

Dear Colleagues,

The following questions were presented by Dr. Fins in our meeting three weeks ago:

- What recommendations are needed for federal agencies to reproduce what has been accomplished in Region X and Washington State?
- What funding for projects is needed to reproduce what we've accomplished in Washington State?
- What kind of RFPs can we recommend for developing integrated clinics such as the King County Natural Medicine Clinic, and collaborative relationships between CAM accredited colleges and universities and conventional medical and nursing schools?

To answer these questions, I have identified three types of federal recommendations for policies and initiatives needed to reproduce what we've accomplished in Washington State and Region X.

- I. **Regulatory and Community Environment:** What policies and activities were necessary to support successful integration in Washington State and Region X? What federal policies and initiatives can replicate this environment?
- II. **The Integrated Models: Successful Models and Initiatives:** What are the initiatives and projects which created successful integration in Washington State and Region X?
- III. **Removing Barriers to Integration: Recommendations Building the Future on the Region X Experience:** What are several key policies to improve integration, based on barriers observed in Region X?

Sincerely,

Joe Pizzorno, N.D.

- I. **Regulatory and Community Environment:** What are the policies and activities creating Washington State and Region X success?

“Many noteworthy factors converge here creating a unique testing ground for piloting and evaluating CAM health services integration” (Richard Lyons, M.D., Regional Health Administrator, USPHS, Region X). This integration is the result of decades of building partnerships among public leaders and health care providers. Uniform licensing local laws, regulations and mandates have also been instrumental in creating this environment. These elements and others are why the Northwest has become a model for the future of collaborative health care (NWIHC 2010).

Uniform licensing, local laws, regulations and mandates create an environment rich in well trained CAM and CM licensed health care professionals. High CAM training and practice standards create public safety and effectiveness. Laws and mandates facilitate integration.

Element: CAM Professional laws and licensing standards

1. **Federal recommendations should be made to support licensure consistent with CAM educational standards.** Federal support for licensure is important for both effectiveness and

public safety. These policies can be enacted by authorizing coverage for federal services access to federal benefits programs and job eligibility based on appropriate training and licensure. Support licensed and licensable CAM health care professions entering mainstream health care systems through the model of “credentialability”. It is appropriate for the federal government to set national goals. It is important for the federal government to take leadership and encourage credentialing and licensing in all fifty states for licensable CAM providers. The federal government must enact policies that will encourage CAM licensure and integration of CAM accredited standards of training.

2. Department of Health Peer Review Committees: Established for LCPs (licensed CAM professionals), CAM providers are held accountable to the public. Provide federal appropriations to DHHS to support states establishing and monitoring peer review at DOH.
3. Malpractice insurance: Licensed CAM providers are able to purchase this service, allowing managed care coverage for LCPs. Provide federal tax incentives to CAM malpractice insurers.

Element: Local laws and mandates

1. Every category of provider law: The law passed in 1993 during health care reform in Washington State under Insurance Commissioner Deborah Senn. Reproduce this law for all states and in federal insurance and benefits programs for federal employees.
2. Health Professional Loan Repayment and Scholarship Program: Washington State’s Department of Health recognized NDs and LMs as primary care providers and incorporated them into this program, providing CAM students and providers loan forgiveness for services to rural and underserved. Primary care LCPs are carrying student loans of up to \$100,000. LCPs express strong interest in working in these communities due to the philosophies of their disciplines and their interests in public and community health. Shortages in CM primary care services are increasing. Rural communities are considering importing foreign graduates of CM schools to provide these services. Naturopathic physicians and chiropractors in some states can provide these services. Licensed acupuncturists, direct entry midwives and nutritionists can make obvious contributions to community health in shortage areas. Propose appropriations to support inclusion of LCPs in the NHSC. Incorporate authorizing language including LCPs in the National Health Services Corp (NHSC) by amending the Primary Health Services Provision in the Reauthorization Bill.
3. State continuous quality assurance and quality improvement plans: Credentialing programs for LCPs assist in insuring and improving quality and safety of services. Establish National Credentialing Clearinghouse through the Bureau of Health Professions or HCFA. Appropriate \$1 million to initiate.
4. Local government (County Council and County Board of Health) innovation and leadership through motions and resolutions of support: King County Council’s resolution initiated and supported the establishment of the King County Natural Medicine Clinic (KCNMC) in 1995. In 2000, the Council passed a motion of support for King County Integrated Health Care 2010 and local integration initiatives. In 2000, the King County Board of Health passed a similar resolution of support for King County Integrated Health Care (KCIHC) 2010 and integration initiatives. Federal authorization and appropriation for KCNMC must take place through DHHS, and is addressed on page 8. Authorization and appropriation for KCIHC 2010, and similar community based initiatives should take place through DHHS through

appropriations to appropriate Regional offices in the USPHS. These groups should be funded for 3 years, and require approximately \$400,000 appropriation to DHHS. Pilot regions recommended to start with regions with all LCPs available.

Element: Rich CAM and conventional educational institutional environment

1. Support and fund CAM accredited schools and universities through the Public Health Services Act, HRSA, NCCAM and DHHS: Support high quality CAM accredited colleges and universities: Region X has the largest number of CAM educational institutions in any Region creating a robust and collegial environment for interdisciplinary collaboration (AOM-5; ND-2; DC-1; LM-4; LMT-39).
2. Authorize immediate and equal inclusion of LCPs and CAM accredited institutions in the Public Health Services Act HRSA, NCCAM, DHHS. Both Title VII and Title VIII are up for re-authorization late this year. Health professions under MODVOP should be expanded to include LCPs. Title VII, which funds medical schools should be amended to include chiropractors and naturopathic physicians and their academic institutions. Title VIII provides funding for non-physician health care programs and should be amended to include licensed acupuncturists, nutritionists, direct entry midwives and licensed massage therapists. Amend and expand the Definitions Section (292A) to include the LCPs: NDs, DCs, LAcS, LMTs, LMs and Nutritionists. Recommending appropriations for CAM schools should be a priority, particularly if recommending increased appropriations to CM schools for CAM or IHC training. Provide equal and immediate access to all other federal programs providing public funding for medical doctors and nurses.
3. Direct the Health Resources and Services Administration to provide federal UME-21 program grants to CAM accredited schools for curricular innovations in these schools.
4. Establish CAM accredited Academic Health Centers of Excellence through the Public Health Services Act. Encourage these Centers to collaborate with IHC and CM colleges. Recommend appropriations to support these Centers of Excellence as national resources, with grants of \$3-8 million.
5. Support CAM students at professionally accredited CAM institutions:
 - *Federal Benefits Programs:* Research legislation and rules which control federal health care agencies. Follow the example of NIHCCAM legislation. Propose legislation, amendments and rule changes necessary to mandate inclusion of LCPs and IHC. Propose adequate appropriations for LCPs and IHC in all appropriate federal programs. Approve accredited CAM colleges and LCP students for grant eligibility and eligibility for federal funding in all federal programs providing eligibility and funding to CM colleges and students. Examples include: add accredited CAM schools and their professional accrediting agencies to the enumerated lists of agencies under the Health Professions Act. Include LCPs in the Health Professions Education Partnership Act of 1998.
 - *Residencies:* Provide funding for postgraduate residencies for licensed naturopathic physicians. Provide support for chiropractors, acupuncturists and direct entry midwives residency needs. Federal GME systems must authorize inclusion of LCPs and appropriations for residencies to establish an adequate number of residency sites for LCPs. Until equal federal funding is available for CAM graduate medical education it is not appropriate to require residencies.

Residencies: support CAM and CM providers training together, and strengthen CAM provider exposure to conventional strategies, as well as enhancing training their own disciplines.

- Federal Graduate Medical Education (GME) financing systems must pass legislation and or rules authorizing GME funding for licensed naturopathic physician residency training and coverage of ND resident services. The Bureau of Primary Health Care, the Bureau of Health Professions and the Health Resources Services Administration should provide grants to each of the accredited naturopathic medical schools to rapidly expand purely naturopathic residency, specialty and postgraduate training programs and sites as well as exchange opportunities with conventional and other accredited CAM schools.
 - The Council on Graduate Medical Education draft report, "*Financing Graduate Medical Education in a Changing Health Care Environment*," recommended "reform of the entire GME financing structure" (Washington Highlights, Vol.1, No. 35, September 22, 2000). Require an addendum to the report concerning licensed CAM professions and GME financing. GME reforms relevant to both CM and licensed CAM provider services should both be addressed before attempting any major reform to GME systems.
 - The professions must receive federal and state funding to establish an adequate number of residency sites. Until funding for graduate medical education is available through the appropriate federal agencies and legislation (HCFA, BPHC, HRSA, GME), it is not appropriate to require this level of training for all naturopathic physicians.
 - Postgraduate naturopathic and LCP training should include at least one year of purely naturopathic or LCP residency training.
 - *School Loans: Improving access to student loans is necessary to remove barriers to CAM students which do not exist for medical and nursing students.* Increase student loan limits to naturopathic medical students. The Secretary of Education has the authority to increase loan limits for unsubsidized loans with respect to students engaged in specialized training requiring exceptionally high costs of education. (Section 428H(d)(2) of the Higher Education Act of 1965). The Secretary has exercised this authority to grant higher loan limits to those types of medical or professional schools that had been part of the original Health Education Assistance Loan program (HEAL). In the interest in fairness, we recommend that the Secretary be directed to add the Colleges of Naturopathic Medicine accredited by the CNME to the list of institutions eligible for the higher limits from the Federal Family Education Loan (FEEL) and the William D. Ford Direct Loan Program.
6. Proximity of important CAM and CM schools in the Region: High quality conventional medical, nursing and public health schools with a long history of exposure to CAM. CM and CAM university and college research partnerships (BU & UW; NCNM, Western States,

OHSU, OCOM). Bastyr University's reputation for high quality and involvement in public policy, proximity has advanced collaboration and integration efforts.

- *Encourage and fund collaboration between CAM and CM academic institutions.* Conventional, traditional, indigenous, complementary and alternative models of care, and their bodies of knowledge, have contributions to make health care which is culturally most appropriate and effective for individuals and communities. Best practices are discovered through exploring diverse structures for integration, including parallel, collaborative and assimilative models. Mandating and investing in true partnerships between accredited CAM and CM academic institutions is in the national public interest.
- *Provide financial incentives for equal CAM/CM institution partnerships.* Establish bonus funding incentives in grant applications between CM and CAM institutions who submit collaborative grants which model institutional partners as equals. Grants can be submitted for partnerships in research, academics, clinical services, and public affairs. For example, when a CAM school develops training opportunities for CM students, CAM students would be provided with equal access to training opportunities in the partnering CM school. Funding and governance structures in such grant applications should be fairly evenly balanced between institutional partners. Appropriate and authorize through NCCAM, BPHC, DHHS, HRSA, Public Health Services Act.
- *Exchange programs should be developed and encouraged between conventional and LCP accredited schools.* Providers who train together, work together. Authorize funding by the Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), to develop programs with AAMC and AANMC, and LCP college consortia. Link licensed CM programs with licensed CAM programs to support dual training with an emphasis on collaboration.

Element: Community participation and leadership. Convening of structured dialogue

1. Government led, mandated or supported interdisciplinary working groups: Integrated working groups produce effective collaboration across diverse organizations and individuals. Examples include Building Bridges Between Provider Communities Group (Region X USPHS and Bastyr University), Clinician Workgroup on the Integration of CAM (State of Washington, Office of the Insurance Commissioner), Northwest Integrated Health Care (NWIHC) 2010* (King County Council). Establish and fund integrated regional public health, state insurance office and local county council workgroups.
Establish an Office on CAM and Integrated Health Care in each DHHS, USPHS Region. Begin with offices in Region X and other regions with most extensive CAM and IM activity. Authorize an interdisciplinary work group for decisions, assessment and implementation of CAM integration. Work in co-ordination under the National Office for CAM and IHC to achieve goals of Healthy People 2010. These “deeply round tables” foster trust and respect for quality, credibility, competence and shared mission – and build a solid foundation for innovation and reform focused on improving community health.
2. The Clinician Workgroup on the Integration of CAM (Washington State) as a national forum: Replicate and establish this workgroup nationally through HRSA or HCFA. Multiple forums in several locations which convene nationally to build collaborative solutions to integration and insurance issues would be most effective.

* formerly King County Integrated Health Care 2010

3. Local community demonstration projects emphasizing public and community health: Provide federal funding through NIHCCAM, HRSA, BPHC, and CDC for local community demonstration projects and strategic planning to integrate CAM and CM health services with an emphasis on public and community health. The Northwest Indian College Regional Memorandum of Understanding with DHHS in USPHS Region X and the Northwest Center for Traditional Indigenous and CAM medicines are excellent examples.
4. Community Health Centers (CHC) leadership in Region X: CHCs historically employed natural medicine providers in attempts to provide integrative health care to the public. Authorize replication of their Integrated Care Model throughout the US. See pg 8 for details.
5. Local convergence of OIC office, Region X: King County, State of Washington, USPHS Region X and CM and CAM profession academic and research centers are locally adjacent, facilitating collaboration. Invest initially in pilot projects with similar predisposing features.
6. Support (through federal agencies and programs) CAM, conventional medicine and public health interdisciplinary advisory boards and working groups for decisions and implementation of CAM integration. These “deeply round advisory tables” foster trust and respect for quality, credibility, competence and shared mission – and build a solid foundation for innovation and reform. Harborview Hospital and King County Board of Health are examples.
7. Underserved populations using indigenous and traditional leaders and medicines: Indian Nation and Asian Pacific Islanders use of traditional medicines is high. Traditional healers practice in their communities and must be included in interdisciplinary workgroups, boards and initiatives. Understand and apply a taxonomy for CAM providers that supports a place for true traditional and indigenous leaders. CAM policy integration should focus on the goals of Healthy People 2010, and emphasize public and community health service and health disparities.

Element - Time: Funding must be provided which allow new ideas and relationships to develop over time.

Funding and consultation should be made available to initiate CWIC 2010 and Bridges type groups in other DHHS Regions. Mandate and fund regional and local public health interdisciplinary working groups to develop collaborative efforts for their regions. Provide a minimum of two years funding (\$400,000/group) to establish agenda, initiatives, resources and priorities. Authorize via HRSA, DHHS, BPHC and the Public Health Services Act.

II. The Integrated Models: Successful Models and Initiatives: What are the initiatives and projects which created successful integration in Washington State and Region X?

Integrated working groups: This was addressed earlier under government led or mandated interdisciplinary work groups. Several successful models (local: King County; state: Clinician workgroup; regional: Building Bridges) should be replicated.

1. Fund “National Credentialing and Standards Roundtable”. Include national conferences, with a Blue Ribbon task force representing accredited colleges of conventional healthcare and the licensed CAM and IHC professions, national associations for licensed CAM,

CM, IHC, and emerging professions. Include organizations and task forces involved with standard setting in CAM and CM education from within conventional medical education. Produce white paper recommendations on training standards for CAM and IHC practice and education through consensus. This roundtable should be the first priority established for the Federal Office on CAM and IHC.

2. King County Natural Medicine Clinic: Fund integrated clinic models and throughout the United States in local and regional Community Health Centers. HHS has increased the national budget for Community Health Centers significantly. An example is the provision of nearly \$9.2 million in grants to 20 local health centers to expand access to health care for medically underserved communities. These grants are provided through the New Start/Expansion Program administered by HRSA. New health care sites will be created in 17 states. The initial round of grants was announced March 27, 2001; the third round will be announced in August with approximately 40 new grants. Authorize replication of the successful Community Health Centers of King County Integrated Clinic model through these grants. In addition, propose that HRSA appropriate funds to replicate this model through its Consolidated Health Centers (CHC) program. The President's proposed budget includes a \$124 million increase in CHC funding. This is an especially timely recommendation as the number of conventionally trained primary care providers is decreasing.
3. Establish Academic Health Centers of Excellence (AHCE) in CAM accredited institutions: This recommendation addressed earlier on pg 4.
4. Loan forgiveness and service to rural and the underserved: This recommendation addressed on pg 2, but cannot be overstated. Incorporate authorizing language including LCPs in the National Health Services Corp (NHSC) by amending the Primary Health Services Provision in the Reauthorization Bill. Propose appropriations to support inclusion of LCPs in the NHSC.
5. Support equal access to licensed CAM providers and services:
 - *Allow access to licensed CAM professionals through federal health care programs.* Include licensed CAM professionals in Public Health Services and Community Health Centers administrative and clinical staff. Authorize LCPs as eligible to apply for federally funded health care positions.
 - *The Health Care Financing Administration (HCFA) must incorporate legislative language and promulgate rules to cover services for LCPs in all licensed states. The Medicare Act must be amended to provide for these changes. This authorizing language is central for LCPs' access to many federal and state programs. Provide Medicare and federal Medicaid state matching for services provided by LCPs within their scope of practice and Medicare/Medicaid's scope of covered services.*
 - *The Balanced Budget Refinement Act of 2000 (HR 3077) would improve services for Medicare recipients. This bill allows GME payments for psychologists. Incorporate GME payments for licensed naturopathic physicians and other LCPs in this legislation or similar legislation. Authorizing language for ND and LCP residency funding in all GME funding*

streams should be written into this legislation (and rules) including authorizing Medicare direct and indirect GME, Children's Hospital GME, and Title VII grants from HRSA.

- *Authorize reimbursement through Medicare, Medicaid, government programs and private payers* for wellness and prevention services. Two examples are the Medicare Medical Wellness Act and the Medicare Medical Nutrition Act providing the sole right to have nutrition services reimbursed to registered dietitians. While registered dietitians should receive this coverage for services, this legislation must be expanded to include all CAM regulated professions whose training scope of practice provides regulated nutrition services. Provide tax incentives to individuals for wellness, prevention and self care. Reimburse for behavior change.
6. Market factors: Access to LCPs and services: Patients have access to all LCPs within their scope of practice in Washington State and Region X. To replicate this on the federal level, the rapid rise in the CAM credentialled workforce must be noted and addressed. There will be an 88% increase in LCPs by 2010, nationally.
- *Provide incentives for insurance coverage of CAM and integrated services:* High penetration of coverage in a non-mandated state (Oregon, Kaiser, Healthy Net, Providence).
 - *Support, as a matter of national policy, the standards of practice inherent in state licensing laws, as credentialing guidelines for State departments of Health, NCQA and JAHCO.*
 - *Support funding by AHCRO for CAM practice guideline projects involving the CAM professions:* Establish both baseline CAM system specific guidelines as a foundation. Then develop integration/integrative practice guidelines.

III. **Removing Barrier to Integration: Recommendations Building the Future on the Region X experience? What are several key policies to improve integration based on experience with barriers observed in Region X?**

1. National Health Services Corp: This recommendation mentioned on pg 2 will improve access to the underserved, and provide CAM strategies to reduce health disparities by qualified providers. Medicaid and Medicare CAM provider and services authorization must be provided.
2. NIHCCAM incentives and other federal CAM/CM partnership initiatives: These recommendations on pg 5 will assist in building true, robust and creative partnerships between CAM and CM Academic and Research Centers.
 - *Encourage and fund collaboration between CAM and CM academic institutions.*
 - *Provide financial incentives for equal CAM/CM institution partnerships.*
 - *Exchange programs should be developed and encouraged between conventional and LCP accredited schools*
3. Uniform CAM licensure through Title Acts: This recommendation, on page 2, will enhance consumer and CM access to qualified partners and qualified workforce.

4. National Credentialing and Standards Round Table: This recommendation on pg 7 will improved integration and exchange of useful standards between CAM and CM of curricula, board exams, etc, saving millions of taxpayer dollars.
5. Access to Medicare and Medicaid for CAM service and providers for all covered conditions
 - *The Health Care Financing Administration (HCFA) must incorporate legislative language and promulgate rules* to cover services for LCPs in all licensed states. The Medicare Act must be amended to provide for these changes. This authorizing language is central for LCPs' access to many federal and state programs. Provide Medicare and federal Medicaid state matching for services provided by LCPs within their scope of practice and Medicare/Medicaid's scope of covered services.
 - *The Balanced Budget Refinement Act of 2000 (HR 3077) would improve services for Medicare recipients.* This bill allows GME payments for psychologists. Incorporate GME payments for licensed naturopathic physicians and other LCPs in this legislation or similar legislation. Authorizing language for ND and LCP residency funding in all GME funding streams should be written into this legislation (and rules) including authorizing Medicare direct and indirect GME, Children's Hospital GME, and Title VII grants from HRSA.
 - *Authorize reimbursement through Medicare, Medicaid, government programs and private payers* for wellness and prevention services. Two examples are the Medicare Medical Wellness Act and the Medicare Medical Nutrition Act providing the sole right to have nutrition services reimbursed to registered dietitians. While registered dietitians should receive this coverage for services, this legislation must be expanded to include all CAM regulated professions whose training scope of practice provides regulated nutrition services. Provide tax incentives to individuals for wellness, prevention and self care. Reimburse for behavior change.
6. Collaborative training for CM/CAM: This recommendation is mentioned on pg 5-6. Providers that train together, work together. Funding this will replicate the CAM/CM rich mix in Washington State and Region X.
7. School Loans: Recommendation on pg 5. Improving access to student loans is necessary to remove barriers to CAM students which do not exist for medial and nursing students.
8. Immunization and CAM: Studying the exempt community: Establish a Region X Immunization/CAM Taskforce to pursue scientific and scholarly discussion on immunization issues. Involve the immunization Action Coalition of Washington, its Health Care Provider Awareness sub-group, Bastyr University clinicians and scientists, Region X, CDC and other key CAM educational and professional organizations.

Varieties of Healing. 2: A Taxonomy of Unconventional Healing Practices

Ted J. Kaptchuk, OMD, and David M. Eisenberg, MD

The first of two essays in this issue demonstrated that the United States has had a rich history of medical pluralism. This essay seeks to present an overview of contemporary unconventional medical practices in the United States. No clear definition of "alternative medicine" is offered because it is a residual category composed of heterogeneous healing methods. A descriptive taxonomy of contemporary unconventional healing could be more helpful. Two broad categories of unconventional medicine are described here: a more prominent, "mainstream" complementary and alternative medicine (CAM) and a more culture-bound, "parochial" unconventional medicine. The CAM component can be

divided into professional groups, layperson-initiated popular health reform movements, New Age healing, alternative psychological therapies, and non-normative scientific enterprises. The parochial category can be divided into ethno-medicine, religious healing, and folk medicine. A topologic examination of U.S. health care can provide an important conceptual framework through which health care providers can understand the current situation in U.S. medical pluralism.

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For author affiliations and current addresses, see end of text.

See editorial comment on p 208.

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Defining unconventional medicine by "what it is" does not work. *Alternative medicine* is an umbrella-like term that "represents a heterogeneous population promoting disparate beliefs and practices that vary considerably from one movement or tradition to another and form no consistent . . . body of knowledge" (1). Alternative medicine is a large residual category of health care practices generally defined by their exclusion and "alienation from the dominant medical profession" (2).

Besides an absence of shared principles, an accurate definition of alternative medicine is further confounded because the boundary demarcating conventional and irregular medicine has always been porous and flexible (3). Therapies move across that border; for example, nitroglycerin (4) and digitalis (5) began as alternative drugs, just as corn flakes and graham crackers began as unconventional health foods (6). Entire professions change sides. In 1903, when the American Medical Association needed both a larger referral base for specialists and new allies in its fight with osteopaths, chiropractors, and Christian Scientists, it boldly reversed its policy and declared homeopaths to be conventional MDs (7). Likewise, osteopathy ceased being a renegade profession after World War II (8-10).

The first of two essays in this issue (pp 189-195) demonstrated that the United States has had a rich history of medical pluralism. This essay offers an overview of alternative medicine. Because of the inherent problems in defining a flexible residual category, we present a

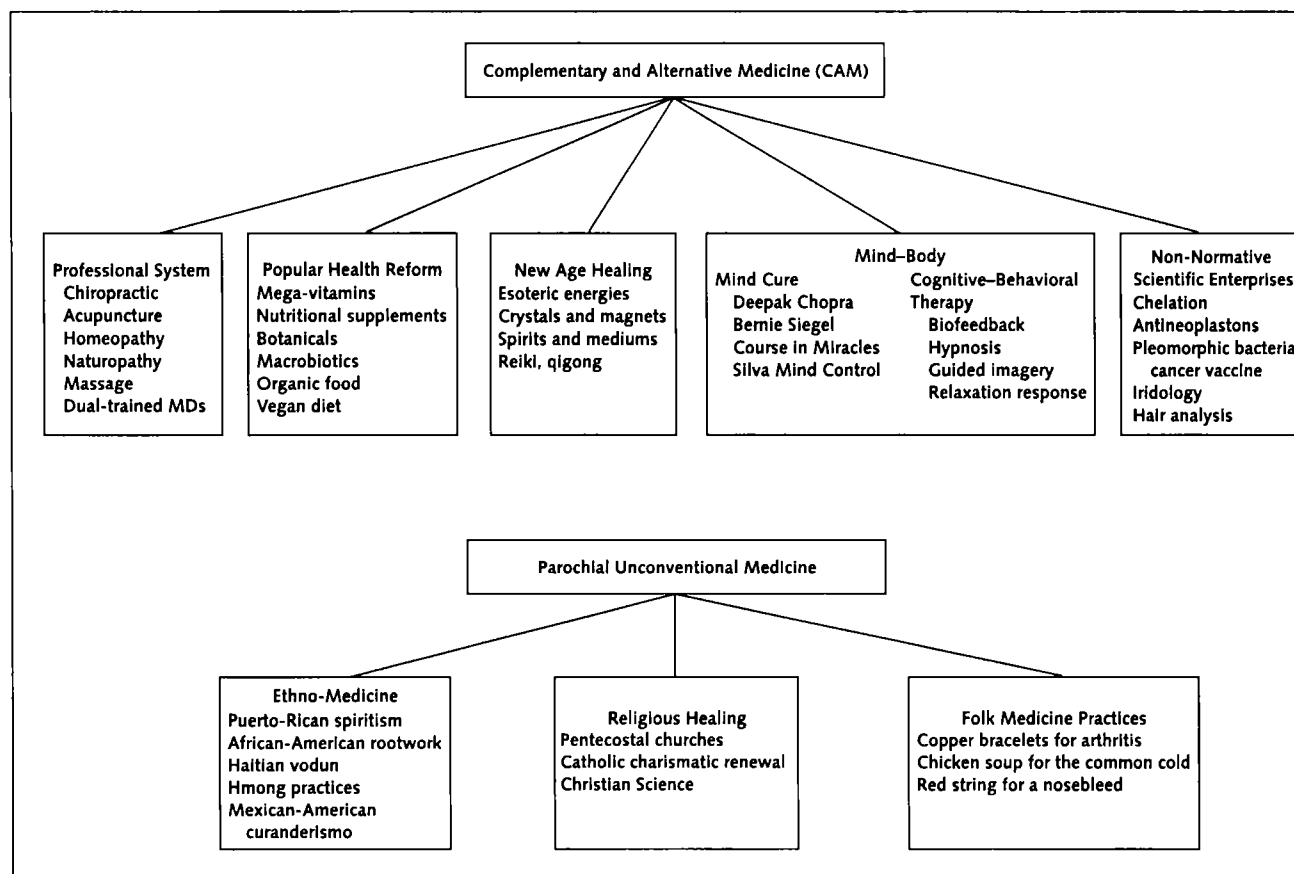
taxonomy of what is currently considered unconventional healing in the United States.

The number of named alternative therapies available in the United States easily soars into the hundreds (11-16). Many classification systems have been proposed (17-24). In an effort to further discussion, we offer a new taxonomy that we believe configures the domains of unconventional medicine across a broader spectrum of health practices. We do not expect that our attempt will be definitive (nor do we necessarily believe a perfect schema is possible). Any classification system is limited because such human phenomena resist discreteness as well as being fixed in time. As we point out, overlap often occurs. Inevitably, subjectivity affects the categorization and perceptions of "affinities." A summary of our schema is presented in the **Figure**.

Unconventional healing practices can be divided into two types: one that appeals to the general public and another that confines itself to specific ethnic or religious groups. The broadest category of unconventional medicine is easily recognized because its health care claims to be independent of any sectarian belief or faith and is said to depend on universal and even "scientific" laws (25). It is the best-known variety of unconventional medicine in the United States and recently, in a loose alliance, has become known as complementary and alternative medicine (CAM) (25).

The second kind of unconventional practice is typically confined to narrow groups, such as members of particular religions (for example, Pentecostal Chris-

Figure. Unconventional healing practices: taxonomy with examples.



tians), ethnic groups (for example, Puerto-Rican spiritism), or regions (for example, southern Appalachian folk beliefs). These practices are culturally self-contained, function outside any broader coalition, often lack the markings of a health delivery system, and in this essay are referred to as parochial unconventional medicine.

COMPLEMENTARY AND ALTERNATIVE MEDICINE

The wide-ranging category of CAM can be divided into five main sectors, which are described below.

Professionalized or Distinct Medical Systems

Probably the most recognizable alternative healing practices are those that are organized into medical movements with distinct theories, practices, and institutions. Licensure as an independent profession is a goal if not always an actuality. Medical institutions, such as schools, professional associations, and offices with secretaries and

billing procedures, are readily visible. An extensive corpus of technical literature helps guide therapy and practice and sharpens distinctness. Because they are easiest to describe and define, these systems are the most prominent in discussions of CAM. The six major components of this sector of CAM are chiropractic, acupuncture, homeopathy, naturopathy, massage, and dual-functioning MDs.

Chiropractic, the largest alternative medical profession in the United States, accounts for almost a third of all visits to CAM providers (26). The body's biomechanical structure, especially the spine, is seen as basic to health, and chiropractic emphasizes spinal manipulation as treatment (27, 28). Licensed as primary health care providers in all 50 states, chiropractors especially treat musculoskeletal disorders (29, 30).

Osteopathy was once a second manual therapy competing for the same patients as chiropractic. Since World

War II, osteopathy has reconfigured itself and has become “conventional”; the status of an osteopathic physician is equivalent to that of an MD. A minority of patients (<17%) visiting DOs receives the kind of manipulative therapy that would still be considered unconventional by orthodox MDs (31, 32).

Acupuncture relies on the insertion of fine needles at well-defined specific sites to regulate and balance humoral forces and “energy” (*qi*) and to promote health (33). As a component of East Asian medicine, acupuncture is often complemented with herbal treatment. Since the 1970s, acupuncture has spread throughout the United States and is independently licensed as a health care profession in 37 states (34).

Homeopathy uses the principle of “like cures like”: A substance that produces a set of symptoms in a healthy person is used to treat an identical symptom complex in a sick person (35, 36). The substance, however, is extremely diluted, often to the extent that none of the original substance is likely to remain. Currently, homeopaths can be independently licensed in only three states, but other licensed practitioners also prescribe these remedies.

Naturopathy uses a wide assortment of therapies that its practitioners call “natural.” Herbs, nutritional supplements, dietary and lifestyle advice, homeopathy, manipulation, and counseling can all be components of the repertoire (37). The term *naturopathy* was adopted in 1902 to replace the old word *hydropathy*, which denoted water-cure therapy. Currently, naturopaths can be licensed as primary care providers in 11 states; naturopathy is most common in the Pacific Northwest (38).

Massage therapists can be professionally licensed in more than 25 states (39). Although massage therapists (also called “body-workers” or “hands-on therapists”) clearly perform unorthodox interventions (40–42), they overlap with recognized biomedical professions, such as physical therapy, or simple attempts at relaxation. Complementary alternative medicine techniques that address body alignment and awareness (such as the Feldenkrais method [43] and the Alexander technique [44]) are often classified as massage therapy because they involve “body-work.”

Medical doctors who have opted to deliver, supervise, or advocate CAM are a significant force in alternative medicine (45, 46). These dual-trained practitioners lend enormous prestige and legitimacy to alternative

medicine and can be prominent spokespersons (47–50). Providing what is sometimes called “integrative” medicine, these physicians can deliver a broad range of CAM services or can focus on a single therapy.

Popular Health Reform (Alternative Dietary and Lifestyle Practices)

The health food movement, also known as alternative dietary and lifestyle practices, is an important component of CAM. Depending on how one calculates, it may in fact dwarf the professional sector (51). In the scholarly literature, this type of healing is labeled “popular health reform” because these practices are often advocated by untrained laypersons who often claim knowledge superior to that of expert scientists (6).

Popular health reform is delivered by a melange of resources, such as health food stores, popular books and journals, charismatic leaders, alternative provider recommendations, mass media attention, and a considerable amount of neighborly advice. This popular movement usually espouses a vegetarian or near-vegetarian diet, or avoidance of chemically treated and, more recently, radiated or genetically altered food. Details of particular programs tend to have enormous heterogeneity. Recommendations might range from eating only cooked food (for example, macrobiotics [52]) to eating only raw food (for example, fruitarianism) (53), or from heavy reliance on nutritional and botanical supplements or aromatherapy to their absolute prohibition. Recent shifts in biomedicine’s understanding of nutrition and its role in pathophysiology have also encouraged a general social movement toward behaviors that were once thought to belong to health food “nuts” (54). This, in turn, has caused a blurring of the distinction between orthodox and unorthodox lifestyles and has helped increase the awareness of CAM in society (51).

New Age Healing

The New Age is the source of many extremely disparate beliefs and practices that can describe overlapping religious and healing movements (55, 56). Furthermore, confounding discussion, the term *New Age* may not be “adopted by a given individual (indeed, may be rejected), even though to outsiders the practice appears to fall into this category” (57). As a religious movement, the New Age is about a “new dispensation”: less about law and limitation and more about unrestricted self-express-

sion and unlimited abundance. Instead of any fixed religious doctrine, the movement emphasizes a fluid “spirituality.” It is not uncommon to see an iconography that is a grab bag of Hindu, Christian, Buddhist, Rosicrucian, and pagan motifs (18).

The New Age is also a health care category because spiritual equanimity and physical health are considered to be linked. In fact, New Age beliefs resist any separation between spirituality and physical health or faith and medicine. Scholars point out that the New Age seeks a “third way,” “a spiritual science,” between revealed biblical religion and “atheistic–materialist” science (58).

A key New Age connection between the spiritual and physical realms involves esoteric energies that resemble a veritable “electromagnetic” dimension of wellness (59, 60). The names of the energies change—life force, universal innate intelligence, psychic, parapsychological, psi, astral, spiritual vital force—but they inevitably elude scientific detection (61). Healers can transmit these forces. Devices and substances that emit them, such as radionic machines, magnetic devices, pyramids, crystals, and other electromagnetic gadgets, are constantly being incarnated. The health influence of planets and stars and some medical astrology could be considered another type of such energy (62). Healing energy therapies not explicitly connected to the New Age, such as “therapeutic touch” (often applied by nurses) (63) and “laying-on of hands” (64), can ultimately be traced here. New “energy” forces are being recruited from Asia. Chinese qigong (65) and Japanese Reiki (66), while obviously not originally New Age, find it a hospitable environment for cross-cultural migration (61).

Sometimes the religious and health domains are bridged through “clairvoyant physicians” or the healing presence of the spirits, religious icons, or leaders (67–70). Best-selling books by spirit mediums who describe spiritual healing for “incurable diseases and maladies” help keep the phenomena in prominent view (71). A third type of New Age healing connection between the cosmos and human health operates through “mind” forces and can also be considered a subcategory of CAM psychological intervention (see following discussion).

Psychological Interventions: Mind Cure and “Mind–Body” Medicine

Psychotherapeutics in CAM has two sources: one that is purely CAM and one that overlaps with conven-

tional psychological interventions. In the scholarly literature, the exclusively CAM psychological tradition is referred to as Mind Cure or New Thought (17, 72–74). These therapies, which can include a myriad assortment of visualizations, affirmations, intentions, meditations, and emotional release techniques, all share a single point: Mental forces are the preeminent arbiters of health. Psychotherapists affiliated with CAM believe that the mind is the most dominant agency for restoring well-being and maintaining health. The notions that “What you think is what is real” and that “Your emotions determine cancer or other major disease” are dogma repeated over and over like mantras. Such bestsellers as Bernie Siegel’s *Love, Medicine and Miracles* and Deepak Chopra’s *Ageless Body, Timeless Mind: The Quantum Alternative to Growing Old* testify to the appeal of these beliefs.

The other sector of CAM “mind–body” therapies merges into conventional psychotherapy and cognitive–behavioral interventions. The relationship can be confusing or can produce gray areas. Generally speaking, in conventional medicine, psychotherapeutics is conceded only limited agency and is primarily used to treat psychological problems or to help patients cope when conventional treatments are not available or are insufficient. Psychotherapeutics remains a subordinate component of the conventional medical system (75, 76).

However, whenever too much power or efficacy is attributed to regular psychological therapies and they are used “off-label,” they “transgress” and can become CAM. For example, most MDs would consider psychotherapy appropriate for reactive depression after a cancer diagnosis, but psychotherapy used to cure a metastatic tumor would be considered unconventional (77). The same holds true for various cognitive–behavioral therapies that use “passive nonvolitional intention,” such as biofeedback, stress management, relaxation response, meditation, guided imagery, and hypnosis. When practitioners of these techniques make modest claims limited to small physiologic changes, the techniques are acceptable as subordinate components of conventional medicine. For example, biofeedback for fecal incontinence (78) or, more debatably, relaxation response for mild hypertension (79, 80) can seem legitimate or can at least achieve borderline acceptability, but both would be considered distinctly alternative if used to treat diabetes.

Another source of CAM psychotherapeutics involves the fact that between 250 (81) and 400 (82)

named types of psychological treatments are thought to exist. Any therapy deemed unacceptable by the mainstream can find a receptive home in CAM. Also, whether self-help groups, such as Alcoholics Anonymous, are CAM is highly debatable, but to the extent that they are not conventional they can automatically be described as alternative (83, 84).

Non-Normative Scientific Enterprises

Non-normative scientific enterprises typically appeal to patients with potentially catastrophic illnesses, such as cancer. These therapies can include sophisticated pharmacologic agents and often revolve around a well-known proponent who can have legitimate and even impressive scientific or medical credentials but advocates theories and practices unacceptable to the general scientific community. Examples include Dr. Stanislaw Burzynski's "antineoplastons" and Dr. Virginia Livingston-Wheeler's "pleomorphic bacteria cancer vaccine" (85, 86). Non-normative interventions can sometimes blur into the conventional practice of prescribing recognized pharmaceuticals for off-label uses (87–89). Unvalidated diagnostic methods and unconventional technological devices that diagnose or heal can be considered part of the non-normative science category. Representative examples are hair analysis, which purportedly detects a wide variety of diseases and nutrient imbalances (90); iridology, in which illness is diagnosed through a detailed examination of the iris (91); and chelation therapy to reverse the processes of arteriosclerotic disease (92).

PAROCHIAL UNCONVENTIONAL MEDICINE

Unlike CAM, parochial unconventional practices appeal to a more narrowly defined constituency. Three main parochial categories exist.

Ethno-Medicine

The healing practices of specific ethnic populations make up a critical component of U.S. community health care (93). These practices are rooted in the widely differing medical or religious traditions of various cultures. Well-known examples include Puerto-Rican spiritism, (94, 95), Mexican-American curanderismo (96, 97), Haitian vodun (98, 99), Native American traditional medicine (100), Hmong folk practices (101), African-American "rootwork" (102), and African-Amer-

ican spiritual church healing (103, 104). Occasionally, a culture-bound medical system ventures outside its historical sphere of influence and becomes another option available to the general U.S. population. This is true of acupuncture and seems to be coming true for India's Ayurvedic medicine as it follows in the footsteps of yoga, its pioneering offspring (105). Partly because of New Age affinities, this may also happen with Tibetan medicine and Native American ceremonies (106, 107). Nonetheless, as a general taxonomic statement, consistent with stubborn racist prejudices, one could say that medical practices of ethnic communities are described as ethno-medicine while the "ethno-medicine" of mainstream white Americans is generally classified as CAM.

Folk Medicine Practices

Folk healing practices form a deeply embedded, unorganized, and seemingly spontaneous response to illness. Many of these practices are confined to specific geographic areas, such as southern Appalachia (108) or rural New Hampshire (109). Sometimes they can be traced back to remnants of ethnic (including Anglo-Saxon) magical traditions or earlier lay forms of self-care and home remedies. Common practices include wearing copper bracelets for arthritis, covering a wart with a penny and then burying the penny, stopping a nosebleed by placing a red string around the neck, and curing a cold with chicken soup (110–113). Besides cures, folk beliefs can also generate culture-bound diseases, symptoms, and treatment-seeking behaviors (114, 115). Some folk practices have a more widespread currency and are derived from earlier layers of premodern medicine (for example, humoral Hippocratic medicine) or medieval medical schools (for example, astrological medicine) (116, 117). Examples of remnants of Hippocratic ideas include such folk wisdom as "Bundle up to prevent a cold" or "Feed a cold and starve a fever" (115, 118, 119).

Religious Healing

Many Americans rely on religion for salutary effects on their health (120, 121). Generally, normative mainstream religious institutions have seen their role as supporting the "spiritual" dimension and avoid direct overlap or competition with the biomedical system (122). This division of labor has weakened somewhat lately;

“healing” services of one kind or another have appeared even in liberal churches and synagogues (123, 124).

The most salient forms of religious healing for physical disease can be found in Christian churches that see their ministry as replicating the miraculous healings recorded in the Bible (125, 126). This is especially true of the Pentecostal and charismatic churches, which seek to encounter and affirm the divine as manifest in both physical and mental healing (127, 128). People rising from wheelchairs or discarding crutches can be convincing signs of God’s power (129, 130). Christian Science, whose origins may be closer to Mind Cure than to Christianity, also continues to be an important non-normative source of healing in the United States (131, 132). Some religious denominations are also known for nonadherence to normative procedures (for example, Jehovah’s Witnesses, who routinely decline blood transfusions) (133, 134). For any of these religious approaches, genuine “faith” is required in exchange for the promised effectiveness. Also, these approaches sharply distinguish themselves from participation in any professed coalition with the CAM movement (135).

OVERVIEW

Unconventional healing is a far-flung landscape of diverse practices. A taxonomy balances distinction with commonality. Other perspectives that emphasize interconnection and common themes are possible. Healing behaviors can be grouped into those that focus on the primacy of substances to be taken orally (herbs, homeopathy, dietary supplements, or food), those that rely on the human hand (manipulation, needles, or anointing the sick), or those that emphasize words (ritual or psychotherapy) (23, 136). One could also discuss CAM approaches on the basis of shared common themes (for example, belief in nature, vitalism, and spirituality), as has been done extensively elsewhere (25). No matter how it is classified, however, this entire domain provides concrete practices and “pathways of words, feelings, values, expectations [and] beliefs” that reorder and organize the illness experience (137). Because patients include unconventional healing as an important component of their response to illness, physicians must understand this complex spectrum of health care practices.

CONCLUSION

A single definition of alternative medicine that tries to state “what it is” inevitably is not satisfying, since alternative healing includes a wide assortment of heterogeneous therapies and beliefs. A taxonomy of unconventional health care practices can help define alternative medicine and provide a conceptual framework for it. Such a model can help physicians understand and participate in the current discussion on unconventional healing practices as it rapidly unfolds.

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Perceptions about Complementary Therapies Relative to Conventional Therapies among Adults Who Use Both: Results from a National Survey

David M. Eisenberg, MD; Ronald C. Kessler, PhD; Maria I. Van Rompay, BA; Ted J. Kaptchuk, OMD; Sonja A. Wilkey, MD; Scott Appel, MS; and Roger B. Davis, ScD

Background: Little is known about perceptions of complementary and alternative medical (CAM) therapy relative to conventional therapy among patients who use both.

Objective: To document perceptions about CAM therapies among persons who use CAM and conventional therapies.

Design: Nationally representative, random-household telephone survey.

Setting: The 48 contiguous U.S. states.

Participants: 831 adults who saw a medical doctor and used CAM therapies in 1997.

Measurements: Perceptions about helpfulness and patterns of CAM therapy use relative to conventional therapy use and reasons for nondisclosure of CAM therapies.

Results: Of 831 respondents who saw a medical doctor and used CAM therapies in the previous 12 months, 79% perceived the combination to be superior to either one alone. Of 411 respondents who reported seeing both a medical doctor and a CAM provider, 70% typically saw a medical doctor before or concurrent with their visits to a CAM provider; 15% typically saw a CAM provider before seeing a medical doctor. Perceived confidence in CAM providers was not substantially different from confidence in medical doctors. Among the 831 respondents who in the past year

had used a CAM therapy and seen a medical doctor, 63% to 72% did not disclose at least one type of CAM therapy to the medical doctor. Among 507 respondents who reported their reasons for nondisclosure of use of 726 alternative therapies, common reasons for nondisclosure were "It wasn't important for the doctor to know" (61%), "The doctor never asked" (60%), "It was none of the doctor's business" (31%), and "The doctor would not understand" (20%). Fewer respondents (14%) thought their doctor would disapprove of or discourage CAM use, and 2% thought their doctor might not continue as their provider. Respondents judged CAM therapies to be more helpful than conventional care for the treatment of headache and neck and back conditions but considered conventional care to be more helpful than CAM therapy for treatment of hypertension.

Conclusions: National survey data do not support the view that use of CAM therapy in the United States primarily reflects dissatisfaction with conventional care. Adults who use both appear to value both and tend to be less concerned about their medical doctor's disapproval than about their doctor's inability to understand or incorporate CAM therapy use within the context of their medical management.

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Complementary and alternative medical (CAM) therapies (also known as integrative or unconventional therapies) have been defined as "those interventions neither taught widely at U.S. medical schools nor generally available in U.S. hospitals" (1, 2). While imperfect, this definition has been used to identify representative CAM therapies, which have been studied for prevalence of use in two national random-household telephone surveys (1, 2). Data from these surveys indicate that CAM therapy use and expenditures increased substantially in the United States between 1990 and 1997 (1). Overall prevalence of use increased by 25%; total visits by an estimated 47%, from 427 to 629 million; and expenditures for CAM services by an estimated 45%, which totaled \$21 billion (1).

National surveys performed in other countries have suggested similar rates of CAM use throughout the industrialized world (3-7). Less well documented, however, are the reasons that adults typically use (and pay out of pocket for) these therapies, most of which have not been satisfactorily evaluated for relative effectiveness, safety, or mechanisms of action. Only one U.S. national survey published in a peer-reviewed journal has explored reasons for CAM use (8). Astin's survey, conducted in 1994 on a convenience sample of 1035 adults, found that reasons for CAM use included "a holistic orientation to health; having had a transformational experience that changed the person's world view; . . . and classification in a cultural group identifiable by their commitment to environmentalism, commitment to feminism,

and interest in spirituality and personal growth psychology" (8).

National surveys in the United States of CAM use in 1990 and 1997 revealed that adults typically do not disclose their use of CAM therapies to their medical doctors (1, 2). In 1997, as in 1990 (1), fewer than 40% of CAM therapies used in the previous 12 months were discussed with a medical doctor. A recent analysis of data on U.S. national medical expenditures corroborated these findings and suggested that the percentage of CAM users who disclose their CAM visits to their medical doctors may be as low as 20% (9).

This paper summarizes 1997 national survey data on respondents' perceptions about use and nondisclosure of CAM therapies relative to conventional medical care.

METHODS

Sample

We conducted a nationally representative telephone survey between November 1997 and February 1998. Survey methods were approved by the Beth Israel Deaconess Committee on Clinical Investigations, Boston, Massachusetts. The survey used random-digit dialing techniques to select households and random selection of one resident per household, age 18 years or older, as the respondent. Eligibility was limited to English-language speakers for whom cognitive or physical impairment did not prevent completion of the interview. The survey sample and weighting methods have been previously described (1).

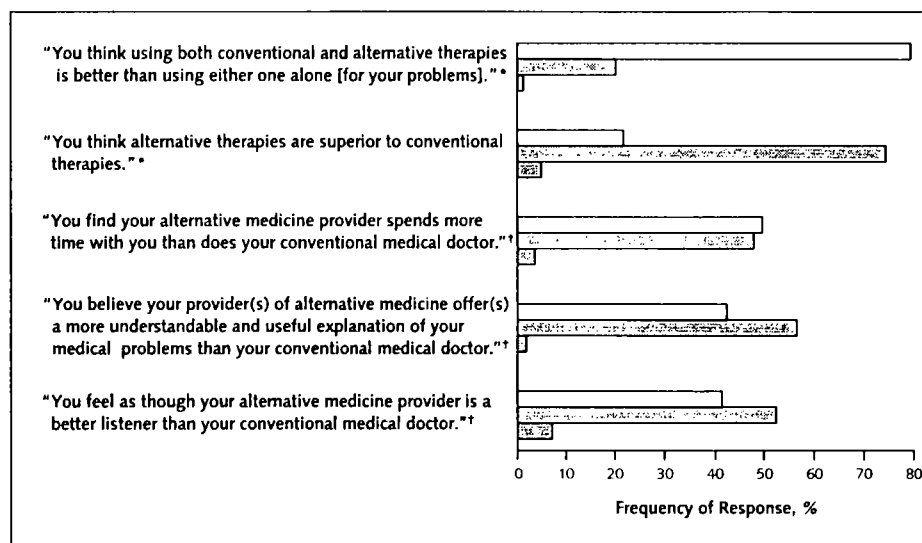
Interview

The interview was presented as a survey by investigators from Harvard Medical School about the health care practices of persons in the United States. No mention was made of "alternative," "integrative," "unproven," or "complementary" therapies in the introductory comments. The first substantive questions addressed perceived health, health worries, days spent in bed, and functional impairment due to health conditions. Next, respondents were asked about their interactions with a "medical doctor," defined as "a medical doctor, MD, or an osteopath, DO—not a chiropractor or other non-medical doctor." The term "medical doctor" was used throughout the remainder of the interview.

Respondents were asked if they had experienced any of a list of specified common medical conditions in the previous 12 months. Those who reported experiencing more than three conditions were asked to identify the three "most bothersome or serious" medical conditions. Respondents were then asked about seeing a medical doctor for these "principal medical conditions" and about perceptions of confidence in the medical doctor and the helpfulness and efficacy of their interactions. Next, respondents were asked about use of CAM therapies in the past 12 months and over their lifetime and whether each of these therapies was used for each of their principal medical conditions. We distinguished between use under the supervision of a professional (a provider of CAM therapy) and personal use without such supervision. Persons who reported having supervised use were asked about the number of visits during the past 12 months to providers of each therapy, perceptions of helpfulness and efficacy, and confidence in their CAM therapy providers. Respondents were asked whether they typically see a CAM provider before, after, or concurrent with their visits to a medical doctor. In addition, respondents were asked whether they agreed or disagreed with a list of "thoughts about the use of alternative therapies" (Figure 1). Each question was intended to elucidate perceptions about CAM therapy use relative to conventional care. All users of CAM therapies who had seen their medical doctor in the past year were asked if they had discussed use of each therapy with their medical doctor and if not, why they had not. They were then provided a list of possible reasons why people might not discuss certain therapies with a medical doctor and were asked to say "yes" to any number of items on the list that explained their own reasons for nondisclosure and "no" to items that did not. Additional details of the survey instrument are described elsewhere (1).

Statistical Analysis

As previously described (1), we calculated sampling weights for each respondent to reflect the probability of selection and to parallel the aggregate distribution of demographic characteristics of the U.S. population. We used SUDAAN software (10) to compute weighted estimates of the proportion of respondents giving specific answers to study questions. We applied the McNemar test to compare respondents' evaluations of the helpful-

Figure 1. Perceptions about complementary and alternative medical (CAM) therapy relative to conventional therapy.

Shown for each statement is the frequency of responses—agree (white bars), disagree (shaded bars), neither agree nor disagree (darkly shaded bars). *Asked of respondents who had seen a medical doctor and used any CAM therapies (excluding use of self-prayer alone) in the past 12 months ($n = 831$). †Asked of respondents who had seen both CAM therapy providers and medical doctors within the past 12 months ($n = 411$).

ness of CAM therapies and conventional care among respondents who used both for the same medical condition.

Role of the Funding Sources

This research was funded by grants from the National Institutes of Health, the John E. Fetzer Institute, and the American Society of Actuaries. Additional support for the completion of analyses and manuscript preparation was provided by unrestricted gifts from the Friends of Beth Israel Deaconess Medical Center, the Kenneth J. Germeshausen Foundation, the J.E. and Z.B. Butler Foundation, and The American Specialties Health Plan. None of the sponsors had access to the primary data, nor did they review the manuscript before submission.

RESULTS

Characteristics of the Respondents

The weighted survey response rate was 60% (1). The sociodemographic characteristics of the survey sample ($n = 2055$) were similar to the population distributions published by the U.S. Bureau of the Census (1). Among the 2055 survey participants, 1802 (87% weighted) reported seeing a medical doctor in the previous 12 months. Of these, 831 (45% weighted) reported

using CAM therapy (excluding use of self-prayer alone) in the past 12 months, and 411 (23% weighted) reported seeing a CAM provider in the past 12 months (1).

Perceptions of CAM Relative to Conventional Therapy Use

Figure 1 summarizes responses among respondents who used conventional care and CAM therapies in the past 12 months. As a preface to these questions, the interview script read,

I am going to read you some thoughts people have about their use of alternative therapies, like chiropractic, massage, acupuncture and the others I mentioned earlier. For each statement, please tell me if you agree or disagree.

As shown in Figure 1, fewer than 1 in 4 (21%) CAM therapy users ($n = 831$) agreed with the statement, "Alternative therapies are superior to conventional therapies," and roughly 4 of 5 (79%) respondents agreed that "Using both conventional and alternative therapies is better than using either one alone [for your problems]." For respondents who saw a CAM therapy provider and a medical doctor ($n = 411$), we asked

whether they agreed or disagreed that their CAM provider did a better job of “listening” or “explaining their medical problems” than their medical doctor. Forty-one percent agreed that their CAM provider was a better listener, and 52% disagreed; 42% agreed that their CAM provider did a better job of explaining their medical conditions, and 56% disagreed.

Sequence of Seeking Care from CAM Providers and Medical Doctors

We asked respondents who reported seeing both a medical doctor and a CAM provider during the past 12 months ($n = 411$) the following:

The next questions are about your use of alternative therapies in general. People generally fall into one of three groups regarding their use of alternative medicine. Some people see an alternative provider before they consult a medical doctor; some see both alternative providers and conventional doctors at the same time; and some see an alternative provider after they have seen a medical doctor. Which of these best describes your pattern of seeing alternative providers?

As summarized in Figure 2, 7 of 10 respondents

reported typically seeking the services of a CAM provider after or concurrent with their visit to a medical doctor. Fewer than 1 in 6 (15%) said they saw a CAM therapy provider before seeing a medical doctor.

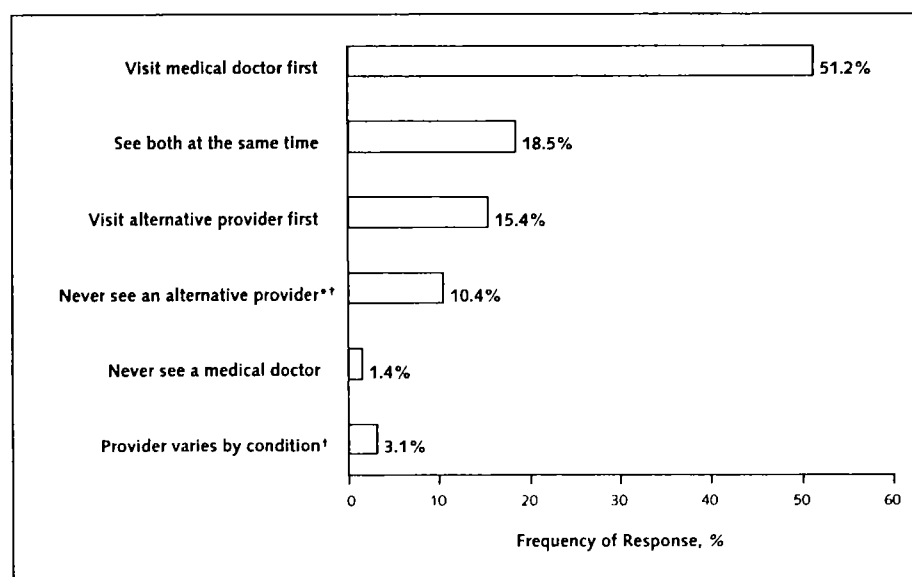
Overall Helpfulness of Therapies

The Table summarizes perceived relative helpfulness for 10 of the most commonly reported principal medical conditions identified in the 1997 national survey among respondents who used both conventional care and CAM therapies for each condition. The CAM therapies were judged more helpful than conventional care for treatment of headache and neck and back conditions; conventional care was considered more helpful for treatment of hypertension. Trends suggesting a perceived difference in helpfulness for other common conditions were observed, but we cannot confirm this because of sample-size limitations for most condition-specific groups.

Confidence in CAM Providers Relative to Medical Doctors

Respondents who reported seeing conventional and CAM providers in the past year ($n = 411$) were asked

Figure 2. Sequence of seeking care from complementary and alternative medical (CAM) providers and medical doctors.



Data are for the respondents who saw a medical doctor and a CAM provider during the past year ($n = 411$). *On further evaluation, this category was found to predominantly represent respondents who sought CAM therapies from a medical doctor. †These response choices were not read but were volunteered by respondents.

Table. Relative Helpfulness of Complementary and Alternative Medical Therapies Compared with Conventional Medical Care among Respondents Who Used Both for Specific Medical Conditions*

Medical Condition	Total Weighted Sample, <i>nt</i>	Respondents' Perception, %†		P Value§
		Conventional Care Was Better	CAM Therapy Was Better	
Back conditions	158.3	12.4	46.1	<0.001
Allergies	48.4	22.7	29.9	>0.2
Fatigue	14.6	9.4	41.3	0.09
Arthritis	72.1	25.9	44.8	0.06
Headaches	71.6	19.0	39.1	0.03
Neck conditions	87.9	6.4	61.0	<0.001
High blood pressure	14.9	57.0	0	0.004
Strains or sprains	17.4	7.8	22.5	>0.2
Lung conditions	36.1	25.9	23.5	>0.2
Digestive conditions	42.7	34.5	25.9	>0.2

* CAM = complementary and alternative medical.

† Values represent the sum of standardized sampling weights for the respondents with the condition.

‡ The remainder of respondents found their physician's care and CAM therapy to be equally helpful.

§ Based on a two-sided McNemar test.

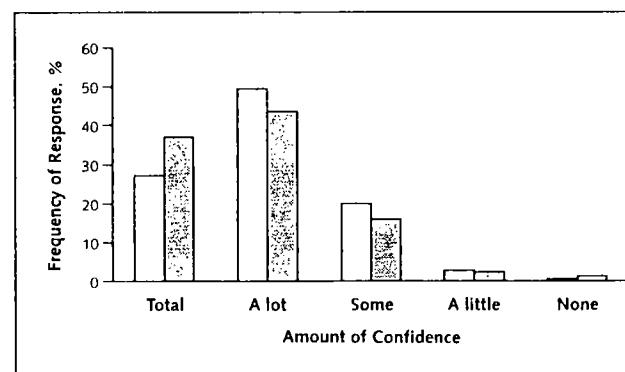
about confidence in their medical doctors and CAM providers (Figure 3). The question regarding confidence in one's CAM providers was asked only of respondents who had seen the provider in the past 12 months, whereas the question about confidence in one's medical doctors was asked of respondents who had ever seen a medical doctor. Furthermore, the question on CAM providers was repeated for each type of CAM provider seen. Therefore, responses in these categories are not ideally suited for formal statistical comparisons. However, the percentage of respondents who perceived "to-

tal" or "a lot of" confidence in their CAM provider was similar to the percentage of respondents who perceived "total" or "a lot of" confidence in their medical doctor (81% and 77%, respectively).

Reasons for Nondisclosure of CAM Therapy Use to Medical Doctors

Among the 831 respondents who saw a medical doctor and used CAM therapies in the past year, 63.0% (*n* = 536) did not disclose use of at least one of their CAM therapies, and 28.1% (*n* = 225) disclosed all of their three or fewer CAM therapies. Information on the remaining 8.8% (*n* = 70) of respondents is incomplete because these individuals used more than three CAM therapies but were asked only about their disclosure of a random three therapies. These 70 respondents reported disclosing the three CAM therapies about which they were asked, but disclosure on use of their other CAM therapies is unknown. Consequently, nondisclosure of at least one type of CAM therapy to a medical doctor was at least 63%, possibly as high as 72%, of these 831 CAM therapy users.

Figure 4 summarizes responses to the following instructions, which were asked of all respondents who used CAM therapy in the past 12 months but did not disclose this use to their medical doctor. The instructions were read for each of the 726 total alternative therapies that these respondents reported as nondisclosed.

Figure 3. The amount of confidence patients reported having in complementary and alternative medical (CAM) providers (shaded bars) and conventional medical doctors (white bars).

Data are for respondents who saw both a medical doctor and a CAM provider in the past year. Overall, these 411 respondents reported using a total of 538 CAM therapies.

Here are some reasons people have for not discussing certain therapies with a medical doctor. As I read each statement, please say "yes" if it applies to your not discussing your therapy with your doctor and "no" if it does not apply.

As shown in **Figure 4**, for three fifths of the CAM therapies that were reported to have been used but not disclosed, respondents agreed with each of the following two statements: "It was not important for the doctor to know" and "The doctor never asked." For nearly one in three therapies (31%) used, respondents considered their CAM therapy use "None of the doctor's business," and for 20% to 34%, depending on the therapy and condition, respondents agreed that "The doctor would not understand." For 14% of all nondisclosed therapies, respondents acknowledged being concerned that their medical doctor would "disapprove" of or "discourage" their CAM use. For 2% of all nondisclosed therapies used, respondents agreed with the statement, "You thought your doctor might not continue as your provider."

DISCUSSION

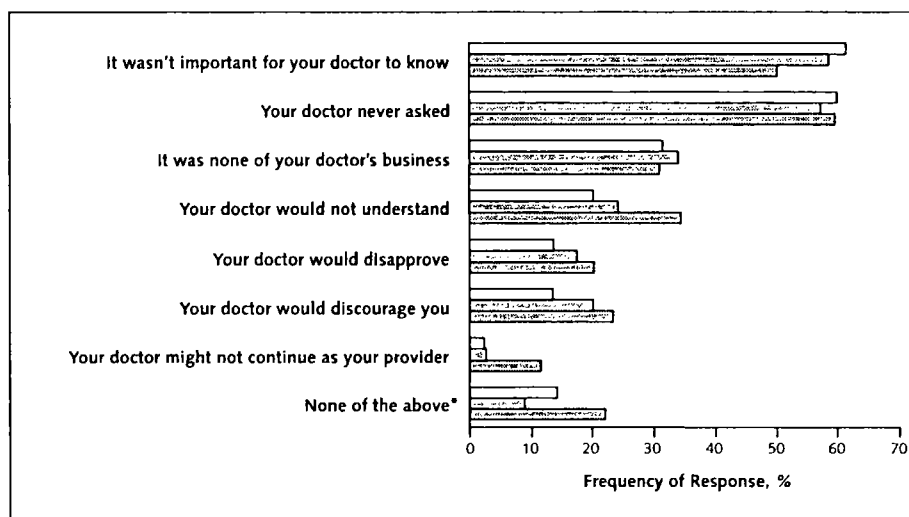
The methodologic limitations of our 1997 national survey, which were previously described (1), include the

sampling restriction to persons who spoke English and lived in households with telephones, the modest response rate, and the use of a financial incentive. Furthermore, we have no data on the accuracy of self-reports concerning recollections of CAM or conventional therapy use. Recall bias is a possibility, and the degree of bias may be related to the time lapsed since the most recent visit to a provider.

Within the context of these caveats, the results of this national survey suggest that the use of CAM therapies cannot be attributed primarily to perceived dissatisfaction with conventional medical care or caregivers. Many adults seek, explore, and experience benefits from both conventional and CAM therapies. These survey data are consistent with the findings of Astin (8), as well as those of Druss and Rosenheck (9), and contrast with previous editorials suggesting that the high prevalence of CAM therapy use in the United States largely represents a societal rejection of orthodox and conventional medical care (11–15).

Regarding CAM therapies for specific medical conditions, we found that CAM therapies were perceived to be more helpful than conventional medical care for chronic, debilitating conditions such as headaches and

Figure 4. Reasons for nondisclosure of complementary and alternative medical (CAM) therapy use.



*This response choice was not read but was volunteered by respondents. White bars represent reasons for nondisclosure of any therapy included in the survey ($n = 726$); the lightly shaded bars depict reasons for nondisclosure of therapies with a recognized potential risk for adverse events—namely, herbal remedies, chiropractic, naturopathy, megavitamins, and chelation therapy ($n = 188$). Our analysis also considered whether reasons for nondisclosure were associated with the severity of the medical condition; the darkly shaded bars summarize reasons for nondisclosure among respondents who reported having a relatively "severe" medical condition—cancer, coronary artery disease, or diabetes mellitus—in the past 12 months ($n = 33$).

neck and back conditions. These findings corroborate the reports of Astin (8) and others who have investigated the reasons for CAM therapy use (16–21). As for the sequence of seeking the services of medical doctors and CAM providers among adults, our data, consistent with other (population-specific) studies, show that adults typically seek the services of their medical doctor before seeing a CAM provider, or they see both concurrently (16, 20). Only a minority of individuals seek the professional services of a CAM practitioner before seeking conventional medical care. As such, medical doctors and other conventional caregivers who are knowledgeable about CAM practices and the evidence to support or refute their application have a unique opportunity to advise patients on the use or avoidance of individual CAM therapies on a case-by-case basis.

Wolpe has suggested that as a society, adults are not abdicating the role of modern biomedicine but rather are redefining biomedicine's responsibility within the larger model of health care delivery (Wolpe PR. *Alternative medicine in the social and historical context*. Presented at Retreat on the Role of Alternative Medicine in the Academic Medical Center, 24 March 1999, Philadelphia, Pennsylvania). The popularity of CAM therapies cannot be attributed solely to a dissatisfaction with or lack of attraction to high-tech, scientifically validated orthodox care.

Our survey data show an interesting split between participants agreeing and disagreeing with the view that CAM therapy providers 1) spend more time with patients, 2) offer more understandable explanations, and 3) are better listeners. Like a Rorschach test, these data offer multiple interpretations. On one hand, 47%, 56%, and 52%, respectively, disagreed with each of these statements. On the other hand, more than 40% agreed with each. Other population-specific studies have reported patients' perceived differences when comparing CAM providers with medical doctors. For example, some studies have found that patients value the counseling aspects of care exhibited by CAM providers compared with the care provided by conventional medical doctors. These aspects of care include an improved explanation of illness (16, 17, 22) and a willingness to discuss emotional factors (16), a better understanding of their problems (17, 20, 22), and the therapist's personal attention and expenditure of time (17, 18, 22). Each of these perceptions warrants further qualitative study.

Clearly, many adults believe that their medical doctor will not understand their use of complementary and alternative therapies, and that "it is not important for the doctor to know" or "it is none of the doctor's business." These findings are consistent with those of other investigators (23–26). Similarly, our observation that fewer than one in five respondents feared disapproval from their physician is consistent with comparable surveys of rheumatology patients (23, 24). Collectively, these data suggest that many patients, in their capacity as consumers of care, view medical doctors as members of a larger, patient-selected health care team. Increasingly, medical doctors are being viewed as one of several professionals whom the average adult seeks for advice or treatment of health-related matters. This is consistent with societal trends toward increased autonomy and personal responsibility for one's health. A deeper understanding of the extent to which these perceptions are affecting CAM use and disclosure will require additional qualitative and quantitative investigation.

Ideally, we should develop an evidence-based approach to CAM therapies that incorporates our patients' perceptions and their right to choose their own therapy and therapist. David Sackett, in an editorial titled "Evidence-Based Medicine: What It Is and What It Isn't" (27), argued that

Evidence-based medicine is not 'cookbook' medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. . . . Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus, whether it should be applied.

As an evidence-based evaluation of CAM therapies materializes, let us be reminded that many adults currently choose to use CAM therapies to treat their most serious medical problems and appear to value both conventional and CAM approaches. Moreover, when patients choose not to tell their physicians that they use CAM therapies, they appear to be less concerned about their physician's disapproval than their physician's per-

ceived inability to understand or incorporate CAM therapy into their overall medical management.

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Background: Little is known about perceptions of complementary and alternative medical (CAM) therapy relative to conventional therapy among patients who use both.

Objective: To document perceptions about CAM therapies among persons who use CAM and conventional therapies.

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Setting: The 48 contiguous U.S. states.

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Measurements: Perceptions about helpfulness and patterns of CAM therapy use relative to conventional therapy use and reasons for nondisclosure of CAM therapies.

Results: Of 831 respondents who saw a medical doctor and used CAM therapies in the previous 12 months, 79% perceived the combination to be superior to either one alone. Of 411 respondents who reported seeing both a medical doctor and a CAM provider, 70% typically saw a medical doctor before or concurrent with their visits to a CAM provider; 15% typically saw a CAM provider before seeing a medical doctor. Perceived confidence in CAM providers was not substantially different from confidence in medical doctors. Among the 831 respondents who in the past year

had used a CAM therapy and seen a medical doctor, 63% to 72% did not disclose at least one type of CAM therapy to the medical doctor. Among 507 respondents who reported their reasons for nondisclosure of use of 726 alternative therapies, common reasons for nondisclosure were "It wasn't important for the doctor to know" (61%), "The doctor never asked" (60%), "It was none of the doctor's business" (31%), and "The doctor would not understand" (20%). Fewer respondents (14%) thought their doctor would disapprove of or discourage CAM use, and 2% thought their doctor might not continue as their provider. Respondents judged CAM therapies to be more helpful than conventional care for the treatment of headache and neck and back conditions but considered conventional care to be more helpful than CAM therapy for treatment of hypertension.

Conclusions: National survey data do not support the view that use of CAM therapy in the United States primarily reflects dissatisfaction with conventional care. Adults who use both appear to value both and tend to be less concerned about their medical doctor's disapproval than about their doctor's inability to understand or incorporate CAM therapy use within the context of their medical management.

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Complementary and alternative medical (CAM) therapies (also known as integrative or unconventional therapies) have been defined as "those interventions neither taught widely at U.S. medical schools nor generally available in U.S. hospitals" (1, 2). While imperfect, this definition has been used to identify representative CAM therapies, which have been studied for prevalence of use in two national random-household telephone surveys (1, 2). Data from these surveys indicate that CAM therapy use and expenditures increased substantially in the United States between 1990 and 1997 (1). Overall prevalence of use increased by 25%; total visits by an estimated 47%, from 427 to 629 million; and expenditures for CAM services by an estimated 45%, which totaled \$21 billion (1).

National surveys performed in other countries have suggested similar rates of CAM use throughout the industrialized world (3-7). Less well documented, however, are the reasons that adults typically use (and pay out of pocket for) these therapies, most of which have not been satisfactorily evaluated for relative effectiveness, safety, or mechanisms of action. Only one U.S. national survey published in a peer-reviewed journal has explored reasons for CAM use (8). Astin's survey, conducted in 1994 on a convenience sample of 1035 adults, found that reasons for CAM use included "a holistic orientation to health; having had a transformational experience that changed the person's world view; . . . and classification in a cultural group identifiable by their commitment to environmentalism, commitment to feminism,

and interest in spirituality and personal growth psychology" (8).

National surveys in the United States of CAM use in 1990 and 1997 revealed that adults typically do not disclose their use of CAM therapies to their medical doctors (1, 2). In 1997, as in 1990 (1), fewer than 40% of CAM therapies used in the previous 12 months were discussed with a medical doctor. A recent analysis of data on U.S. national medical expenditures corroborated these findings and suggested that the percentage of CAM users who disclose their CAM visits to their medical doctors may be as low as 20% (9).

This paper summarizes 1997 national survey data on respondents' perceptions about use and nondisclosure of CAM therapies relative to conventional medical care.

METHODS

Sample

We conducted a nationally representative telephone survey between November 1997 and February 1998. Survey methods were approved by the Beth Israel Deaconess Committee on Clinical Investigations, Boston, Massachusetts. The survey used random-digit dialing techniques to select households and random selection of one resident per household, age 18 years or older, as the respondent. Eligibility was limited to English-language speakers for whom cognitive or physical impairment did not prevent completion of the interview. The survey sample and weighting methods have been previously described (1).

Interview

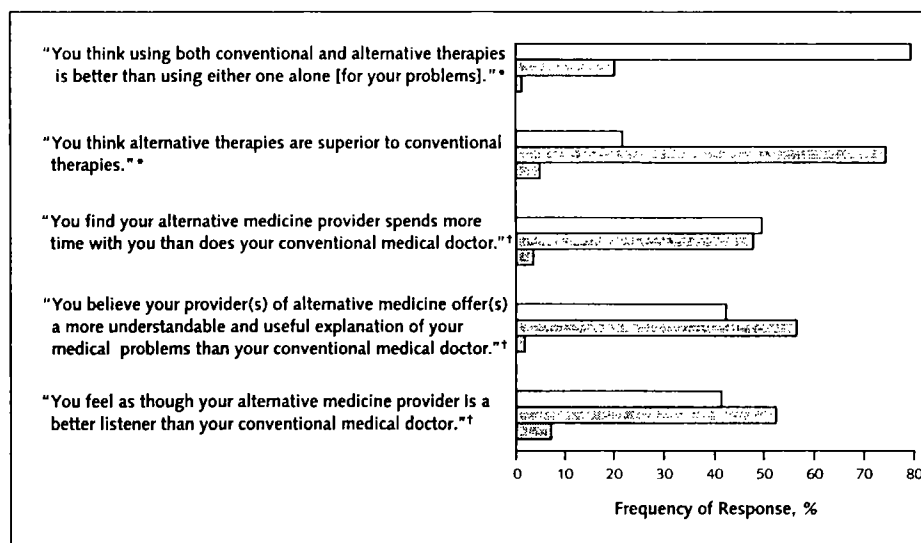
The interview was presented as a survey by investigators from Harvard Medical School about the health care practices of persons in the United States. No mention was made of "alternative," "integrative," "unproven," or "complementary" therapies in the introductory comments. The first substantive questions addressed perceived health, health worries, days spent in bed, and functional impairment due to health conditions. Next, respondents were asked about their interactions with a "medical doctor," defined as "a medical doctor, MD, or an osteopath, DO—not a chiropractor or other non-medical doctor." The term "medical doctor" was used throughout the remainder of the interview.

Respondents were asked if they had experienced any of a list of specified common medical conditions in the previous 12 months. Those who reported experiencing more than three conditions were asked to identify the three "most bothersome or serious" medical conditions. Respondents were then asked about seeing a medical doctor for these "principal medical conditions" and about perceptions of confidence in the medical doctor and the helpfulness and efficacy of their interactions. Next, respondents were asked about use of CAM therapies in the past 12 months and over their lifetime and whether each of these therapies was used for each of their principal medical conditions. We distinguished between use under the supervision of a professional (a provider of CAM therapy) and personal use without such supervision. Persons who reported having supervised use were asked about the number of visits during the past 12 months to providers of each therapy, perceptions of helpfulness and efficacy, and confidence in their CAM therapy providers. Respondents were asked whether they typically see a CAM provider before, after, or concurrent with their visits to a medical doctor. In addition, respondents were asked whether they agreed or disagreed with a list of "thoughts about the use of alternative therapies" (Figure 1). Each question was intended to elucidate perceptions about CAM therapy use relative to conventional care. All users of CAM therapies who had seen their medical doctor in the past year were asked if they had discussed use of each therapy with their medical doctor and if not, why they had not. They were then provided a list of possible reasons why people might not discuss certain therapies with a medical doctor and were asked to say "yes" to any number of items on the list that explained their own reasons for nondisclosure and "no" to items that did not. Additional details of the survey instrument are described elsewhere (1).

Statistical Analysis

As previously described (1), we calculated sampling weights for each respondent to reflect the probability of selection and to parallel the aggregate distribution of demographic characteristics of the U.S. population. We used SUDAAN software (10) to compute weighted estimates of the proportion of respondents giving specific answers to study questions. We applied the McNemar test to compare respondents' evaluations of the helpful-

Figure 1. Perceptions about complementary and alternative medical (CAM) therapy relative to conventional therapy.



Shown for each statement is the frequency of responses—agree (white bars), disagree (shaded bars), neither agree nor disagree (darkly shaded bars). *Asked of respondents who had seen a medical doctor and used any CAM therapies (excluding use of self-prayer alone) in the past 12 months ($n = 831$). †Asked of respondents who had seen both CAM therapy providers and medical doctors within the past 12 months ($n = 411$).

ness of CAM therapies and conventional care among respondents who used both for the same medical condition.

Role of the Funding Sources

This research was funded by grants from the National Institutes of Health, the John E. Fetzer Institute, and the American Society of Actuaries. Additional support for the completion of analyses and manuscript preparation was provided by unrestricted gifts from the Friends of Beth Israel Deaconess Medical Center, the Kenneth J. Germeshausen Foundation, the J.E. and Z.B. Butler Foundation, and The American Specialties Health Plan. None of the sponsors had access to the primary data, nor did they review the manuscript before submission.

RESULTS

Characteristics of the Respondents

The weighted survey response rate was 60% (1). The sociodemographic characteristics of the survey sample ($n = 2055$) were similar to the population distributions published by the U.S. Bureau of the Census (1). Among the 2055 survey participants, 1802 (87% weighted) reported seeing a medical doctor in the previous 12 months. Of these, 831 (45% weighted) reported

using CAM therapy (excluding use of self-prayer alone) in the past 12 months, and 411 (23% weighted) reported seeing a CAM provider in the past 12 months (1).

Perceptions of CAM Relative to Conventional Therapy Use

Figure 1 summarizes responses among respondents who used conventional care and CAM therapies in the past 12 months. As a preface to these questions, the interview script read,

I am going to read you some thoughts people have about their use of alternative therapies, like chiropractic, massage, acupuncture and the others I mentioned earlier. For each statement, please tell me if you agree or disagree.

As shown in Figure 1, fewer than 1 in 4 (21%) CAM therapy users ($n = 831$) agreed with the statement, "Alternative therapies are superior to conventional therapies," and roughly 4 of 5 (79%) respondents agreed that "Using both conventional and alternative therapies is better than using either one alone [for your problems]." For respondents who saw a CAM therapy provider and a medical doctor ($n = 411$), we asked

whether they agreed or disagreed that their CAM provider did a better job of “listening” or “explaining their medical problems” than their medical doctor. Forty-one percent agreed that their CAM provider was a better listener, and 52% disagreed; 42% agreed that their CAM provider did a better job of explaining their medical conditions, and 56% disagreed.

Sequence of Seeking Care from CAM Providers and Medical Doctors

We asked respondents who reported seeing both a medical doctor and a CAM provider during the past 12 months ($n = 411$) the following:

The next questions are about your use of alternative therapies in general. People generally fall into one of three groups regarding their use of alternative medicine. Some people see an alternative provider before they consult a medical doctor; some see both alternative providers and conventional doctors at the same time; and some see an alternative provider after they have seen a medical doctor. Which of these best describes your pattern of seeing alternative providers?

As summarized in Figure 2, 7 of 10 respondents

reported typically seeking the services of a CAM provider after or concurrent with their visit to a medical doctor. Fewer than 1 in 6 (15%) said they saw a CAM therapy provider before seeing a medical doctor.

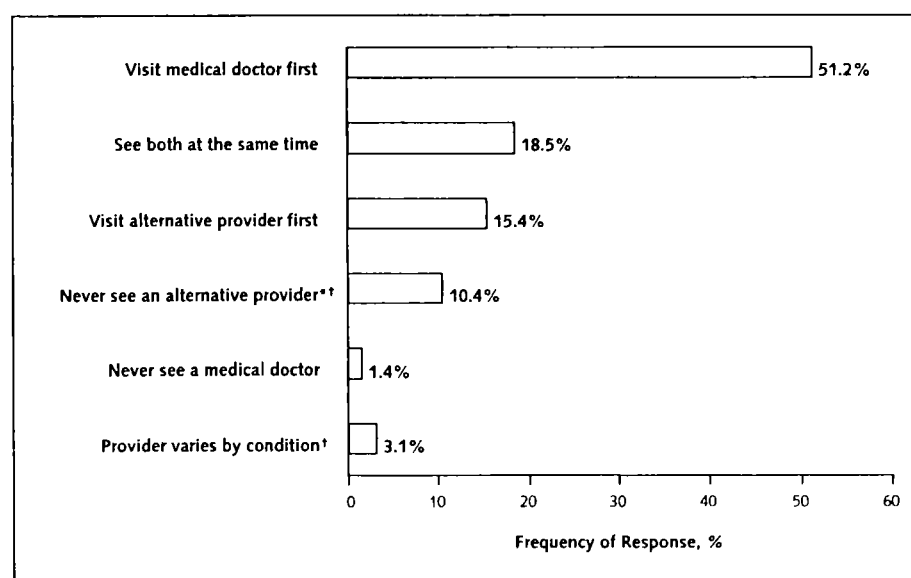
Overall Helpfulness of Therapies

The Table summarizes perceived relative helpfulness for 10 of the most commonly reported principal medical conditions identified in the 1997 national survey among respondents who used both conventional care and CAM therapies for each condition. The CAM therapies were judged more helpful than conventional care for treatment of headache and neck and back conditions; conventional care was considered more helpful for treatment of hypertension. Trends suggesting a perceived difference in helpfulness for other common conditions were observed, but we cannot confirm this because of sample-size limitations for most condition-specific groups.

Confidence in CAM Providers Relative to Medical Doctors

Respondents who reported seeing conventional and CAM providers in the past year ($n = 411$) were asked

Figure 2. Sequence of seeking care from complementary and alternative medical (CAM) providers and medical doctors.



Data are for the respondents who saw a medical doctor and a CAM provider during the past year ($n = 411$). *On further evaluation, this category was found to predominantly represent respondents who sought CAM therapies from a medical doctor. †These response choices were not read but were volunteered by respondents.

Table. Relative Helpfulness of Complementary and Alternative Medical Therapies Compared with Conventional Medical Care among Respondents Who Used Both for Specific Medical Conditions*

Medical Condition	Total Weighted Sample, <i>n</i> †	Respondents' Perception, %‡		<i>P</i> Value§
		Conventional Care Was Better	CAM Therapy Was Better	
Back conditions	158.3	12.4	46.1	<0.001
Allergies	48.4	22.7	29.9	>0.2
Fatigue	14.6	9.4	41.3	0.09
Arthritis	72.1	25.9	44.8	0.06
Headaches	71.6	19.0	39.1	0.03
Neck conditions	87.9	6.4	61.0	<0.001
High blood pressure	14.9	57.0	0	0.004
Strains or sprains	17.4	7.8	22.5	>0.2
Lung conditions	36.1	25.9	23.5	>0.2
Digestive conditions	42.7	34.5	25.9	>0.2

* CAM = complementary and alternative medical.

† Values represent the sum of standardized sampling weights for the respondents with the condition.

‡ The remainder of respondents found their physician's care and CAM therapy to be equally helpful.

§ Based on a two-sided McNemar test.

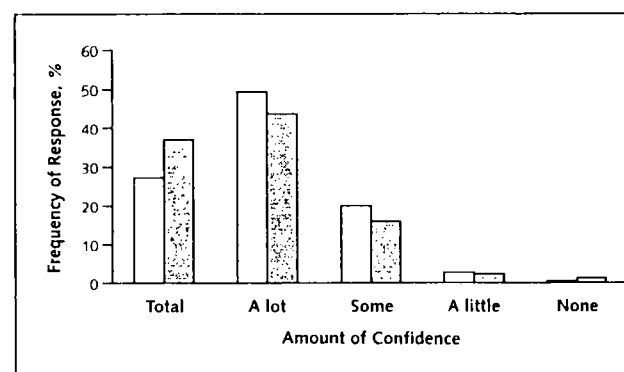
about confidence in their medical doctors and CAM providers (Figure 3). The question regarding confidence in one's CAM providers was asked only of respondents who had seen the provider in the past 12 months, whereas the question about confidence in one's medical doctors was asked of respondents who had ever seen a medical doctor. Furthermore, the question on CAM providers was repeated for each type of CAM provider seen. Therefore, responses in these categories are not ideally suited for formal statistical comparisons. However, the percentage of respondents who perceived "to-

tal" or "a lot of" confidence in their CAM provider was similar to the percentage of respondents who perceived "total" or "a lot of" confidence in their medical doctor (81% and 77%, respectively).

Reasons for Nondisclosure of CAM Therapy Use to Medical Doctors

Among the 831 respondents who saw a medical doctor and used CAM therapies in the past year, 63.0% (*n* = 536) did not disclose use of at least one of their CAM therapies, and 28.1% (*n* = 225) disclosed all of their three or fewer CAM therapies. Information on the remaining 8.8% (*n* = 70) of respondents is incomplete because these individuals used more than three CAM therapies but were asked only about their disclosure of a random three therapies. These 70 respondents reported disclosing the three CAM therapies about which they were asked, but disclosure on use of their other CAM therapies is unknown. Consequently, nondisclosure of at least one type of CAM therapy to a medical doctor was at least 63%, possibly as high as 72%, of these 831 CAM therapy users.

Figure 4 summarizes responses to the following instructions, which were asked of all respondents who used CAM therapy in the past 12 months but did not disclose this use to their medical doctor. The instructions were read for each of the 726 total alternative therapies that these respondents reported as nondisclosed.

Figure 3. The amount of confidence patients reported having in complementary and alternative medical (CAM) providers (shaded bars) and conventional medical doctors (white bars).

Data are for respondents who saw both a medical doctor and a CAM provider in the past year. Overall, these 411 respondents reported using a total of 538 CAM therapies.

Here are some reasons people have for not discussing certain therapies with a medical doctor. As I read each statement, please say "yes" if it applies to your not discussing your therapy with your doctor and "no" if it does not apply.

As shown in Figure 4, for three fifths of the CAM therapies that were reported to have been used but not disclosed, respondents agreed with each of the following two statements: "It was not important for the doctor to know" and "The doctor never asked." For nearly one in three therapies (31%) used, respondents considered their CAM therapy use "None of the doctor's business," and for 20% to 34%, depending on the therapy and condition, respondents agreed that "The doctor would not understand." For 14% of all nondisclosed therapies, respondents acknowledged being concerned that their medical doctor would "disapprove" of or "discourage" their CAM use. For 2% of all nondisclosed therapies used, respondents agreed with the statement, "You thought your doctor might not continue as your provider."

DISCUSSION

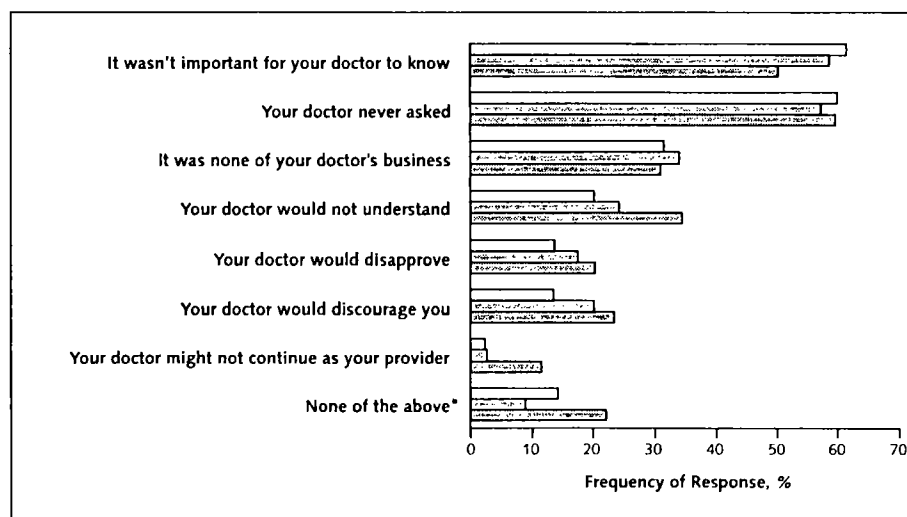
The methodologic limitations of our 1997 national survey, which were previously described (1), include the

sampling restriction to persons who spoke English and lived in households with telephones, the modest response rate, and the use of a financial incentive. Furthermore, we have no data on the accuracy of self-reports concerning recollections of CAM or conventional therapy use. Recall bias is a possibility, and the degree of bias may be related to the time lapsed since the most recent visit to a provider.

Within the context of these caveats, the results of this national survey suggest that the use of CAM therapies cannot be attributed primarily to perceived dissatisfaction with conventional medical care or caregivers. Many adults seek, explore, and experience benefits from both conventional and CAM therapies. These survey data are consistent with the findings of Astin (8), as well as those of Druss and Rosenheck (9), and contrast with previous editorials suggesting that the high prevalence of CAM therapy use in the United States largely represents a societal rejection of orthodox and conventional medical care (11–15).

Regarding CAM therapies for specific medical conditions, we found that CAM therapies were perceived to be more helpful than conventional medical care for chronic, debilitating conditions such as headaches and

Figure 4. Reasons for nondisclosure of complementary and alternative medical (CAM) therapy use.



*This response choice was not read but was volunteered by respondents. White bars represent reasons for nondisclosure of any therapy included in the survey ($n = 726$); the lightly shaded bars depict reasons for nondisclosure of therapies with a recognized potential risk for adverse events—namely, herbal remedies, chiropractic, naturopathy, megavitamins, and chelation therapy ($n = 188$). Our analysis also considered whether reasons for nondisclosure were associated with the severity of the medical condition; the darkly shaded bars summarize reasons for nondisclosure among respondents who reported having a relatively "severe" medical condition—cancer, coronary artery disease, or diabetes mellitus—in the past 12 months ($n = 33$).

neck and back conditions. These findings corroborate the reports of Astin (8) and others who have investigated the reasons for CAM therapy use (16–21). As for the sequence of seeking the services of medical doctors and CAM providers among adults, our data, consistent with other (population-specific) studies, show that adults typically seek the services of their medical doctor before seeing a CAM provider, or they see both concurrently (16, 20). Only a minority of individuals seek the professional services of a CAM practitioner before seeking conventional medical care. As such, medical doctors and other conventional caregivers who are knowledgeable about CAM practices and the evidence to support or refute their application have a unique opportunity to advise patients on the use or avoidance of individual CAM therapies on a case-by-case basis.

Wolpe has suggested that as a society, adults are not abdicating the role of modern biomedicine but rather are redefining biomedicine's responsibility within the larger model of health care delivery (Wolpe PR. *Alternative medicine in the social and historical context*. Presented at Retreat on the Role of Alternative Medicine in the Academic Medical Center, 24 March 1999, Philadelphia, Pennsylvania). The popularity of CAM therapies cannot be attributed solely to a dissatisfaction with or lack of attraction to high-tech, scientifically validated orthodox care.

Our survey data show an interesting split between participants agreeing and disagreeing with the view that CAM therapy providers 1) spend more time with patients, 2) offer more understandable explanations, and 3) are better listeners. Like a Rorschach test, these data offer multiple interpretations. On one hand, 47%, 56%, and 52%, respectively, disagreed with each of these statements. On the other hand, more than 40% agreed with each. Other population-specific studies have reported patients' perceived differences when comparing CAM providers with medical doctors. For example, some studies have found that patients value the counseling aspects of care exhibited by CAM providers compared with the care provided by conventional medical doctors. These aspects of care include an improved explanation of illness (16, 17, 22) and a willingness to discuss emotional factors (16), a better understanding of their problems (17, 20, 22), and the therapist's personal attention and expenditure of time (17, 18, 22). Each of these perceptions warrants further qualitative study.

Clearly, many adults believe that their medical doctor will not understand their use of complementary and alternative therapies, and that "it is not important for the doctor to know" or "it is none of the doctor's business." These findings are consistent with those of other investigators (23–26). Similarly, our observation that fewer than one in five respondents feared disapproval from their physician is consistent with comparable surveys of rheumatology patients (23, 24). Collectively, these data suggest that many patients, in their capacity as consumers of care, view medical doctors as members of a larger, patient-selected health care team. Increasingly, medical doctors are being viewed as one of several professionals whom the average adult seeks for advice or treatment of health-related matters. This is consistent with societal trends toward increased autonomy and personal responsibility for one's health. A deeper understanding of the extent to which these perceptions are affecting CAM use and disclosure will require additional qualitative and quantitative investigation.

Ideally, we should develop an evidence-based approach to CAM therapies that incorporates our patients' perceptions and their right to choose their own therapy and therapist. David Sackett, in an editorial titled "Evidence-Based Medicine: What It Is and What It Isn't" (27), argued that

Evidence-based medicine is not 'cookbook' medicine. Because it requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice, it cannot result in slavish, cookbook approaches to individual patient care. . . . Similarly, any external guideline must be integrated with individual clinical expertise in deciding whether and how it matches the patient's clinical state, predicament, and preferences, and thus, whether it should be applied.

As an evidence-based evaluation of CAM therapies materializes, let us be reminded that many adults currently choose to use CAM therapies to treat their most serious medical problems and appear to value both conventional and CAM approaches. Moreover, when patients choose not to tell their physicians that they use CAM therapies, they appear to be less concerned about their physician's disapproval than their physician's per-

ceived inability to understand or incorporate CAM therapy into their overall medical management.

From Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, Massachusetts.

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ABSTRACT

INTRODUCTION

METHODS

RESULTS

COMMENT

AUTHOR/ARTICLE INFORMATION

REFERENCES

INDEX OF FIGURES AND TABLES

Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines

How Quickly Do Guidelines Become Outdated?

1 Paul G. Shekelle, MD, PhD; Eduardo Ortiz, MD, MPH; Shannon Rhodes, MFA; Sally C. Morton, PhD; Martin P. Eccles, MD; Jeremy M. Grimshaw, MD; Steven H. Woolf, MD, MPH

Context Practice guidelines need to be up-to-date to be useful to clinicians. No published methods are available for assessing whether existing practice guidelines are still valid, nor does any empirical information exist regarding how often such assessments need to be made.

Objectives To assess the current validity of 17 clinical practice guidelines published by the US Agency for Healthcare Research and Quality (AHRQ) that are still in circulation, and to use this information to estimate how quickly guidelines become obsolete.

Design, Setting, and Participants We developed criteria for defining when a guideline needs updating, mailed surveys to members of the original AHRQ guideline panels (n = 170; response rate, 71%), and searched the literature for evidence through March 2000 (n = 6994 titles yielding 173 articles plus 159 new guidelines on the same topics).

Main Outcome Measures Identification of new evidence calling for a major, minor, or no update of the 17 guidelines; survival analysis of the rate at which guidelines became outdated.

Results For 7 guidelines, new evidence and expert judgment indicated that a major update is required; 6 were found to be in need of a minor update; 3 were judged as still valid; and for 1 guideline, we could reach no conclusion. Survival analysis indicated that about half the guidelines were outdated in 5.8 years (95% confidence interval [CI], 5.0-6.6 years). The point at which no more than 90% of the guidelines were still valid was 3.6 years (95% CI, 2.6-4.6 years).

Conclusions More than three quarters of the AHRQ guidelines need updating. As a general rule, guidelines should be reassessed for validity every 3 years.

JAMA. 2001;286:1461-1467

Considerable effort and resources have been expended internationally during the past decade on development and dissemination of clinical guidelines.¹ Many authorities have emphasized that guidelines are not valuable to clinicians unless they

[ABSTRACT](#)[INTRODUCTION](#)[METHODS](#)[RESULTS](#)[COMMENT](#)[AUTHOR/ARTICLE
INFORMATION](#)[REFERENCES](#)[INDEX OF
FIGURES AND
TABLES](#)

are up-to-date and present current scientific knowledge.⁴ Some guidelines specify an arbitrary prescheduled review date. The National Guidelines Clearinghouse will not retain guidelines in their database unless they have been developed, reviewed, or revised within the last 5 years.³ The limitations of an arbitrary date for scheduled review include wasted resources if a full update is undertaken prematurely within a slowly evolving field. Conversely, guidelines in a rapidly evolving field may become outdated before the scheduled review. Some guidelines state that they should be updated when new information becomes available; however, we are unaware of any published attempts to clarify the criteria that define this "new information" or the methods for gathering it. To our knowledge, empirical data about the rate at which clinical practice guidelines become obsolete and practical methods for assessing guidelines for current validity are not available.

The US Agency for Healthcare Research and Quality (AHRQ; formerly the Agency for Health Care Policy and Research) facilitated development of 19 clinical practice guidelines, 17 of which were still in use in 2000, when this study was undertaken. These guidelines cover a broad range of topics, including acute and chronic conditions, illnesses of children and adults, geriatric syndromes, and rehabilitation. The AHRQ guidelines were developed using a combination of systematic literature synthesis and multidisciplinary expert panels and were perceived to have advanced significantly the science of practice guideline development.² These guidelines were considered to represent state-of-the-art management of the selected conditions.

Several years have elapsed since the AHRQ clinical practice guidelines were developed. At the request of and with support from the agency, we undertook a systematic assessment of the current validity of these guidelines. We used these data to provide empirical estimates of the rate at which guidelines become outdated.

METHODS

Conceptual Model

Our first task was to develop a conceptual model for assessing the validity of existing practice guidelines. No attempt to define the underlying criteria on which to base decisions about the current validity of guidelines has been published, nor does an operational method exist for doing so. A complete description of our conceptual model and its implications is described elsewhere.⁴

In brief, we identified 6 situations that may require a guideline to be updated (or withdrawn), including changes in (1) the available interventions, (2) the evidence on the benefits and harms of existing interventions, (3) the outcomes that are considered important, (4) the evidence that current practice is optimal, (5) the values placed on outcomes, and (6) the resources available for health care.

In assessing the current validity of AHRQ guidelines, we focused on identifying when new information on interventions, outcomes, and performance justifies changing a guideline. Changes in the values placed on outcomes occur as societal norms change. Measuring

ABSTRACT
INTRODUCTION
METHODS
RESULTS
COMMENT
AUTHOR/ARTICLE INFORMATION
REFERENCES
INDEX OF FIGURES AND TABLES
▼
▲
ABSTRACT
INTRODUCTION
METHODS
RESULTS
COMMENT

these values and how they change over time is complex and is not dealt with herein, nor are changes in the availability of resources for health care or the costs of interventions, since policymakers in disparate health care systems consider different factors when deciding whether services remain affordable.

Identifying new information on interventions, outcomes, and performance that justifies changing a guideline involves 2 stages: identifying significant new evidence and assessing whether the new evidence warrants updating. Ideally, the most thorough way to identify significant new evidence would be to conduct a new systematic review. Our mandate, however, was to devise an approach that could be operationalized feasibly for larger numbers of guidelines. On that scale, conducting a systematic review for each guideline would be too costly and time consuming—it would be tantamount to completing the first step of updating, rather than determining whether updating was even necessary. The AHRQ currently spends approximately \$250 000 to conduct a systematic review through its Evidence-Based Practice Center program; it would have therefore cost more than \$4 million to perform one for each of the 17 guidelines that were still in use.

We therefore used a combination of a focused literature search and the guidance of experts from relevant disciplines as a more pragmatic way to help identify potentially significant new evidence. We reasoned that evidence sufficient to invalidate an existing national practice guideline would, in general, be of such a magnitude that it is known to experts in the field or would have been published in significant articles in major general interest or specialty medical journals. Our model for assessing the current validity of AHRQ guidelines is outlined in [Figure 1](#).

We requested the assistance of each of the chairs of the original AHRQ clinical practice guideline expert panels in identifying the members of their panel whom they believed were most qualified to assess the current validity of each of the individual guideline statements within their respective clinical practice guidelines. Guideline statements were considered to be those set off in the document in bold, in a box, or as a bulleted point in the "recommendations for care" section. We used this information to assign individual guideline statements to these experts, who were then sent a survey that assessed the statements' current validity. For each guideline statement, we asked 3 questions: (1) "Are you aware of new evidence or developments in the field relevant to this guideline statement?" (2) "Is the new evidence or development of sufficient importance to invalidate the guideline statement?" and (3) "Are there new guideline statements (within the boundaries of the original guideline) that should be present?" Respondents were told to consider validity within the context of our conceptual model (eg, changes in the available interventions, changes in the evidence on the benefits and harms of existing interventions). A second round of mailings was sent to nonrespondents. Respondents were given no financial incentives to reply. For each clinical practice guideline, we also attempted to obtain an evaluation of validity from at least 1 expert not associated with the original practice guideline panel.

We conducted limited literature searches for significant new evidence that may have an effect on the validity of the guideline statements. These limited literature searches were restricted, using the "document type" Medical Subject Heading terms to retrieve only review articles, editorials, and commentaries published through March 2000 on the particular guideline topic. Our reasoning for this

**AUTHOR/ARTICLE
INFORMATION****REFERENCES****INDEX OF
FIGURES AND
TABLES**

restriction was that new evidence that is sufficient to change practice would frequently be accompanied by an editorial or commentary, making the latter a sentinel marker for new evidence. We further restricted the search to key journals, ie, those most likely to have published evidence of sufficient magnitude to warrant the revision of an existing national practice guideline. Key journals included the 5 major general interest publications (*Annals of Internal Medicine*, *British Medical Journal*, *JAMA*, *The Lancet*, and *New England Journal of Medicine*) and key specialty journals for each topic identified by local experts in the field. For some guidelines, we did not identify key specialty journals and, therefore, conducted searches unrestricted by journal.

We defined the ideal starting point for each search as the end date for the original AHRQ guideline search. Only 5 (29%) of the 17 guidelines, however, identified this date. For the remainder, we conservatively chose the starting point to be 2 years prior to the publication date of the guideline; in the 5 guidelines for which we did have data, this was the lag period between the end of the search and publication. Two reviewers (P.G.S. and E.O.) reviewed the literature searches. Titles, abstracts, and articles were reviewed sequentially, seeking new evidence regarding the guideline statements. New evidence (principally randomized clinical trials) referenced in the review articles, editorials, or commentaries was retrieved and reviewed for relevance.

To assess the current validity of the AHRQ guideline statements, we also searched for practice guidelines that had been published after the release of the original AHRQ documents and that were related to the same conditions. We used the National Guideline Clearinghouse (<http://www.guidelines.gov>) and the Web sites of publishing organizations to identify relevant materials, downloading either the full text or the summary statements provided by the National Guideline Clearinghouse.

We identified additional evidence from the responses to our survey. For each guideline statement judged invalid for which supporting evidence was referenced, these references were retrieved.

Analysis

The process described identified evidence about the current validity of the individual statement within each guideline. To make a judgment about retaining or withdrawing the entire guideline, we reviewed all of the evidence for each guideline. We considered the studies identified and the responses of the experts to the survey questions about validity and new guideline statements. We also placed greater emphasis on new evidence regarding the principal diagnostic or therapeutic procedures that have a major impact on outcomes (eg, mortality). Based on these sources and our judgment, we assigned the guidelines into 1 of 3 categories.

Major Update Required

New evidence called into question 1 or more principal diagnostic or therapeutic recommendations or new evidence suggested the need for new principal diagnostic or therapeutic guideline recommendations. A major update of the guideline or its withdrawal from circulation is warranted.

Minor Update Required

The principal diagnostic or therapeutic recommendations were still valid, but new evidence supported changes to other

ABSTRACT**INTRODUCTION****METHODS****RESULTS****COMMENT****AUTHOR/ARTICLE
INFORMATION****REFERENCES****INDEX OF
FIGURES AND
TABLES**

valid, but new evidence supported changes to other recommendations or greater refinement of existing recommendations. A minor update of the guideline is warranted.

Still Valid

The recommendations remain valid; no update is warranted.

Next, we conducted a survival analysis of the AHRQ guidelines to estimate the rate at which guidelines become outdated. For each guideline, we determined a date of "birth"; that is, when work on the guideline was completed. We also determined whether the guideline had "died" by the time we reviewed it (April 2000). If so, we determined the date of "death," and if not, we treated the observation as right-censored with a lifetime at least as long as the time from birth to April 2000.

For all 19 original guidelines, we defined birth as 12 months prior to the publication date of the guideline (which approximates the date when the completed guideline was delivered to the AHRQ). Three guidelines had dates of death corresponding to when they were withdrawn or had updates initiated by the AHRQ or the US Public Health Service (human immunodeficiency virus infection, smoking cessation, and urinary incontinence). For guidelines judged to require updating, we assumed conservatively that their deaths occurred in April 2000. This assumption is conservative because their actual lifetimes were of that length or less; hence, our lifetime estimates are biased positively.

To estimate the survival curve, we first fit a nonparametric Kaplan-Meier curve to this lifetime data set of censored and uncensored observations. We also fit a parametric model assuming that the survival function followed the Weibull distribution.⁵ Both of these methods take into account that some observations are censored in that the true lifetimes of 3 of the guidelines are unknown. This analysis was conducted using S-PLUS statistical analysis software.⁶

RESULTS

Of the 19 clinical practice guidelines for which development was facilitated by the AHRQ, we assessed the 17 shown in [Table 1](#). The urinary incontinence guideline underwent an update in 1996 to provide more specific recommendations; we consider only this 1996 update in our assessment of current validity. The AHRQ withdrew the human immunodeficiency virus guideline in October 1999 because the AHRQ judged it to be invalid. Similarly, the smoking cessation guideline recently underwent a Public Health Service-sponsored update.⁷

We received replies from the panel chairs for 15 of the 17 clinical practice guidelines identifying whom among their respective panel members should be contacted to assess the current validity of their practice guideline statements. For 1 of the 2 practice guidelines for which we did not receive this information, we contacted the evidence-based practice center that had participated in the AHRQ-sponsored literature review that was used in the specialty society-sponsored guideline update process and asked the appropriate member of the task order team to complete the survey.

ABSTRACT

INTRODUCTION

METHODS

RESULTS

COMMENT

AUTHOR/ARTICLE
INFORMATION

REFERENCES

INDEX OF
FIGURES AND
TABLES

ABSTRACT**INTRODUCTION****METHODS****RESULTS****COMMENT****AUTHOR/ARTICLE
INFORMATION****REFERENCES****INDEX OF
FIGURES AND
TABLES**

appropriate member of the task order team to complete the survey. For the remaining clinical practice guideline, 1 of the authors coincidentally had participated in the original guideline development process and decided which statements to send to which experts.

We were unable to attain current contact information for 4 of the recommended experts, and in 2 instances, the panelists were deceased. We then sent out the individual guideline statements to the respective experts ($n = 175$). Five surveys were returned with the notation that the panelist was no longer at the given address and no forwarding address was known. Of the remaining 170 surveys, 121 (71%) were returned. Four panelists explicitly declined to participate in the survey. The number of responses varied by guideline. For all but 3 guidelines, more than 60% of the surveys were returned. We were also able to obtain assessments of the validity of the practice guideline statement from 8 nonpanel experts for 7 of the guidelines. Among all questions about validity or the need for new recommendations across guidelines, there was complete agreement among respondents for 71% of questions, and only 5% of questions had more than 1 dissent.

Our focused literature searches identified 6994 titles. From these titles, 610 were selected for abstract review based on their potential for providing new information relating to the respective guideline areas. Of these, 173 full-text articles were identified and reviewed. In addition, 159 guidelines were also retrieved and reviewed. Experts identified an additional 156 references, so a total of 766 abstracts and 208 articles were reviewed.

Current Validity of AHRQ Guidelines

Table 1 lists our classification for each AHRQ guideline along with a succinct description of the key evidence on which we based our decision. The new evidence in Table 1 is not a complete recapitulation of all that was identified but shows the evidence that was most influential in making classifications. In all, we found that 7 guidelines needed a major update; 3 guidelines were still valid; and 6 guidelines needed a minor update. For 1 guideline (quality determinants of mammography), we reached no conclusion because we had an insufficient response rate to our survey and were unable to adequately interpret the highly technical literature regarding possible improvements in mammographic imaging.

The Rate at Which Guidelines Become Outdated

Figure 2 shows the Kaplan-Meier survival curve for the AHRQ guidelines. The solid line shows the estimated proportion of guidelines that survive at each point (ie, that have lifetimes at least as long as the horizontal time in years), with dashed lines representing the 95% confidence interval (CI) bounds. The Weibull parametric model produced estimates similar to the nonparametric approach, and we used the former to construct estimates and 95% CIs for certain survival deciles. Table 2 shows the Weibull model estimates for lifetimes of certain proportions (eg, 50% of the guidelines will survive at least 5.8 years [95% CI, 5.0-6.6 years]). A sensitivity analysis using only guidelines judged as requiring a major update (death) yielded a 90% survival estimate of 5.5 years (95% CI, 4.5-6.5 years) and a 50% survival estimate of 7.1 years (95% CI, 6.4-7.8 years).

COMMENT

ABSTRACT

INTRODUCTION

METHODS

RESULTS

COMMENT

AUTHOR/ARTICLE INFORMATION

REFERENCES

INDEX OF FIGURES AND TABLES

Of the 17 clinical practice guidelines developed under the auspices of the AHRQ between 1990 and 1996, we determined that more than three quarters need updating. This finding provides the first empirical evidence of the rate at which a collection of well-constructed clinical practice guidelines go out-of-date. Our survival analysis estimated that half of the guidelines became obsolete in 5.8 years. This estimate must be considered an upper bound since some of the guidelines in this cohort certainly became obsolete earlier than April 2000, the date of the judgment in our study. It is tempting to try to more precisely estimate the date when these guidelines became outdated by using the publication date of the new evidence used to reach the decision about validity. However, determinations of guideline validity require both evidence and judgment, and we did not collect judgments earlier than March 2000. We refrained from making assumptions about judgment at earlier points.

Our study has implications for the developers and users of clinical practice guidelines. Guidelines should be reviewed regularly to assess whether they are up-to-date. Given that our estimates of the lifetime of validity represent upper bounds, we believe that the best interval to recommend for this assessment is a conservative one — 3 years, the lower bound of the 95% CI for the period when 90% of the guidelines were estimated to be still valid. A shorter interval may be indicated for topics noted for rapid scientific advances and a longer interval for fields that are more stable. Given the limited sample size in our study, we cannot provide estimates of survival stratified this way.

Our study also yielded important lessons about the practical methods to accomplish guideline review. Our combination of focused literature searches and expert opinion was a feasible way to review the validity of guidelines without expending considerable resources (approximately \$100 000 to assess 17 guidelines). We consider our work to be only a first step, however, and further work is needed to better establish the optimal method of limited literature searches and how this should be integrated with expert judgment.

We found that we were able to identify relevant information from our limited literature searches in a more expeditious manner for topic areas with which we were clinically familiar. For topics with which we were unfamiliar, selecting and retrieving a larger proportion of irrelevant articles (lower specificity) became necessary to maximize sensitivity. Having the limited literature searches conducted by groups already familiar with the topic, such as relevant Cochrane Review groups or evidence-based practice centers, is likely to be more efficient.

Our search for new evidence would have been more efficient if we had been able to better target our search. Developers of guidelines could greatly ease the resources required for subsequent updating if future guidelines described the type of evidence that they anticipated would play a pivotal role in requiring revision of a guideline statement.

The relatively high response rate to our survey (without financial incentives) suggests that it might have been important to the

ABSTRACTINTRODUCTIONMETHODSRESULTSCOMMENTAUTHOR/ARTICLE
INFORMATIONREFERENCESINDEX OF
FIGURES AND
TABLES

members of the original guideline expert panels to keep their respective guidelines up-to-date. The lower response rate we achieved to our survey of experts who were not on the original guidelines panel indicates that more effort (eg, financial incentives) may be needed to obtain an acceptable response rate from experts without this personal investment. Having periodic review by experts who were not involved with the initial guideline may help protect against perpetuating underlying bias introduced by the members of the original guideline panel, but it would come at increased cost.

All of these difficulties may be overcome by considering development of guidelines an ongoing process rather than a discrete event. Organizations developing guidelines should consider impaneling guideline groups for a fixed period, with a rotating membership analogous to a National Institutes of Health study section. After guideline development, automated literature searching could be conducted at regular intervals (eg, every 6-12 months) and relevant citations reviewed by subgroups of the panel. Relevant articles could then be distributed to the entire panel for consideration of the impact of new evidence on the validity of the existing guideline, using the criteria we have articulated. Areas of the guideline judged to be invalid could then be changed expeditiously if the guidelines were available in electronic form on the Web. In addition, Web-based availability would facilitate easy replacement of only those sections of the guidelines judged to be in need of change. Furthermore, this could be linked through list servers to electronically alert interested parties that a change has been made. In this way, guidelines would always be up-to-date and readily available.

Our study has several limitations. First, we assessed a relatively small number of existing clinical practice guidelines. The National Guideline Clearinghouse currently contains more than 1050. However, the guidelines we assessed represent the entire output of a high-profile program to develop national guidelines on a broad range of topics, which increases the generalizability of our estimates of shelf life. Second, these guidelines were not selected randomly; they came from 1 developer with a particular approach to guideline development. Guidelines that are less rigorously developed may become outdated at a different rate than what we report here. Third, we could not determine the actual date that guidelines became outdated, only that they had done so within a certain interval. This probably overestimates the useful life of these guidelines and is the reason we used the lower bound of the 95% CI to recommend when a review should be initiated. Fourth, our method of assessing the current validity of the guidelines has not been validated against the ideal gold standard: a simultaneous full update of the guidelines. Until such a comparison is undertaken, the methods we report here, which appear to have face validity, offer a practical way to make these determinations with limited resources.

In summary, we found that more than 75% of the AHRQ guidelines developed between 1990 and 1996 need updating. Half of these guidelines were certainly outdated in 5.8 years. To keep practice guidelines up-to-date, we recommend that as a general rule they be reviewed no later than 3 years after completion. This 3-year rule should be moved forward or backward in time if there is an expectation that the topic area of a particular guideline is evolving quickly or slowly.

ABSTRACTINTRODUCTIONMETHODS

RESULTS

COMMENT

AUTHOR/ARTICLE
INFORMATION

REFERENCES

INDEX OF
FIGURES AND
TABLES



ABSTRACT

INTRODUCTION

METHODS

RESULTS

COMMENT

AUTHOR/ARTICLE
INFORMATION

REFERENCES

INDEX OF

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Obtained funding: Shekelle.

Administrative, technical, or material support: Rhodes.

Study supervision: Shekelle.

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Disclaimer: The authors of this article are responsible for its contents. No statement in this article should be construed as an official position of the AHRQ or the US Department of Health and Human Services.

REFERENCES

**FIGURES AND
TABLES**

ABSTRACT

INTRODUCTION

METHODS

RESULTS

COMMENT

**AUTHOR/ARTICLE
INFORMATION**

REFERENCES

**INDEX OF
FIGURES AND
TABLES**

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JCAHO 1/3/02
1975 ^{organized} ambulatory setting

1966 - LTC

Recommendation

College
- Staff rating
- Individual Practitioners

Lenora Larson
Joe Fain
Michele
Steve H

① Senior VP
VP
Resident
Paul Shiny
Bob Weiss
Marjorie
John
VP for
External
Relations
Research
& In

CAM Representation - Involvement in Process

80's non Hospital > Hospital Accreditation

2/3 MCO, PPO, Behavioral Health, Melphalan Treatment
HMO Community Mental Health Center
Ambulatory Surgical Center

80% of Hospitals are
26% of Hospital Beds

Integrated Model

- Access is predicated on good Regulations

Issue CAM Practitioner & Allopathic Practitioner Join
CAM Interventions

* ② Issue - Service Issue - Use of Supplements in Hospital

③ Education - Family & PE Education - any movement
for info on SE Adverse Event

④ Adverse Event Monitoring - Sentinel Event
Modeling

⑤ QC - for Information Technology / HIPAA
Transfer of Information

⑥ Research and IRB Review

⑦ Use of CAM Practitioners in accreditation processes

Patron Tom #8

① Access to CAM Practitioners

Comments - allpathic Provider - have a long Hx of Accredited Education + Training - Can fall back to T-Board

Don't know what to do in emergency field that hasn't setup criteria or credentials

* Can't find a good answer or a model for the country * Needs National Consensus of a minimal competencies / training

e.g. Physicians Assistants - Training & Education are not reaching minimal standards

State by State Variation in - Regulate states that have set minimum standards - Certification / License, determine if person is currently competent Education + Fellowship - can lead to state that a person can do x e.g. physician -> pediatric -> pediatric cardiology

Practitioners Accredited institution go through appropriate process to qualify
② Do they apply the criteria

many roles State Medical Boards, Schools Mission to help improve Safety & Quality of Healthcare delivery; Rules tied in to education goals * Bring groups together to develop guidelines educational efforts - ID useful guidelines to guide credentialing process

Problem eg. Office Based Surgery - Operating under scope of license but may not be under the scope of their expertise.

Large Org -

F.S.M.B. Am Board of Surgery, A.S. of Anesthesiologists
trying to struggle with information

JCAHO → Consensus Group ←

- Educate Provider about what it is safe
- Educate Public about practice

nothing is "joining"

3 factors affect level of regulation

- 1) Risk of Practice
- 2) ~~Scope~~ Practice - How wide is independent decision making & i. higher control
- 3) Readiness for Licensure
- 4) Independence of Decision Making

No Standard Definition

Licensed Independent Practitioner - Credentialed or Certification (authorized by the state), M.D., D.O., D.D.S., Podiatrists, some CAH
other Not

Certification of services - e.g. disease management ~~service~~

• Allopathic practitioners who expand their practice into CAH

Glossary

* JCAHO Def of Medication In Standard Manual

Any substance other than

may be used as an aid to diagnosis, prevention, or ~~treatment~~ treatment of disease or condition

At Johnson's report in hospital - mild to moderate depression

- Hospital can decide what to do - Hospital develop policy on how they are going to handle this and how they can monitor use
- Dis. decide on medication "order" - can include use of supplements - Hospital can refuse to permit use of supplements
- org have alternative medication system - Hospital has system to safely monitor system medication use - ; Need an education campaign to include in the need to monitor use of pt use of supplements

Standards for Nutrition Care -

If not a drug, is it part of nutrition care?

114-115 Mini Manual	Policy 3-97	Nutrition 4
---------------------	-------------	-------------

Types of Recommendations JCAHO would like
Approach taken in standards - apply to all services -

Help Healthcare Orgs understand current expectations of patients; safety of supplements - competencies of healthcare providers

Issue of Medication

* Provide educational guidance to healthcare practitioners

* accreditation increased the sensitivity to these practices
& practices not inadvertently exclude C&AM practices
fully integrated & coordinated with
current standards

Develop an appropriate guidance to best
practices

What training would "regulators" have to receive
Can the Organization itself determine the usefulness
& effectiveness of C&AM - then how have they done
minimal initial education

- Required "if licensing & certification"

① Can the Clinic establish standards of outcome

② How can we educate the health care organization

"increased sensitivity" to concepts that lead to S&E

"Content knowledge" of what is C&AM

Bottom line

Education of practitioners & mutual understanding
of knowledge

Principal Standards of Care - Interpretation of specialty
Adverse Event Monitoring - just as reportable as
any other intervention

[IT] - Human Resources + Information Resource

- mgt of information; encourage people to use computers even - Health Record -
 same principle apply in Hospital, nursery home, etc - to have good integration care

Refers to AM practitioners

One of standard - AM educated by institutions
 Pain = Managing Pain part of TX; manual has

about other services & treatment

* P's Rights Standard / P't have the right to be informed of alternative treatment that are considered to be safe & effective

Practitioner Issue not institution. Issue

① Derived from Informed Consent of alternatives

② Managed Care - "can't be gag order"; is there a policy that prohibits a practitioner from telling what services are there & what practitioners strongly recommended

③ Network Listing Forum

* Field Evaluation / Internet Availability -
 ID of prospective AM Orgs to gain access to ICAHO → 2 way street -
 AM - approach ICAHO accredit business

Draft Discussion Document for December 6-7, 2001 Meeting

TOPIC: Access and Delivery of CAM

Facilitators: Joseph Fins, Linnea Larson

Staff Lead: Michele Chang

Introduction:

Access to health care has been described as a multi-dimensional concept that balances factors such as human resources, financing, transportation, freedom of choice, public education, quality, and allocation of technology (1). There are other factors that contribute to the quantity and quality of care received by a population, and determine the nature and extent of access to care in the United States; many of these apply particularly to the access and availability of complementary and alternative medicine (CAM) in the United States. Among those considered by the Commission are the growth and influence of: chronic illness and their impact on disability and death; the availability of information, especially through the Internet; disparities in income and its impact on health; consumer involvement in their personal health care and consumer interest in CAM. In fact, the rise in CAM use is most often characterized as a "consumer-based movement," reflecting broader concerns by the American public to re-examine and revitalize how health care currently is delivered and received.

Many of the reasons influencing consumers' decisions to try unconventional approaches are the same as those stimulating change in the current health care system. Foremost among these include pressures to reduce the costs of health care, which are expected to reach the \$2.1 trillion mark by 2007. CAM, especially those approaches that attempt to induce auto-regulation and self-healing, offers opportunities to reduce the escalating costs of health care. For example, mind-body therapies, such as meditation and biofeedback, that are used to control chronic pain and stress have been estimated to eliminate 37 percent of doctor visits, potentially saving the country some \$54 billion a year (2, 3).

Many of the holistic philosophies and traditions often emphasized in CAM approaches focus on a prevention (rather than treatment) orientation, which tends to promote self-healing and rely on more healthy lifestyle and self-care changes, beginning early in life. This has potentially significant implications for both preventing and addressing chronic conditions, which are now the leading cause of illness, disability, and death in the United States, affecting nearly half of the U.S. population and accounting for the majority of health care expenditures. (4) Many patients who seek out CAM for chronic conditions suffer from syndromes (back pain, fibromyalgia, arthritis) for which a specific underlying cause of the disease is unknown or cannot be stopped. For many of these patients, conventional medical approaches may not work well. The IOM's 2001 report, *Crossing the Quality Chasm*, reported that more than 40 percent of those who suffer from chronic conditions have more than one such condition, suggesting that coordinated care including such supportive mechanisms that often characterize CAM approaches may be particularly effective. For example, relaxation therapies, acupuncture and herbal medicine, all of which share an emphasis on spiritual health and mind-body links, have demonstrated effectiveness with chronic disease patients. (3)

Another influence on the use of CAM and on the health care system is the accessibility of health information through the Internet and other communication technologies. While the impact and opportunity presented by the rapid evolution of health information technology is addressed elsewhere in this report, it is important to acknowledge its influence on consumer demand for CAM products and services. As of 1997, 35 percent of US households owned a computer, approximately 25 million Americans used the Internet weekly, and some websites provide information on more than three hundred different diseases. (5) A growing number of patients are equipping themselves with more, often quite detailed, information, not only about conventional treatments to their ailments, but about more unorthodox approaches as well. The ready availability of consumer information about such topics, whether accurate or not, and the ability to experience diverse cultures around the world have had a significant impact on the accelerated consumer movement toward CAM.

Patients are increasingly more interested in being active participants in their health care decisions. This participation includes evaluating information about treatment options, accessing products and practices that enable them to explore those options, and engaging in activities that may help them remain healthy through all stages of life. (6) Consumers' expectations are expanding the definition of health care from beyond treatment of illness to include prevention and wellness. A 1998 study indicated that those who use CAM do so because they find such approaches to be congruent with their own values, beliefs and philosophical orientations toward health and life. (7) As consumers become more empowered users of health care, whether to address chronic health conditions, or in an effort to increase overall wellness, their expectations for high quality, affordable, effective and safe health care from a range of providers and competent practitioners, both CAM and allopathic, also will increase.

Another factor influencing changes in the current health care system is the growing disparity of health indicators among U.S. populations. Research has found that income disparity between the rich and poor is the most powerful predictor of a nation's health as measured by life expectancy. (8) CAM services that are most commonly used by the general public, such as chiropractic, acupuncture, and massage therapy, are delivered primarily through non-reimbursable mechanisms, paid for out-of-pocket by the majority of its users. However, among immigrant populations, another type of CAM exists, comprised primarily of culturally-based home remedies and provided by members of a community with little or no formal training in health care, whether conventional or CAM in orientation. Such care often is more readily available than conventional care in many immigrant communities, where patients may depend upon them first, especially for seemingly minor disorders or for chronic conditions for which there is little known treatment in conventional medicine. (9)

In 2000, the Kaiser Commission on Medicaid and the Uninsured (9) reported that the most common barrier to care cited by immigrants was cost, followed by language. A supplement to the 2001 Surgeon General's Report on Mental Illness (10) also underscored the barriers for adequate health services experienced by racial and ethnic

minorities collectively. The report cited a constellation of barriers, many of which operate for all Americans: cost, fragmentation of services, and lack of availability of services. In the absence of affordable care, many immigrants, especially the uninsured, look to culturally-based home remedies to treat illness and disease.(9)

In the context of this more overall lack of access to care, adequate and appropriate access and delivery of CAM by qualified practitioners also possibly is most limited among those who can least afford to pay out-of-pocket. The cost of maintaining public health centers (county hospitals, public health centers), through which such care might be delivered to such populations, continues to increase. CAM proponents argue that many of the patients waiting hours for treatment are suffering from problems that might be appropriately treated by qualified CAM practitioners (acupuncture, homeopathy, bodywork). Many of the indigent and homeless that comprise the patient population at publicly run health centers, clinics and hospitals also present a diverse range of health challenges, including current or former alcohol and drug addiction problems. The use of appropriate CAM approaches by Federally funded programs has been shown to play a significant and cost-effective role in the recovery of these patients.

The consumer movement toward increased CAM use is only one of the forces through which health care is changing. Access to CAM will be subjected to the same demands placed on access to conventional health care: more efficient and effective use of available resources. To accomplish resource management goals will require, at least, identifying clearly intended outcomes for care, using evidenced-based best practices to achieve measurable goals, and improving overall systems of care delivery.

The Commission believes that CAM practitioners and the health care institutions delivering such care also should be properly regulated and accountable to the public. This chapter addresses the respective regulatory roles of Federal and State governments and those regulatory issues attendant to the delivery of CAM services and oversight of the broad spectrum of institutions through which CAM services are delivered; lays out the challenges in delivering CAM services; provides an overview of current CAM service delivery models within the range of health care systems from hospitals to individual private practice, and provides recommendations regarding each of these major issues.

Issue 1: The Effects of Regulation on Access

Ideally, health care access would define an ability to choose from both conventional and CAM practices and products, with assurances that all practitioners are qualified and products are safe and efficacious. States regulate health care practitioners by helping to assure quality and accountability of professions and providing a process for professional conduct review and disciplinary action. However, there is much variability State-by-State in regulatory approaches to licensure and scope of practice of CAM practitioners. For example, chiropractors are licensed in all States, while acupuncturists, massage therapists, and naturopathic physicians are licensed in 40, 30, and 11 States, respectively. These variations impact access to and delivery of CAM by limiting practitioners' ability to practice

lawfully and obtain malpractice insurance.

Most practitioners, whether CAM or conventional, will practice where they have the legal authority to do so. For naturopaths and practitioners of oriental medicine, the most influential factor in distribution appears to be licensure; these clinicians are concentrated in Northeastern and Northwestern States, where the greatest professional opportunities exist. Similar observations have been made about specialty providers and nurse practitioners or physician assistants, whose number per capita in each State correlates with the professional prerogatives granted to them. (11) The variability of regulation between States for any given CAM practice, the role of regulatory bodies, and the ambivalence of CAM practitioners towards regulation all contribute to the lack of definition and clarity on this issue.

In general, States that have fewer CAM providers also appear to have the lowest numbers of physicians and physician assistants per capita, as well. A better understanding of CAM utilization in such areas is needed to determine what can be done to improve access to CAM within the proper context of other public health and medical needs. Additionally, more information is needed on what constitutes "appropriate access" to CAM to better facilitate the mobility of qualified CAM practitioners within the health care system, and in collaboration with current services.

Early studies of licensure sponsored by the U.S. Department of Labor focused on licensure's impact on workforce availability, and the cost and quality of services. (12) The principle findings challenged the conventional wisdom that occupational regulation results in higher service quality and benefits consumers beyond the increased cost that licensure causes. These reports recommended that regulation should evaluate carefully the need for new licensed occupations, assure the continuing competence of licensees and greater equity in the discipline of licensed practitioners, improve public representation on licensing boards, remove artificial barriers to interstate mobility, and remove the control of educational functions from boards.

In 1990, the Federal Trade Commission (FTC) reported that occupational licensing had the capacity to "protect the public's health and safety by increasing the quality of professionals' services through mandatory entry requirements, such as education." (13) The report also found that many occupational licensing restrictions often did not accomplish these goals, but rather had the effect of increasing prices and imposing costs on the consumers. Despite this, the FTC concluded that the "costs of licensing did not always exceed the benefits to consumers," and recommended that such cost-to-benefits ratios should figure into the consideration of any licensing proposal.

In view of these concerns about the adequacy of current regulatory systems, and in a effort to return the focus of such oversight to promote the public health, the Pew Charitable Trusts established the Pew Health Professions Commission in 1989. Recognizing that health care workforce reform would necessitate regulatory reform, the Pew

Commission assembled the Taskforce on Health Care Workforce Regulation to identify and explore how regulation protects the public's health and to propose new approaches to health care workforce regulation to better serve the public's interest. (14)

In 1995, the Taskforce published 10 recommendations for regulatory reform and offered policy options for State considerations under each recommendation as a way of stimulating debate and discussion. The 10 recommendations made by the Taskforce are as follows:

PEW Taskforce Commission Recommendations for Regulation of the Health Care Workforce

1. States should use standardized and understandable language for health professions regulation and its functions to clearly describe them for consumers, provider organizations, businesses, and the professions.
2. States should standardize entry-to-practice requirements and limit them to competence assessments for health professions to facilitate the physical and professional mobility of the health professions.
3. States should base practice acts on demonstrated initial and continuing competence. This process must allow and expect different professions to share overlapping scopes of practice. States should explore pathways to allow all professionals to provide services to the full extent of their current knowledge, training, experience and skills.
4. States should redesign health professional boards and their functions to reflect the interdisciplinary and public accountability demands of the changing health care delivery system.
5. Boards should educate consumers to assist them in obtaining the information necessary to make decision about practitioners and to improve the boards's public accountability.
6. Boards should cooperate with other public and private organizations in collecting data on regulated health professions to support effective workforce planning.
7. States should require each board to develop, implement and evaluate continuing competency requirements to assure the continuing competence of regulated health care professionals.
8. States should maintain a fair, cost-effective and uniform disciplinary process to exclude incompetent practitioners to protect and promote the public's health.
9. States should develop evaluation tools that assess the objectives, successes and

1 shortcomings of their regulatory systems and bodies to best protect and promote the
2 public's health.

3 10. States should understand the links, overlaps and conflicts between their health care
4 workforce regulatory systems and other systems which affect the education, regulation and
5 practice of health care practitioners and work to develop partnerships to streamline
6 regulatory structures and processes.
7

8 The recommendations made by the Pew Commission, which focused primarily on the conventional health care
9 workforce, stimulated significant response from that community and subsequently fostered a high level of regulatory
10 activity and policy discussions that were captured in a 1998 follow up report by the Pew Commission. (15) Many of
11 these recommendations and subsequent discussions are equally appropriate to the regulation of CAM practitioners.
12

13 The Mechanics of Regulation

14 The power to protect citizens' health, safety, and welfare authorizes States to decide who may practice medicine,
15 and to establish licensing boards that admit or exclude persons from practice. The U.S. Supreme Court has affirmed
16 the constitutional right of State licensing boards to require a specific educational credential for health professionals.
17 Therefore, occupational regulation is a "State's right." However, the Federal government has contributed to the
18 shape of health professional regulation through its reimbursement and other policies in Medicare and Medicaid;
19 research on regulation's effects on health care cost, access and quality; practitioner data collection; education
20 funding; and other initiatives. A simple example of the Federal regulatory effect is the mandate for States to license
21 nursing home administrators, and to regulate nurse aides as a condition for Medicare and Medicaid reimbursement.
22

23 Concerns over excessive or intrusive Federal regulation into States' and private market affairs are most likely
24 sufficient to effectively eliminate the possibility of "Federalized" health professions regulations. It will be more
25 important for Federal agencies – through reimbursement and facility licensing, education funding and other efforts –
26 to facilitate the development, dissemination, and evaluation of uniform (non-Federal) entry-to-practice standards,
27 model scopes of practice, and innovations in education and workplace design.
28

29 The Commission fully acknowledges the different roles and authorities of both the Federal and State governments in
30 regulating CAM practitioners. The intention of the recommendations provided is not to usurp these responsibilities
31 but rather to provide guidance for actions to improve the public's access to qualified, safe and effective CAM
32 practitioners. For this reason, the Commission has included a recommendation for the development of a Federally
33 appointed, national advisory policy board that will support and coordinate efforts with a designated Federal office
34 for CAM to develop policy guidelines on issues related to the access and delivery of CAM. The advisory policy
35 board should be comprised of a broad representation of members from the health care arenas, including, but not

limited to CAM practitioners and professionals, CAM educators, researchers and policy makers; members of the allopathic professions, including educators, researchers and policy makers; insurers, and others in the health care industry; State and Federal regulators of health care practitioners, and representatives from professional oversight institutions and organizations.

States, who have the authority to determine who will be granted a professional health care license and what will be the requirements for licensure, often look to national professional groups to set standards of education and training as prerequisites to licensure, and to create accrediting bodies that can set standards and evaluative criteria for professional educational institutions. This process of licensure ostensibly creates a distinction between professional and non-professional occupations based on technical training and qualification.

The Federation of State Medical Boards of the United States, Inc., is a national organization comprised of the 69 medical boards of the United States, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. The Federation primarily serves to establish and promulgate professional standards of quality, safety and integrity of health care through physician licensure and practice. Recognizing the growing interest of the public in CAM practices and products, as well as that of many licensed physicians, some of whom may be incorporating CAM approaches and products into their practices, the Federation also has underway an initiative to develop model guidelines for State medical boards to use in regulating the use of "unconventional medical practices." These guidelines, currently under review, are expected to be released in 2002.

In keeping with its overall mandate, in its draft guidelines to States regarding CAM practices, the Federation recognizes and preserves a wide latitude in physicians' exercise of their professional judgment, not precluding the use of methods that are "reasonably likely to benefit patients without undue risk." The States are encouraged to establish and apply standards for effectiveness and safety equally to conventional and CAM practices and products. Therefore, licensed physicians should not be found guilty of "unprofessional conduct to practice medicine in an acceptable manner" solely on the basis of utilizing unconventional practices, but rather on a uniform set of professional guidelines that emphasize patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

The discussion and debate stimulated by the Pew Health Commission's 1995 recommendations have also had an effect on States' considerations of CAM, especially as practiced by licensed physicians. Pre-empting even the FSMB guidelines, the Texas State Board of Medical Examiners published Standards for Physicians Practicing Integrative and Complementary Medicine in November 1998. These standards recognized "health care methods of diagnosis, treatment, or interventions that are not acknowledged to be conventional but that may be offered by some licensed physicians in addition to, or as an alternative to, conventional medicine, and that provide a reasonable potential for therapeutic gain in a patient's medical condition and that are not reasonably outweighed by the risk of

such methods.” The guidelines to determine violations focus on patient evaluation, adequate informed consent, thorough documentation, follow up, and appropriate consultation.

[ED NOTE: we will include here a table describing the oversight/regulatory bodies of licensed CAM practices, State-by-State]

Most licensed practitioners must follow a legal and ethical code to refer the patient to **another** licensed medical **health care provider** when the patient’s clinical condition exceeds the practitioner’s scope of competence **or understanding**. If the practitioner violates this duty to refer and the patient is injured, the patient may sue for malpractice. In addition, the practitioner who fails to refer when necessary may face professional discipline from the relevant regulatory board. The duty to refer helps to ensure that all practitioners, both allopathic and unconventional, remain within the scope of their competence. These are critical protections that are not provided to the public when CAM practitioners and professionals remain unregistered or unlicensed.

Most States use one or more of the following mechanisms to regulate health care practices:

[Editor’s note: it was suggested that clarifying language or examples should be inserted under each description.]

Mandatory Licensure prohibits the practice of a profession without a license.

Title Licensure permits anyone to practice the profession, but only those granted a license may use the designated title.

Registration typically imposes lower educational and training requirements than licensure, and requires that a provider register his or her name, address and training with a designated State agency, which has the power to receive consumer complaints and revoke registration. (A variation of the registration regulatory model has been implemented by Minnesota, and allows CAM practitioners and professionals to practice without licensure, provided they meet a number of basic requirements.)

Exemption is a special status granted by most States to religious healers, exempting them from medical licensing statutes provided they practice within the tenets of a recognized church (i.e., praying vs recommending medication).

Ostensibly, the goal of regulating CAM practices is to establish standards that protect consumers from incompetent practitioners, however, current regulatory schemas have been used quite effectively by organized professional groups as entry barriers of other potential health care providers into the competitive market. The Commission believes that the highest priorities to consider are the quality of care, treatment and patient safety, and that a regulatory infrastructure for CAM practices and products is necessary to do so. **In fact, the Commission strongly**

believes that regulation of CAM practitioners is necessary, feasible and highly beneficial to the public's safety. Any such regulatory scheme also must consider and promote efforts toward a more coordinated care approach that incorporates and appropriately integrates the best of conventional medicine and CAM approaches. To ensure that this goal remains primary, at least two regulatory issues must be addressed: Professional practice authority, and regulatory and oversight structures.

Before making recommendations on these primary issues, it is important to note several unique challenges that face regulation of CAM practitioners. First, dispute amongst CAM practitioners, themselves, continues as to how much training should be required for licensure in any given field; the extent to which such training should be required for licensure in any given field; and whether and how such education and training can incorporate intuitive and individualized expression of professional health care services. From the CAM provider's perspective, licensure presents a tension between the desire to increase standardization of CAM education, training, and practices across States and the desire to keep CAM practice flexible, non-standardized, and linked to subjective, interpersonal and intuitive aspects of care. While increased licensure of CAM may help facilitate research and ease referrals, enhance patient access and increase consumer protection, it also may decrease the inherent differentiation of CAM (individualization of services, time spent per patient, range of patient options).

Secondly, the ambiguity and variance of what is considered "CAM" along a health professional continuum makes the useful assessment of CAM as value-added services difficult, at best. In September 2001, the University of California, San Francisco's Center for Health Professions published "Profiling the Professions: A Model for Evaluating Emerging Health Professions," (16) which discusses this evolutionary process. In addition to questions to help characterize the viability and growth trends of an emerging profession, the UCSF report outlined the need for a professional consensus description. Questions posed by the UCSF report included: How does the profession describe itself in terms of the types of care it provides, and the types of care beyond its professional scope? Are there differences of opinion within the profession about the range of care that is appropriate for the profession to provide? What interventions and modalities does the profession use? What is the diagnostic range and scope of pathology of the profession? Such descriptive statements are essential tools that enable both the public and other health professionals evaluate and understand, not only the practice itself, but how and whether the practice provides a value-added service.

Relatedly, a third concern is the overlap of approaches and technique between CAM modalities. For example, homeopathy and acupuncture are included in many States' definition of the practice scopes for naturopathy or chiropractic. Currently, even licensed CAM providers can be prosecuted for unlicensed medical practice if they are considered to have exceeded their scope of practice (e.g. massage therapists who offer emotional counseling and support, chiropractors who provide nutritional advice, nurses who offer therapeutic touch). The potential for criminal liability creates fear and uncertainty in CAM practice; it is often difficult to predict boundary violations.

(Licensed professionals inherently overlap in their scope of practice even in conventional care). If “whole person” medicine is the goal, these boundaries become even more ill-defined.

To address many of these concerns, the Commission has recommended that Federal support be provided to foster CAM practitioners’ efforts to establish a single, national, voluntary self-regulatory body, funded by registration fees, that will contribute to and uphold national standards for the practice of CAM; determine training and minimum levels of clinical competence for its specific modality; foster collaborative opportunities between its members and conventional practitioners; support, promote and publicize evidence for effectiveness, safety, and efficacy; serve as a national data bank for all practitioners under that profession and as the official liaison between its members and State regulators and professional oversight institutions; and provide an effective, accessible, supportive, and publically accountable mechanism (including disciplinary sanctions and publication of the findings of professional conduct committees) for addressing complaints about practitioners from members of the public. This body should work to advance public confidence in its practitioners, and demonstrate the readiness and ability of the profession to self-regulate. The establishment of a single lead organization should not preclude the continuation of healthy, progressive debate and exploration within the profession’s members of divergent mechanisms and approaches, but should seek simply to organize its general philosophy around a consensus scope of practice, and provide accountability to the public.

Professional Practice Authority

The determination of just which CAM practitioners are permitted to provide what specific services remains among the most controversial and complex issues when considering regulation. Often characterized as “turf battles,” the argument over scopes of practice is not unique to CAM. The Pew Health Commission’s Taskforce on Workforce Regulation found that, despite the ostensible goal of regulation to protect consumer interests, regulatory changes to practice acts always occurred at the request of professions, and never were done at the request of public or consumer advocates. (15) The Taskforce found that every proposal by one party for changes to one practice act is viewed by another as expansions, encroachments, and infringements, regardless of the competence or qualification of the first party.

Contributing to this confusion is the use of terms to describe levels and functions of regulation, not only among States, but between professions. This lack of uniformity in language limits effective professional practice and mobility, creates barriers to high quality health care, and confuses regulators, legislators, professionals and the public.

The inconsistency of State regulatory schemas and the lack of uniformity in terms have direct impact on efforts toward collaborative care. For example, hospitals that attempt to make CAM treatments available to patients may face liability for negligent referrals within the institution to potentially unqualified practitioners. (17) At issue is the variability, inconsistency and reliability of the wide range of certifications and licenses available from CAM

professional organizations, especially those which do not carry national consensus even among a given CAM modality. The liability, then, falls on the hospital or clinic, who must formulate and defend credentialing standards and procedures of each CAM practice for which it would like to refer. Similarly, managed care organizations face the same task of selecting which CAM practices and practitioners to include in their payment networks from among a diverse assortment of variously-certified providers. This task is compounded for those organizations that operate across State lines, and which must then contend with completely divergent occupational certification and licensure regimes State-to-State.

The Commission recognizes an urgent need to have clarity about the appropriate roles for CAM practitioners, professionals and clinicians at all levels of the health care system. The Commission believes that CAM practitioners need an appropriate level of legal authority granted by the State, both to protect and ensure the public's access to safe and effective practices. It seems clear that, given the diversity within the field, no single, overarching system of regulation, such as a national (Federal) licensing act, is appropriate to encompass all the different CAM practitioners, professionals, or address variations in State needs.

The Commission also recognizes that these different CAM practitioners and professionals may aspire to – and be qualified for – widely differing roles within the health care system, involving very different levels of intervention. For example, the scope of practice and education of a CAM professional such as an accredited naturopathic physician, may allow him to examine a patient, diagnose a health condition and treat the condition (all States include these functions under the definition of the “practice of medicine.”) This type of scope of practice reflects a greater level of potential risks to and needs of patients, and therefore requires more regulatory oversight than CAM practitioners who use less comprehensive approaches. Regardless of the orientation of the practitioner, whether allopathic or CAM, those who practice comprehensive health care approaches must demonstrate evidence of effectiveness and safety, educational, ethical and practice standards, and other characteristics of a cohesive professional status, all of which facilitate accountability to the public. An increasing number of CAM professional organizations are moving toward such professional status, adopting national standards for examination, certification, and accreditation. Such credentials promote public confidence in the safety and efficacy of these endeavors, and make more State-to-State uniformity of regulation more feasible.

It remains the prerogative of States to determine the scope of practice authority for any health care provider, and the mechanism, i.e., registration, licensure, by which such authority is implemented. The Commission offers the following framework for understanding the evolution of CAM practitioners and professionals as a tool for States to use when considering regulation of CAM practitioners and professionals.

CAM Professionals Ready for Licensure: The most evolved category of professional status is comprised of providers with an established, well-articulated and cohesive healing philosophy, defined practice standards, accredited

education, state licensing, documented safety and at least some research substantiation of effective outcomes.

These professionals are most ready to collaborate with conventional health care providers, but may lack the legal authority from States to practice at all. Many of these professionals already collaborate informally with conventional health care providers, usually as part of a supportive or palliative care approach.

Emerging CAM Professions: This is the most dynamic category of professional evolution, where lay and inconsistently trained practitioners are working to establish standards. Many of these so-called “emerging professions” enjoy rich traditions of education, training and practice in other countries, but may still be working toward establishing professional cohesiveness on such standards in the United States. Many levels of qualified practitioners exist in this status, and may already be collaborating informally with conventional health care providers and more professionally-evolved CAM practitioners.

Static Practitioners: Self-proclaimed or minimally educated healers who practice without apparent standards or community oversight comprise the currently least dynamic category of professional evolution. These practitioners may use titles associated with more evolved CAM professions, but do not adhere to the educational, training or other practice standards established by those professions.

Conventionally- trained CAM Practitioners: These providers are most often comprised of conventionally-trained allopaths who utilize therapies and practices that are highly controversial or excluded from conventional standards of care. They usually do not identify with a specific CAM profession, but may ascribe to certain empirical philosophies that tend to characterize CAM, rather than allopathic approaches. Most often individual practitioners, they are unlikely to organize as a profession, and focus their efforts on the development of their particular and unique technology or approach.

Traditional healers: These practitioners do so within a community that provides centuries-old traditions and oversight, such as Native American healers, shamans, and curanderos. They do not identify with a specific CAM “profession,” and often relate only to their cultural origins in any organizational sense, with little interest in recognition outside of their communities.

From the consumer’s perspective, access to competent CAM practitioners must be improved, as well as their ability to choose from among many types of CAM practitioners, or from among coordinated care plans that integrate conventional and CAM care. The public has a reasonable expectation that the care they access is provided by a competent practitioner able to help them navigate through multiple choices and decisions about the care they can receive.

Regulation and Oversight

In addition to assuring the competence and qualifications of the CAM practitioner, the consumer expects that the facility through which care is delivered also is safe and accountable. Most health care facilities and organizations are regulated by private organizations through accreditation processes that substitute for licensure.

The largest such private organization is The Joint Commission on the Accreditation of Health Care Organization (JCAHO), which evaluates and accredits nearly 18,000 health care organizations and programs in the United States. An independent, not-for-profit organization, JCAHO uses professionally based standards against which compliance of health care organizations are measured.

JCAHO's evaluates and accredits a long list of organizations, including general, psychiatric, children's and rehabilitation hospitals; health care networks (including Health Maintenance Organizations (HMOs); Integrated Delivery Networks (IDNs), Preferred Provider Organizations (PPOs), and managed behavioral health care organizations; home care organizations, including those that provide home health services, personal care and support services, home infusion and other pharmacy services; durable medical equipment services and hospice services; nursing homes and other long term care facilities, including subacute care programs, dementia programs and long term care pharmacies; assisted living facilities that provide or coordinate personal services, 24-hour supervision and assistance (scheduled and unscheduled), activities and health-related services; behavioral health care organizations, including those that provide mental health and addiction services, and services to persons with developmental disabilities of various ages, in various organized service settings; ambulatory care providers, including outpatient surgery facilities, rehabilitation centers, infusion centers, group practices and others; and clinical laboratories. CAM is delivered primarily through out-patient (private practitioners) facilities, and easily could be included on this list, yet little or no standards exist to regulate them. [ED NOTE: Information from JCAHO is pending on this issue. No formal guidelines exists]

JCAHO and most other accreditation organizations that are used by regulatory bodies to ensure quality health care require that staff of such facilities be licensed, meet relevant training and experience standards, demonstrate current competence, and have acceptable health status. In addition, the Health Plan Employer Data and Information Set (HEDIS 2.0) reports on general consumer satisfaction with provider accessibility and interaction, turnover, and board certification status. In some cases, individual health plans may also require medical and other staff to provide information on disciplinary or other actions taken against them, and many plans include some degree of "economic credentialing" to assess practice patterns against the organization's philosophical principles or business plans. None of these regulatory and quality control mechanisms currently are applied to CAM service delivery.

JCAHO is governed by a 28-member Board of Commissioners that includes nurses, physicians, consumers, medical directors, administrators, providers, employers, labor representatives, health plan leaders, quality experts, ethicists,

health insurance administrators and educators. This composition is reflective of most accrediting bodies, and presently most do not include CAM practitioners or experts in these fields.

[Add Joe Fin's example of how pain assessment was added to the accreditation model. Clarify that this action item does not refer to organizations that accredit CAM schools....also include AHA documentation on the increasing use of CAM in hospitals...]

Issue 2: Coordinated Delivery Systems

Increasingly, health providers are being challenged to develop practice protocols and other methodologies that coordinate care across the continuum. The foundation of such care is built best by first establishing a strong base of primary care. As defined by the Institute of Medicine in 1996, primary care involves the "provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing sustained partnership with patients, and practicing in the context of family and community" (18) All health care practitioners, including CAM providers, should adequately understand and appropriately value the role of primary care, which should remain the launching point for all care, regardless of the providers. A more comprehensive discussion of the role that CAM practitioners and professionals may play with regard to primary care is included in another chapter of this report.

Integrative, or collaborative health care should not be about promoting complementary therapies but about providing comprehensive, collaborative, personalized care by drawing on the resources, skills and perspectives of a wide variety of disciplines, specialties and therapies, including complementary and alternative therapies when clinically appropriate. In the same vein, defining integrative, or collaborative health care should not be either polarizing or divisive. By pairing a holistic philosophy (comprehensive, collaborative and personalized) with a systematic and well reasoned clinical strategy, integrative health care treats illness and promotes health in a manner that always keeps the patient and community at the center.

The emergence of CAM approaches as a consumer movement suggests a shift from the application of using only science and technology to overcome disease and dysfunction, to the acknowledgment of an integrated, self-healing life system with the role of internal self-regulation, personal attitudes and beliefs, and the healing nature of relationships as paramount. Consumers are doing their own research, and serving as individual research models, trying alternatives to conventional treatments, and pressing for more options. Nutrition, exercise and lifestyle changes that include increasingly more CAM products and practices play a significant role in preventing and treating disease, and improving quality of life. In most instances, health care providers can be used to guide consumers to safe and effective paths to recovery and health. In all cases, providers should be well-trained, highly qualified practitioners.

In response to growing patient (and health practitioner) dissatisfaction with the current system, innovative centers and practitioner groups are emerging at a growing rate. The trend toward patient-centered (rather than diagnosis-centered) and self-healing care is beginning to be reflected in employee assistance programs, hospice centers and community-based public health clinics and services.

CAM, like all health care services, is delivered through the public or private health care sectors. The public delivery system, in this context, includes Federal health systems (including those of the military and Veterans Administration), public hospital systems, community health centers, local public health clinics, home care, etc. Private sector systems include office-based practices of medical and health professionals, hospitals, multiple-facility health care systems, clinics, nursing homes, home health agencies, etc. These systems continuously evolve, especially in response to the mechanisms under which the systems are financed and other market pressures. For example, managed care has had a significant impact on systems of delivery, and managed care itself has changed in response to market pressures. CAM practitioners are most often found in private sector settings, and are usually in solo or small office-based practices. Increasingly, hospitals, managed care organizations, health insurers and large, self-insured corporations are developing models whereby CAM therapies are made available to members/subscribers/ employees. These models bring CAM to the practice of conventional medicine through referral, consultation, co-management, and adjunct (supportive) therapies. The spectrum of existing models, all relatively new, is broad and includes:

Solo practitioners deliver often multi-modal CAM services in an office-based practice or outpatient (ambulatory) setting. In some cases, several such CAM practitioners may share office space without working collaboratively on cases, although they may refer to one another as appropriate.

CAM clinics, usually a group CAM practitioners, work collaboratively to offer patients integrated services. Such clinics may include allopathic practitioners, either as part of the integrative services on-site, or as case consultants.

Vertically integrated services are usually CAM clinics, but may be solo practitioners, that are linked with primarily allopathic delivery systems, such as teaching hospitals or community health clinic networks. Such services operate independently of the allopathic system, but are considered adjunct.

Because most of CAM is delivered through the private practice arena, it is less readily available to the populations served by community health centers and others who cannot afford to pay out-of-pocket for services. CAM practitioners who participate in referral or practitioner networks usually do so at discounted rates, a system that works as a disincentive for most CAM practitioners. Currently, few incentives exist to encourage more CAM practitioners into either the public or managed care delivery systems. Until these issues are resolved, CAM services and products will remain largely inaccessible to the populations in most need.

As new delivery models for CAM develop, the need to assure accountability and quality will become even more critical. The Institute of Medicine's report, *Crossing the Quality Chasm*, identifies six aims for improvement, all of which apply equally to conventional and CAM care (4):

Safe: avoiding injuries to patients from the care that is intended to help them.

Effective: providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).

Patient-centered: providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

Timely: reducing waits and sometimes harmful delays for both those who receive and those who give care.

Efficient: avoiding waste, including waste of equipment, supplies, ideas, and energy.

Equitable: providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socio-economic status.

A particularly salient example of both the need for collaborative care, and of how well CAM approaches can be incorporated into a care system can be found in end-of-life care. While the incorporation of CAM is applicable throughout the life-cycle, by the year 2020, 20% of the world's population will be older than 65 years. In this country, 8% of the population currently is older than 65 years and in 2020, it is estimated that 25% will be older than 65 years (roughly 65 million older adults). As the population ages, problems in end of life care have been increasingly well-documented, from under-treated pain to unwanted or futile therapies. Among the concerns for older adults is polypharmacy, the use of multiple medications. Older adults consume approximately 25% of prescription medication each year. In this country, it has been estimated that older adults take an average of 5 medications at any one time, often mixing them with over-the-counter medications and nutraceuticals. Given the significant increase in the number of adverse drug effects known to occur with the number of medications, this presents a particular public safety concern. The potential for CAM therapies to reduce the number of medications older adults take provides an important and cost-sensitive opportunity.

End-of-life care is not limited to the elderly. A report by the Association of American Medical Colleges defined end-of-life issues as those that the individual person faces when confronted with a condition in which dying is a distinct possibility. (19) In this context, no clear demarcation exists between active treatment of an illness and the end of life. Rather, end-of-life refers to the entire time, even during treatment of an illness, when dying becomes an

important consideration. For the patient, personal spirituality and culture may significantly affect his beliefs, attitudes and behaviors toward end-of-life health care interventions.

Indeed, there is evidence to suggest that spirituality may be helpful to people as they cope with dying or with loss. For example, patients with advanced cancer who also found comfort from their religious and spiritual beliefs had diminished pain; women with breast cancer reported that their spiritual beliefs helped them cope with their illness and with facing the possibility of death. In a national survey by the American Pain Society, prayer was stated as the most common non-drug method for dealing with pain, followed by relaxation response, meditation, touch and massage. The work of Dr. Herbert Benson on the role of meditation, specifically the relaxation response, as an adjunct to treatment of patients with serious disease is well-known in the medical community. Despite clear evidence of the important role of spirituality in end-of-life care, and the availability of Clinical Pastoral Education (CPE)-trained chaplains and other spiritual care providers, current systems of care do not easily incorporate spirituality into the care of patients.

The 1999 report of the Association of American Medical Colleges (Report III of the Medical School Objectives Project) suggested strategies to improve medical student education on spirituality, cultural issues and end-of-life care. Demonstration projects that further explore the potential benefits and opportunities of collaborative care (that incorporates or coordinates conventional and CAM approaches) is both appropriate and of critical value.

ACCESS AND DELIVERY REVISED AND NEW RECOMMENDATIONS
DECEMBER 21, 2001 (Revised)

RECOMMENDATION 1.

The Commission recommends that access to qualified practitioners, affordable, safe and effective CAM services, and beneficial CAM products be better facilitated for all Americans.

RECOMMENDATION 2.

The Commission recommends that practitioners who provide CAM services and/or products be regulated by States using a more standardized and understandable framework that includes exemption categories, registration, and licensure, and that ensures accountability to the public.

Action Items:

1. The Secretary of HHS (together with a designated Federal office for CAM) should convene a national policy advisory committee to: a) address issues related to the licensing and certification of CAM practitioners; b) provide guidance to States as they develop regulatory and oversight standards applicable to CAM practitioners; and c) provide a forum for dialogue on other issues related to maximizing access to qualified practitioners, safe and effective CAM services, and beneficial CAM products.

2. Utilize health care workforce data and data from national surveys on CAM to identify current and future health care needs that qualified CAM practitioners may help to address.

[A recommendation for demonstration projects to evaluate the usefulness, effectiveness and cost-benefits of collaborative care models at three delivery levels: office-based; free-standing CAM clinics, and vertically integrated services will be added to either the Research and/or the Coverage and Reimbursement chapters. However, it was also suggested that this particular "research-oriented" recommendation strengthens the Access section and should also be covered here as an additional action item. Regardless, the text in the Access chapter will be revised to discuss the need for such projects, including the importance of the results of such studies should inclusion in loan-forgiveness programs of CAM ever be considered or evaluated more formally.]

3. The Federal Government should convene conferences on effective approaches to the integration of safe and beneficial CAM into allopathic settings, using successful models of integrated care, such as hospice settings, community health clinics, and the private and non-profit sector, and make this information available to practitioners and the public.

4. The Secretary of HHS should produce a report on indigenous healing traditions in the United States that identifies common use and practices, and provides recommendations to improve collaboration between such practices and current health care systems in a manner that protects the cultural heritage of such traditions, appropriately educates health care practitioners, involves members from these traditions, and maximizes access to qualified practitioners, safe and beneficial services, and effective products.

5. The Federal Government, in collaboration with States, should assist CAM practitioners and organizations, especially those that are unlicensed, as they move towards developing consensus within their respective modalities and disciplines on: Definition / Description of the Profession/Practice; Safety and Efficacy; Regulation and Oversight; Education and Training; and the Viability of the Profession, for consideration by States and regulatory bodies in determining the appropriate regulatory status of these practitioners, including exemption, registration, or licensure.

6. The HHS' advisory committee (through the designated Federal office for CAM) should work closely with State legislatures and regulatory boards to develop guidelines for the regulation and oversight of licensed and registered practitioners who utilize CAM services and products.

7. State regulatory boards should develop processes to protect CAM and conventional practitioners who use CAM services or interventions in IRB-approved research should not be from being sanctioned solely for their use of such approaches.

8. Nationally recognized accrediting bodies of health care organizations and facilities should include appropriate CAM representation in accreditation processes.

9. Nationally recognized accrediting bodies of health care organizations and facilities should incorporate in their accreditation processes CAM services and products, and CAM practitioners.

[Recommendations on a Food Stamp benefit are being considered by Wellness and Access staff for proper disposition into the text.]

Original access to expertise