of CAM researchers and the research infrastructure at conventional and CAM institutions, supports educational activities, and offers opportunities for collaborations between CAM practitioners and researchers and mainstream investigators. The Commission commends current collaborations and encourages further collaboration between NCCAM and other Federal agencies, such as the Agency for Health Care Research and Quality, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Health Research and Services Administration, the Substance Abuse and Mental Health Services Administration, the Department of Veterans Affairs, and the Department of Defense.

The NIH Office of Dietary Supplements is also carrying out important work. The mandate of this office includes exploring the role of dietary supplements in the improvement of health care, promoting scientific study, and supporting conferences, workshops, and symposia, which it does in conjunction with NCCAM, other NIH institutes, centers, and offices, other government agencies, professional organizations, and public groups. The Commission also recognizes the support for CAM research by the other NIH components, encourages them to increase their valuable support, and notes especially the work of the National Cancer Institute (NCI)'s Office of Cancer Complementary and Alternative Medicine and the National Library of Medicine.

In response to the public's use of CAM practices and products, overall NIH funding for research on CAM increased from \$116.0 million in FY 1999 to an estimated \$247.6 million in FY 2002. During the same period, funding by NCCAM increased from \$48.9 million to an estimated \$104.6 million. Despite this increase, an analysis of NCCAM's extramural research trends between FY 1999 and FY 2003 indicates a growing number of applications and a decreasing number of new awards, resulting in a declining success rate, which is the percentage of research project grant applications that receive funding.

Research project grants are awarded for an average of four years during which time they are considered non-competing grants. As an increasing number of

quality CAM research applications are submitted and awarded, the number of non-competing grants to which funds are committed (the commitment base) grows. The increasing commitment base, which also may include some larger and longer-term clinical studies is a likely cause of the estimated decline in new awards. Therefore, in order to build the much needed evidence base for CAM, adequate funding is essential to support NCCAM's commitment base, grant renewals, and as many meritorious new awards as possible. Historically, as new NIH grant-awarding organizations move through budget allocation cycles and develop longer grant histories, they gradually improve the balance between non-competing and competing grants, but they are always aware of the need for adequate funding to support both. The Commission believes that NCCAM's budget increases should be sufficient to support growing numbers of awards to meet research needs and opportunities in crucial areas to ensure public health and safety.

To help identify research needs and promising research opportunities, NCCAM, assisted by the Institute of Medicine, should develop guidelines for establishing research priorities in CAM. Because of the diversity of CAM systems and practices and the wide range and fluidity of opinions on the definition of what constitutes complementary and alternative medicine, it is important also to address the issue of definition because the current ambiguity makes it difficult to set priorities for guiding the use of resources.

Other Federal agencies with research or health care responsibilities need to take a more active role in developing programs to evaluate biomedical and health services aspects of CAM to ensure that CAM use by the public is safe and effective. Funding for these programs should be sufficient to accomplish this goal. The Agency for Health Care Research and Quality together with NCCAM should develop ways to expand health services research in CAM and explore methodologies for conducting health services research in this area. Federal agencies should assess the scientific, clinical practice, and public needs regarding CAM that are relative to their missions, examine their portfolios, and develop funding strategies to address these needs. They should ensure that applicants are aware of any technical assistance available to them. Agencies might consider such activities as funding initiatives (requests for applications and proposals), establishing CAM-focused offices or centers, designating CAM-focused staff positions, and creating CAM advisory committees or ensuring the representation of qualified CAM professionals on such committees.

Public and Private Research Funding for CAM Products That May Not Be Patentable

Federal agencies need to develop outreach programs to inform manufacturers of CAM products and devices about the Federal research support available to private industry, such as the Small Business Innovative Research Grant

(R43/44), the Small Business Technology Transfer Research Grant (R41/42),¹ and the Cooperative Research and Development Agreement.² The manufacturers of CAM products and devices should become acquainted with potential sources of funding and with the requirements they must meet to receive such funds. Federal agency staff members are available to assist applicants with protocol development and to help them understand the grant process.

CAM's Emphasis on Health and the Whole Person

Public interest in CAM has renewed awareness of and respect for the importance of the whole person in maintaining health and treating disease. Members of the public have expressed appreciation for the attention many CAM practitioners and disciplines give to wellness and health promotion, self-care, lifestyle, quality of life, behavior, and the combined role of mind, body, and spirituality in health, disease, and healing. People also appreciate the importance many CAM practitioners and disciplines place on the interactions between patient and practitioner and on individualizing treatments. CAM's emphasis on the individual's biochemical uniqueness³ and the value of tailoring treatments to the biological, psychological, sociological and spiritual aspects of the person, reinforces the need to increase studies on individualized CAM treatments and the variations in patients' responses to conventional medical treatments.

Research in these areas, which converges with conventional behavioral and psychosocial research, may contribute in important ways to health care, particularly in rehabilitation and the management of chronic diseases and disorders, and merits increased public and private investment. Treatments, such as biofeedback, meditation, guided imagery, art therapy and music therapy, which appear to be effective but may not be profitable to private investors, should also receive Federal support. In addition, research on 1) the synergistic activities of complex compounds and mixtures frequently found in CAM products; 2) clinical interventions consisting of multiple, combined treatments; 3) how patient-practitioner interactions affect treatment outcomes; and 4) the individualization of treatments should be supported by the public, private, and nonprofit sectors. Traditional Chinese Medicine and Ayurvedic medicine are examples of systems of practice that target specific conditions and might provide interesting and worthwhile research avenues to follow in studying some of these areas.

Pluralism in Research Approaches and Quality in Research Methodology

Various research approaches, if pertinent to the CAM question being asked, contribute to developing evidence of safety and clinical efficacy, understanding basic mechanisms of action underlying practices and products, and evaluating general effectiveness in the health-care system. Among these approaches are basic research, randomized controlled clinical trials, non-randomized studies, empirical observation, case studies, evaluations of practice-based data, and practice-based outcomes research. Also included are epidemiological and

surveillance studies, behavioral and quality-of-life studies, qualitative research, systematic reviews and meta-analyses, cost-effectiveness and cost-benefit studies, population and utilization studies, studies on health care delivery, and health care demonstration projects on various aspects of CAM use and services. To be methodologically sound, CAM studies must have a clear question (hypothesis), a sound study design, a qualified and appropriately constituted research team, objective and verifiable data, carefully defined outcome measures, and balanced conclusions that meet acceptable standards of evidence. The randomized controlled clinical trial is recognized as the gold standard for examining many clinical questions. Because of the complexity and uniqueness of illness and CAM approaches to illness, it may be necessary to adapt clinical trial methodology, in a flexible, step-wise fashion, to the unique characteristics of CAM questions and systems of care, while complying with protections for human subjects and institutional review board (IRB) guidelines. Questions of standardization and non-standardization, individualization and generalization, blinding, randomization, the placebo effect, compound mixtures, and many other research methodology challenges need to be resolved within the context of the study question and design and the overall research strategy.

It is important to note that investigators in conventional clinical research have also adapted methodology and design to meet the needs of a study. Scientists have always followed their quests for knowledge by developing new ways to answer difficult questions, and pluralism in research design will allow scientists to develop innovative methods to examine complex CAM questions.⁴ Funding mechanisms that have promoted interdisciplinary exchange of ideas in addressing difficult research questions in conventional research may offer settings in which creative ways of approaching difficult CAM research questions can be developed. Examples of such mechanisms include Specialized Center Awards (P50), Exploratory Grants (P20), and Center Core Grants (P30). Other awards of interest are the Exploratory/Developmental Grants (R21), which encourage the development of new research activities in categorical program areas, and the James A. Shannon Director's Award (R55), which is a limited grant mechanism for developing, testing, and defining research techniques and the feasibility of innovative, creative, research approaches.⁵ In addition, multidisciplinary conferences, workshops, and expert panels, such as the CAM cancer symptom management research panel convened in November 2001, provide effective forums for exploring ways to address CAM research-related issues and challenges. The results of meetings such as these are often published in peer-reviewed journals and can stimulate new research and public and private investment.

Exploring Whole Systems Concepts and Expanding Areas of Scientific Inquiry

In addition to the primary task of identifying practices and products that could become complementary to conventional care or possibly alternative treatments,

CAM research may go beyond isolated treatments and contribute innovative ideas to emerging areas of science that might help expand our understanding of health, disease, and healing. The CAM research spectrum is broad. It includes areas that in some cases may be almost indistinguishable from conventional medicine except for pharmacological agents, techniques, or application, such as exercise/diet/lifestyle therapies, herbal/nutritional supplements, behavioral/mind-body methods, pain management, the effects of culture on health and treatment, and the ability of the body to heal. The spectrum also includes areas that may receive less attention but are, or are becoming, areas of interest to conventional science, such as increasing our understanding of complete biological systems and how they interact, the placebo effect, spirituality, consciousness, and electromagnetic fields. Finally, the spectrum includes areas that challenge current biological and scientific concepts and assumptions, such as homeopathy, bioenergy (vital force; e.g., Qi, prana), bioelectromagnetic therapy, and therapeutic prayer. Answers to some of these and other research questions posed by such CAM concepts may be found in the study of Ayurvedic medicine, Traditional Chinese Medicine, Tibetan medicine, Native American medicine, medicine of Africa, Latin American and Caribbean medicine, as well as naturopathic medicine, chiropractic, and other systems of healing.

Applying rigorous scientific methods to the exploration of such frontier areas of inquiry may require merging whole system concepts with objective measurements used in research. It will also require the input of CAM professionals working with experts in a wide variety of fields, including but not limited to physics, cell and molecular biology, genetics, immunology, physiology, chemistry, neurobiology, epidemiology, psychology, sociology, and engineering. In addition to NCCAM, which has issued a request for applications to foster research in frontier areas of inquiry, the National Institute of General Medical Sciences of the NIH, the Department of Energy, the Department of Defense, and the National Science Foundation are examples of Federal organizations that should consider contributing collaboratively or independently to the support of research on core CAM questions in areas described in many CAM systems.

Moving Non-approved Treatments to Clinical Investigation

Physicians and other health care practitioners who believe they have promising data on non-approved CAM treatments need more assistance in moving successfully to clinical investigation of the treatment while meeting their professional, ethical, and human subject protection responsibilities. It is essential to note here that, in addition to Federal requirements concerning research, all CAM and conventional practitioners, whether or not they are engaged in research, must meet whatever State practice requirements or standards govern their authorization to practice.

In CAM research, as in conventional research, the following standards apply: 1) the practitioner engaging in research must be knowledgeable about the collection

of objective and valid observational data and record keeping; 2) the investigation of the treatment must be part of a well designed study that meets rigorous scientific standards; and 3) protections for human subjects and IRB guidelines must be in place and followed. Practitioners, however, often do not have the expertise, the resources, or the time to conduct high-quality, scientifically rigorous practice-based research. They need both the support of research institutions and the opportunity to collaborate with expert researchers in evaluating their observations and in designing and implementing clinical studies.

To help implement and accelerate the process, NIH and other Federal agencies, as appropriate, should develop programs to evaluate practice-based observational data as the basis for potential research support and communicate the availability of such programs to practitioners. If a project merits funding, CAM practitioners and CAM-trained researchers should be part of the research team. These programs may also offer training in data collection, the scientific method, protocol development, and ethical guidelines and human subject protection. Support for research can be obtained as well from reputable, high-quality private or nonprofit institutions or organizations, which could develop ways to assist practitioners in moving successfully from preliminary data to quality clinical research.

The NCI's Office of Cancer Complementary and Alternative Medicine conducts reviews of practice-based data through its best-case series program. Members of the Cancer Advisory Panel for Complementary and Alternative Medicine (CAPCAM), medical oncologists, and CAM experts also provide NCCAM with a field investigation function to collect and evaluate outcomes data on promising complementary and alternative cancer therapies. To stimulate practitioner response, NCCAM in collaboration with NCI, has called for the submission of case histories through notices in leading conventional and CAM periodicals, with letters, and at meetings. This effort has resulted in one study under way, another under negotiation, and a third under review. NCCAM has also, through the Agency for Health Care Research and Quality, contracted with the RAND Corporation to compile data histories of best-case studies for review and assessment by CAPCAM. NCCAM has also explored a pilot project with the Centers for Disease Control and Prevention to develop methods for identifying practitioners who have data on new therapies and to conduct systematic reviews of the case files and identify practices worthy of research support.

Using both the NCI best-case series and the NCCAM collaboration with NCI as a model, concerted efforts are needed to continue strengthening existing outreach activities to CAM practitioners and conventional researchers and to create outreach programs for evaluating practice-based observational data in additional areas of research. Activities should also offer guidance and training to facilitate the move by CAM professionals from promising preliminary data to scientifically rigorous clinical studies.

Recommendation 1: Federal agencies should receive increased funding for clinical, basic, and health services research on CAM.

Actions

- 1.1 Federal agencies should increase their activities with respect to CAM in accordance with their biomedical research, health services research, or other health care-related responsibilities and communicate to CAM and conventional researchers and practitioners about these activities, including available technical assistance. Activities might include funding initiatives such as requests for applications and proposals, CAM-focused offices or centers, CAM-focused staff positions, CAM advisory committees or the representation of qualified CAM professionals on such committees.
- 1.2 Federal agencies should assess the scientific, clinical practice, and public needs regarding CAM that are relative to their missions, examine their portfolios, and develop funding strategies to address these needs.
- 1.3 The Agency for Health Care Research and Quality together with NCCAM should develop ways to expand health services research in CAM and explore methodologies for health services research in this area.
- 1.4 The Federal, private, and nonprofit sectors should support more research on 1) the synergistic activities of complex compounds and mixtures frequently found in CAM products, 2) clinical interventions consisting of multiple, combined treatments, 3) how patient-practitioner interactions affect treatment outcomes, and 4) the individualization of treatments.
- 1.5 In order to protect public health and maximize benefits, Congress should provide adequate public funding for research on frequently used or promising CAM products that would be unlikely to receive private research support.
- 1.6 The Federal government should support research on CAM practices that appear to be effective but may not be profitable to private investors, such as biofeedback, meditation, guided imagery, art therapy, and music therapy.

Recommendation 2: Congress and the Administration should consider legislative and administrative incentives to stimulate private sector investment on research on CAM products that may not be patentable.

Actions

- 2.1 Incentives to stimulate private sector investment in CAM research should focus on 1) research on dietary supplements and other natural products that may not be patentable, 2) research on other CAM products that may not be patentable, including therapeutic devices, and 3) the development of analytical methods for improving the quality of CAM products.

- 2.2 The Federal and private sectors should provide support for workshops to discuss the research needed by regulatory agencies for the review and approval processes for CAM products and devices.
- 2.3 Federal agencies should develop outreach programs to inform manufacturers of CAM products and devices about the Federal research support available to private industry and how the agencies can assist them.

Recommendation 3: Federal, private, and nonprofit sectors should support research on CAM modalities and approaches that are designed to improve self-care and behaviors that promote wellness.

Recommendation 4: Federal, private, and nonprofit sectors should support innovative research on core questions posed by CAM in frontier areas of scientific study that might expand our understanding of health and disease.

Actions

- 2.1 NCCAM, assisted by the Institute of Medicine, should develop guidelines for establishing research priorities in CAM, and address the issue of definition to facilitate the allocation of resources.
- 2.2 The National Science Foundation, in collaboration with NCCAM, should examine areas of science associated with CAM that are outside the current research paradigm and methodological approaches to study them.
- 2.3 Multidisciplinary workshops and expert panels should be convened by Federal, private, and nonprofit organizations, collaboratively or independently, to explore the challenges in design and methodology presented by research questions in CAM areas that are outside the current research paradigm.
- 2.4 The National Institute of General Medical Sciences of the NIH, the Department of Energy, and the Department of Defense are among the Federal organizations that should consider contributing collaboratively or independently to the support of research on core questions in areas described in many CAM systems.
- 2.5 NCCAM, working with the World Health Organization, should examine investigative approaches for studying the traditional systems of medical practice of a variety of cultures.

Recommendation 5: Investigators engaged in research on CAM should ensure that human subjects participating in clinical studies receive the same protections as are required in conventional medical research and to which they are entitled.

Actions

- 5.1 Licensed practitioners using CAM systems and modalities who wish to conduct or collaborate in clinical research should be subject to the same requirements as conventional medical researchers. They should develop, or collaborate with a research institution to develop, a scientifically valid research protocol and obtain IRB approval to ensure that they meet accepted standards of ethical conduct and their responsibilities to protect human subjects.
- 5.2 Accredited CAM institutions and CAM professional organizations should establish IRBs where possible and guide their colleagues and members in using the IRB process, which is required to conduct clinical research.
- 5.3 IRBs that review CAM research studies should include the expertise of qualified CAM professionals in the review.
- 5.4 Research institutions and NIH and other Federal research and health-care agencies should be more proactive in developing programs that 1) provide opportunities for expert review by experienced researchers of promising CAM practice-based observational data, 2) stimulate practitioner response to the opportunities offered by the programs, and 3) facilitate communication and stimulate partnerships between CAM practitioners and conventionally-trained researchers in designing and implementing clinical studies.

Recommendation 6: The Commission recommends that State professional regulatory bodies include language in their guidelines stating that licensed, certified, or otherwise authorized practitioners who are engaged in research on CAM will not be sanctioned solely because they are engaged in such research if they: 1) are engaged in well-designed research that is approved by an appropriately constituted IRB, 2) are following the requirements for the protection of human subjects, and 3) are meeting their professional and ethical responsibilities. All CAM and conventional practitioners, whether or not they are engaged in research, must meet whatever State practice requirements or standards govern their authorization to practice.

Dialogue, Partnerships, and Public Input

Emerging Dialogue and Collaboration between CAM and Conventional Medicine

Largely in response to the public's use of CAM practices and products, an emerging dialogue between CAM and conventional medicine appears to be taking place, along with a growing willingness to study CAM and experiment with its inclusion in health care.⁵ This gradual change, which presents an exciting and hopeful prospect for meaningful collaborations, is reflected in an increase in cooperation and opportunities for cooperation between CAM and conventional health care professionals and institutions. A major challenge facing both CAM and conventional medicine is to foster this emerging dialogue and, by doing so, increase mutual respect and better understanding of one another's expertise, concerns, and contributions. Strengthening the dialogue will not only help protect the public from unsafe treatments, but will also expand opportunities to improve health care.

A recent national survey indicates that most people who use CAM value both CAM and conventional approaches.⁶ The goal of integrative medicine is to identify the most appropriate treatments available from a broad spectrum of evidence-supported care.⁷ To name just a few examples, in integrative cancer treatment, a patient may undergo individualized acupuncture treatment for nausea and vomiting following chemotherapy; relaxation techniques and support groups are used with cancer patients to reduce stress, improve mood, and enhance the immune system; and mind-body interactions and stress management are being studied with respect to the treatment of hypertension and coronary heart disease. The Commission supports collaboration between CAM and conventional medicine and believes that combining the best of CAM with conventional medical care may help reunite the art and science of medicine.

Applying the Same Standards

It is the view of some CAM professionals that the requirements for CAM research are higher than for conventional research. On the other hand, some representatives of the conventional medical research community have expressed the belief that CAM research often is not held to as high a standard as conventional research. The Commission's position is that the same high standards of quality, rigor, and ethics must be met in both CAM and conventional medical research, research training, publication of research results in scientific and medical journals, presentations at research conferences, and review of products and devices.

Cooperation and Partnerships

Cooperation and partnerships are at the heart of the challenge to foster dialogue and improve the quality of CAM research and the success of research applications, including those that may lie outside mainstream research. Building working relationships among professionals from conventional medical, allied health, and CAM disciplines is essential to progress in studying CAM practices and products. The absence of these relationships impedes progress in building knowledge about CAM and establishing the appropriate use of CAM within the health care system.

To be most effective, CAM and conventional researchers, clinicians, practitioners, and the leadership of their institutions and organizations need to communicate with one another and form working relationships. Federal and State research and health care agencies, the private and nonprofit sectors, and the public are also integral to this cooperative environment that gives the scientific and health care community an opportunity to raise the quality of CAM research and improve the research infrastructure. The effective regulation of CAM research, the publication of CAM research results, and the review and approval of CAM practices and products also depend on increased interaction among these various constituencies. Therefore trained, experienced, and properly qualified CAM and conventional medical professionals need to be represented on research, journal, regulatory, and health insurance review and advisory committees, as well as in discussions on CAM-related research policy issues.

Because conferences, workshops, and expert panels are excellent instruments for enhancing communication, participants at such meetings should include CAM and conventional medical and health care professionals and the public, private, and nonprofit sectors. As stated earlier, multidisciplinary meetings offer the opportunity for people from a broad variety of disciplines and interests to build on each others' knowledge and experience in discussions about promising research topics and research planning, program development, and policy considerations, and to explore innovative methodological approaches to solving difficult research questions in focused CAM areas.

Examples of interdisciplinary activities that have contributed to progress in CAM include the conference on "Exploring Opportunities for Collaboration with Industry" supported by NCCAM, the Josiah Macy, Jr. Foundation's "Conference on the Education of Health Professionals in Complementary/Alternative Medicine," the conference on "Building Bridges: the Link between Allopathic and Alternative Medicine in Clinical Practice and Research" sponsored by Johns Hopkins University School of Medicine and School of Hygiene and Public Health and the Traditional Acupuncture Institute, and the Center for Mind-Body Medicine's "Comprehensive Cancer Care Conference" cosponsored by NCI and NCCAM. The symposia and conferences on "Complementary, Alternative and

Integrative Medical Research" sponsored by the Harvard Medical School, Division of Research and Education in Complementary and Integrative Medical Therapies are another example of this type of activity. Federal public health grants for conference support, such as the R13, H13, and T14,⁸ are available to qualified applicants.

Partnerships and collaborations between and among public, private, and nonprofit organizations are also very important to the support of CAM research. Interested nonprofit organizations should consider pooling their resources, independently or collaboratively with the public or private sectors, to support interdisciplinary conferences on CAM research, as well as to support CAM research, research infrastructure and training at CAM institutions, and the dissemination of CAM information.

Public Input and Public Use

The public's growing influence on the health care system has created a need for more research, including population-based research on why people are turning to CAM, as well as a need to ensure public participation in shaping the direction of CAM research. In its 1998 report, *Scientific Opportunities and Public Needs*, the Institute of Medicine described public input as an essential and integral part of the democratic process, which if done well, can improve the knowledge base for public policy decisions. The report goes on to recognize the intense public interest in health issues, and agreement on the part of the public, Congress and the Executive Branch that investing in research is the right thing to do.⁹

Federal requirements and opportunities for public participation in the shaping of health care research and related activities currently exist. Examples include the NIH Director's Council of Public Representatives, which was recommended by the Institute of Medicine, and the long standing requirement that there be public members on NIH advisory councils, boards, and committees, Food and Drug Administration advisory committees, and IRBs¹⁰. Such opportunities are available to members of the public representing CAM research and related areas. Public members of Federal advisory committees as well as the agencies they advise would gain from programs designed to orient and train them on how to provide their input most effectively, particularly with regard to 1) moving from promising basic science findings to clinical treatments, 2) identifying health services research needs, and 3) improving the dissemination of research information.

Because of the increased use of CAM products and the published reports of adverse events, including loss of therapeutic drug effectiveness and compromised perioperative care, the NIH Warren Grant Magnuson Clinical Center established a policy in June 2001 requiring that all inpatients and outpatients be asked, during the admission process, about their use of herbal or other dietary supplements. There is also a growing trend to include questions about herbal or other dietary supplement use in research protocols. The possibility of including such questions in all NIH Clinical Center IRB protocols is

being considered. The knowledge gained from this questioning would benefit research subjects and future protocol development by contributing important information about the use of dietary supplements and other natural products.¹¹ The collection of such information may in the future also offer a data source for research on consumer use of CAM. Because reliable information, including patient disclosure, is necessary to ensure informed decision making, patient safety and valid research outcomes, it is once again clear that 1) more research is needed on CAM practices and products and 2) health care professionals and researchers need to be knowledgeable about CAM.

Recommendation 7: Increased efforts should be made to strengthen the emerging dialogue among CAM and conventional medical allied health practitioners, researchers and accredited research institutions; Federal and State research, health care, and regulatory agencies; the private and nonprofit sectors; and the general public.

Actions

- 7.1 CAM and conventional medical researchers and practitioners should adhere to the same high standards of quality and ethics in all aspects of research and related activities.
- 7.2 Federal agencies should develop programs to stimulate cooperation and partnerships between CAM and conventional medical professionals and accredited institutions.
- 7.3 Committees reviewing or advising on research, journal submissions, regulatory compliance, and health insurance coverage in both the public and private sectors should include as members or consultants trained, experienced, and properly qualified CAM health care professionals.
- 7.4 Multidisciplinary conferences, workshops, and expert panels on CAM research and related activities, including research methodology, should be supported independently or collaboratively by the public, private, and nonprofit sectors.
- 7.5 The nonprofit sector and the private sector should create funding partnerships, whether independently or with Federal agencies, to augment support for CAM research, research infrastructure and training, research conferences, and information dissemination.
- 7.6 The Federal government should support research, including population-based research, to learn more about why people use CAM practices and products, how they determine the safety and effectiveness of the practices and products they use, and what they find satisfying or unsatisfying about

them.

- 7.7 To benefit patients and future research protocol development and to add to existing knowledge about the use of CAM, IRBs should consider requiring that research subjects be asked about their use of herbal or other dietary supplements.
- 7.8 Federal agencies supporting biomedical and health services research should develop orientation and training programs for public representatives to enhance the effectiveness of their participation on advisory committees concerned with CAM.

Research Training and Infrastructure

A strong research infrastructure is crucial to training skilled investigators to study CAM questions, producing grant applications in CAM that successfully compete for support, and conducting rigorous CAM research. Sustained, adequate funding is essential to building and maintaining a long-term research capacity for training clinical investigators and health services researchers in CAM, and for training scientists who are interested in studying the underlying mechanisms of CAM products, practices, systems and concepts.

A government-wide effort involving NIH, the Department of Defense, the Department of Veterans Affairs and other Federal agencies would strengthen the funding and strategic planning for developing or enhancing CAM research sites and training programs. Supporting research training and infrastructure in accredited CAM institutions would help build their capability to conduct high quality research and enhance their opportunities to form research collaborations with conventional medical research centers.

Accredited CAM and conventional medical institutions might consider developing joint research and professional education and training programs to enhance the quality and clinical relevance of CAM research and link the research with evidence-based education and training of practitioners.

The Need for Rigorous Training

The same rigorous training is required for both CAM and conventional medical researchers and must be available to both. Conventional researchers need to understand CAM concepts and approaches, and both CAM and conventional investigators must have thorough training in the fundamental elements of quality clinical, basic, or health services research. Training should include a strong grounding in 1) the research process and methodology, 2) the collection and recording of unbiased data, 3) all aspects of protocol or study design and execution, 4) an understanding of the expertise needed to form a research team,

5) IRB and other regulatory requirements, and 6) the grant application, submission, and review processes.

Research training in CAM should also teach multiple outcomes measures, including social and biopsychological measures of health, and offer experience working as part of a multidisciplinary research team. The opportunity to gain solid training in a supportive environment on how to conduct quality research in CAM should continue to attract students from both CAM and conventional medicine who are interested in studying CAM questions. In addition, all Federal agencies that have training programs as part of their health care missions should support the training of researchers to address CAM-related questions that are relevant to their missions.

Elements of a Strong Research Infrastructure

Research sites, whether supported publicly, privately, or by foundations, need to be strategically located and structured to conduct basic, clinical, and health services research, adequately train researchers and clinical experts, and deliver integrated care services. The success of each site depends on a critical mass of personnel, equipment, basic and clinical research expertise, core laboratory facilities, and clinical environments with access to patients.

CAM research sites should be developed at public, private and accredited CAM institutions with both CAM-trained and conventional medical professionals serving on faculty or as consultants and with experienced researchers serving as mentors. Cooperation between CAM and conventional medical researchers and institutions and joint research grant applications can contribute to success in obtaining funding.

Current Research and Research Training Activities and Opportunities

Academic health centers at conventional institutions offer excellent venues for exchanging experiences with CAM professionals on how best to educate conventional researchers in CAM practices and how to introduce CAM practitioners to the conventional research culture.

Conventional health centers are gradually including CAM in their research, research training, clinical, and medical education activities. For example, the Medical Center Health System of the University of Pennsylvania, recognizing that CAM therapies merit evaluation, recently reviewed the role of CAM in the medical center and health system and is beginning to incorporate the study of CAM therapies into its research, clinical, research training and educational activities, including stimulating interdisciplinary collaboration.¹² Harvard University, Duke University, the University of Maryland, the University of Oregon, the University of Washington, Georgetown University, and many other institutions across the country have incorporated CAM into their academic health centers; each has done so in its own way. Some conventional health centers have cooperative

arrangements with CAM institutions and such cooperation should be encouraged.

Accredited CAM institutions are gradually expanding their activities to develop research and research training capacity, form interdisciplinary collaborations, and establish cooperative arrangements with conventional health centers. For example, a neurophysiology laboratory focusing on research of interest to the chiropractic field has been established at the Parker College of Chiropractic by a conventionally trained neurophysiologist.

NCCAM has awarded grants to CAM institutions, such as the Bastyr University Naturopathic Medicine Program, the Oregon College of Oriental Medicine, the Center for Natural Medicine and Prevention of the Maharishi University of Management, and to a consortium of chiropractic colleges. The number of accredited CAM institutions that receive research support should increase as their capacity to conduct rigorous research improves and they submit more applications.

NCCAM provides funding for approximately ¹⁵ CAM Specialty Centers of Research in collaboration with other NIH institutes and centers and the Office of Dietary Supplements. In addition to botanicals, the specialty centers focus on such areas as arthritis, women's health, pediatrics, cardiovascular disease, addiction, cancer, and craniofacial disorders. These Centers as well as others supported by NCCAM offer research training opportunities. NCCAM and the other institutes and centers are encouraged to develop a cadre of well-trained CAM and conventional medical investigators in basic, clinical, or health services CAM research and to support career development awards. The Commission also encourages support of CAM research training and infrastructure by the private and nonprofit sectors.

The General Clinical Research Centers, supported by the NIH National Center for Research Resources, form a national network of hospital-based centers that provide a research infrastructure for clinical investigators who receive NIH and other Federal agency support, and an environment and resources for developing future scientists in clinical research. In addition to the NCCAM-supported centers, the General Clinical Research Centers might offer opportunities to conduct clinical research and training in CAM and examine the inclusion of CAM in the clinical setting.

In addition to continued strong support for pre- and post-doctoral fellowship (F) and institutional (T) research training awards, CAM research trainees need experienced mentors. Incentives may have to be developed to attract mentors to this field. Strong support of career development (K) awards--including those that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards to provide the time required to mentor new CAM investigators--are of considerable importance. ¹³ Also, the NIH

Loan Repayment Program is offered to individuals holding doctoral degrees who participate in clinical research. Among those who are eligible are, DCs, NDs, and OMDs.¹⁴

Recommendation 8: Public and private resources should be increased to strengthen the infrastructure for CAM research and research training at conventional medical and CAM institutions and to expand the cadre of basic, clinical, and health services researchers who are knowledgeable about CAM and have received rigorous research training.

Actions

- 8.1 Funding should be made available to accredited CAM and conventional medical institutions to develop programs that examine CAM research questions and that stimulate cross-institutional collaborations involving faculty and students in research and research training.
 - 8.2 Funding should be made available to accredited CAM and conventional medical institutions to support joint research and professional education and training programs to enhance the quality and clinical relevance of CAM research and link the research with evidence-based education and training of practitioners.
 - 8.3 Federal health agencies with research training programs and responsibilities that encompass CAM-related questions should be given adequate support to increase research training in CAM.
 - 8.4 Existing resources, such as NCCAM-supported centers and the National Center for Research Resources' General Clinical Research Centers should be utilized to increase opportunities for conducting clinical research and training on CAM and to examine the possibility of including CAM in the clinical setting.
 - 8.5 Federal support for career development awards should be increased, including awards that enable investigators focusing on CAM to develop into independent investigators and faculty members, and mid-career awards that provide the time required to mentor new CAM investigators.
- CAM Research Results: Systematic Reviews and Evaluations

Publication of CAM Research Results in Peer-Reviewed Journals

Publication of CAM research results in recognized, rigorously peer-reviewed research journals is needed to provide reliable information about CAM to researchers, practitioners, and ultimately the public. Decisions on regulating the use of and reimbursement for CAM therapies should be based on published evidence of safety (including toxicity, side effects, and adverse interactions),

clinical efficacy, general effectiveness, and cost-effectiveness and cost-benefit analyses rather than on traditional use, anecdotal reports, consumer interest, and market demand. The quality of the research and the standards of review required for journal publication affect how readers determine the reliability and usefulness of the information. To ensure a fair and accurate review, both CAM and conventional medical and scientific expertise should be represented on journal review boards when reviewing CAM research submissions.

Systematic Reviews

Reviews of published research from sources such as the Cochrane Collaboration's collection of systematic reviews, the evidence-based reports developed by the Agency for Health Care Research and Quality, and the databases of the National Library of Medicine, such as PubMed and MedlinePlus, are valuable resources for scientists, research planners, practitioners, community health centers, policy makers, and the public. The Commission is pleased with these organizations' CAM-related activities, especially their efforts to cooperate with one another, and their collaborations with NCCAM.

Efforts to increase the availability of concise and understandable summaries of the research literature for the public and other audiences through MedlinePlus and other dependable information sources should be supported. Examples that could be effectively applied to CAM-related information are the Department of Health and Human Services' "Report of the U.S. Preventive Task Force Guide to Clinical Preventive Services," which is a complete assessment of the literature on preventive medicine, and the more recent British Medical Journal publication, Clinical Evidence, which regularly updates information on clinical evidence.

Recommendation 9: Public and private resources should be used to support, conduct, and update systematic reviews of the peer-reviewed research literature on the safety, efficacy, and cost-benefits of CAM practices and products.

Actions

- 9.1 The Agency for Health Care Research and Quality should expand its Evidence-Based Practice Center systematic reviews on CAM systems and treatments for use by private and public entities in developing tools, such as practice guidelines, performance measures, and review criteria, and for identifying future research needs.
- 9.2 NCCAM should issue a comprehensive, understandable, and regularly updated summary of current clinical evidence on the safety and efficacy of CAM systems and treatments for health care practitioners and the public.

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