

What Is CAM?

Complementary and alternative medicine (CAM) had become an increasing feature of healthcare practice, but considerable confusion remains about what exactly it is and what position the disciplines included under this term should hold in relation to conventional medicine. A number of professional bodies have attempted to define CAM over the past few years. In the early 1990s, Eisenberg and colleagues (1993) defined “unconventional” medicine as those practices “neither taught widely in U.S. medical schools nor generally available in U.S. hospitals.”

This definition has been widely adopted as the definition for CAM as well. For example, the National Center for Complementary and Alternative Medicine (NCCAM) at the NIH currently defines CAM as those healthcare and medical practices that are not currently an integral part of conventional medicine (NCCAM, 2000). However, this definition has proven unsatisfactory for some because it medicalizes self-help practices, such as weight loss programs and Alcoholics Anonymous (Cassileth, 1993). Others, on the other hand, have found it lacking because it has too narrow of a focus (Panel on Definition and Description, 1997).

In an attempt to develop a more precise concept of what CAM encompasses, the Office of Alternative Medicine of the National Institutes of Health (currently known as NCCAM) sponsored a work group in 1995 to define CAM. After extensive discussions, this work group defined CAM as “a broad domain of medical or healing systems that are

outside the range of those that are intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp and fixed” (Panel on Definition and Description, 1997).

The Panel was careful to note, however, that identifying a health system as “politically dominant” does not imply that it achieved its dominant position through political means. Rather, the phrase “political dominance” merely recognizes the fact that the dominant system of health often has broad cultural authority. This, in turn, gives it greater legislative and social institutional support and, thus, greater access to medical practice laws, legally recognized accreditation and rights of self-regulation, third-party payment, public research funds, and to prestigious scientific publications, than less dominant systems of health.

The Complementary Medicine Field Group of the international Cochrane Collaboration (see Part I) has adopted a variation of this latter definition, which reads: “Complementary and alternative medicine (CAM) is a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture of a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or

promoting health and well-being. Boundaries within CAM and between the CAM domain and that of the dominant system are not always fixed (Zolman and Vickers, 1999). The Cochrane definition, therefore, further broadens the definition to include all healing resources and accompanying theories and beliefs. Furthermore, the Cochrane Collaboration has established a common set of modalities and systems of medicine that it generally recognizes as being encompassed by this definition (See Table 1 below).

Table 1: Common CAM Therapies and Systems of Medicine		
Acupuncture	Chiropractic	Naturopathy
Acupressure	(Sacral) Cranial Osteopathy	Nutritional Therapy
Alexander Technique	Environmental Medicine	Osteopathy
Applied Kinesiology	Herbal Medicine	Reflexology
Anthroposophic Medicine	Homeopathy	Relaxation and Visualization
Aromatherapy	Hypnosis	Shiatsu
Autogenic Training	Imagery	Spiritual Healing
Ayurvedic Medicine	Magnets	Therapeutic Touch
Energy Medicine	Massage and Bodywork	Traditional Chinese Medicine
	Meditation	Yoga
Adapted from Zollman C, Vickers A. What is complementary medicine? BMJ 1999;319:693-696.		

These latter two definitions incorporate a larger worldview by acknowledging that many health care practices that are considered "complementary," "alternative" or "unconventional" in the United States, such as herbal medicine, are often the main system of treatment in many developing countries (Bannerman et al., 1983; WHO, 1978) as well as in many ethnic communities in this country (Berman, Swyers, Kaczmarczyk, 1999). These definitions also acknowledge that the boundaries between CAM and biomedicine are constantly changing and are likely to evolve even further in the years to come as

therapies that are now considered CAM become integrated into mainstream medicine and new, untested therapies appear on the horizon to take their place.

The Commission's Definition of CAM

Many of the Commissioners believed that the Commission could not fulfill its duties without considering “wellness” as an integral part of the definition of CAM. Although the concept of wellness has been part of allopathic medicine in the form of preventive medicine for many years, it is an aspect of allopathic medicine that has largely been under-emphasized and researched. In fact, a recent survey of 144 allopathic and osteopathic medical schools found a greater emphasis on teaching and evaluating medical students’ knowledge in the areas of clinical preventive services and quantitative methods, and less emphasis on the community dimensions of medical practice and health services organization and delivery. More revealing, however, was the finding that fewer than half of all respondents were satisfied with the quality of their assessment of student achievement in any of the four domains of prevention education. More than 30% expressed a desire to receive assistance with designing curricula and/ or evaluation methods in prevention education (Garr, Lackland, & Wilson, 2000).

In addition, given the prevalence of nutritionally related chronic diseases in American society, it would seem imperative that the training of physicians should include a focus on the relationship of diet to disease. Yet, despite scientific data, public interest, US government reports, society studies, and congressional mandates, the teaching of

nutrition in medical schools and residency programs remains woefully inadequate (National Education Consortium, 1997). Indeed, most medical schools do not have faculty trained specifically in nutrition (Cooksey et al, 2000), and faculty resistance to changing medical school curricula is a major barrier to overcome in the effort to expand such education (Armstrong & Koffman, 1998).

Finally, despite the importance of culture in health care and the rapid growth of ethnic diversity in this country, a recent survey of medical schools in the U.S. and Canada found that very few schools (U.S. = 8%; and Canada = 0%) had separate courses specifically addressing cultural issues (Flores, Gee, & Kastner, 2000). Schools in both countries usually addressed cultural issues in one to three lectures as part of larger, mostly preclinical courses. Significantly more Canadian than U.S. schools provided no instruction on cultural issues (27% versus 8%). Few schools taught about the specific cultural issues of the largest minority groups in their geographic areas: only 28% and 26% of U.S. schools taught about African American and Latino issues, respectively, and only two thirds of Canadian schools taught about either Asian or Native Canadian issues. Only 35% of U.S. schools addressed the cultural issues of the largest minority groups in their particular states.

Therefore, in attempting to provide a framework for its definition of CAM, the Commission decided to incorporate elements of health, which have been embraced by some circles of conventional medicine, but have largely been ignored or marginalized by the majority of conventional medical education institutions.

**[Note: This section will be completed after receiving feedback from the
Commissioners]**

Need a CPM Punch
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INTRODUCTION: A ^{new age} TALE OF TWO SYSTEMS

[In many ways, it is the best of times and the worst of times for medicine. It is the best of times,] because biomedicine--the system of medicine upon which our dominant health care system is based--has provided physicians with an astounding array of diagnostic technologies and remedies. Doctors and other health care providers now have the means of detecting, preventing, and curing many diseases that only a generation ago wrought death and destruction across the globe.

Combined with the development of drugs that are increasingly more effective in preventing tissue rejection, surgical advances have made organ transplants that were unthinkable only a few decades ago, a reality. Indeed, people are now surviving decades and living happy, productive lives with transplanted organs, such as hearts, livers, lungs, and even limbs.

There also has been a dramatic increase in knowledge of the biochemical or molecular origin of many diseases. This knowledge has led to the development of new, extremely sensitive diagnostic tests that can measure minute concentration of various biochemical entities or organisms in the blood stream or in a single cell. The recent announcement that the entire human genome has been successfully sequenced will undoubtedly herald a new age of understanding the genetic basis of many illnesses and afflictions, both physical and mental.

Yet, these are also extremely difficult times for biomedicine, or allopathic medicine as it is often called. Indeed, at a time when modern, scientific medicine is making some of its most important clinical advances, it is pricing itself out of the financial reach of many individuals. Health care spending exceeded \$1 trillion in 1996 updates ? and, based on projections, will increase an astounding 50%, to nearly \$1.5 trillion, by the year 2002 (Thorpe, 1997). Even with the unprecedented rise in employment and standards of living that occurred in the last decade, current trends indicate that the number of uninsured non-elderly Americans is rising and will approach 47 million by the year 2005. That means nearly 20 percent of the non-elderly population or 1 out of 5 of all Americans under age 65 soon will be without health insurance (Current Population Survey, 1996).

The skyrocketing cost of health care has forced both Government and private health plans to attempt to control costs by limiting payments to hospitals, clinics, doctors, and other health care providers. Such efforts to limit costs have forced many health care practitioners to increasingly reduce the time they spend with each patient in consultation. This situation has produced mounting frustration and humiliation for both doctors and patients alike. Patients are frustrated not only about limited time they can spend with their physicians but also about the litany of pre-certifications and specialist referrals they are required to obtain and about losing access to services they believe they need. Most physicians are equally frustrated by the layers of requirements and policies of placed on them by managed care plans, which they believe are undermining the traditional doctor-patient relationship and making them question their role as patient advocates.

The very success allopathic of medicine is partly responsible for this predicament. By significantly lessening the threat of infectious disease, the major killer in the 19th and early 20th century, allopathic medicine has left us to deal with chronic, degenerative illness, a much more stubborn and costly problem. The success of allopathic medicine in extending life has also contributed to the aging of the population, further increasing the prevalence of chronic illnesses, such as arthritis, back pain, diabetes, depression, hypertension, Alzheimer's Disease, and cancer.

For many of these chronic conditions, allopathic medicine's ability to develop new drugs and surgical interventions has so far provided only modest gains in outcomes. Furthermore, many of the drugs that are effective in the short-term for these conditions often entail significant side effects that can be toxic and sometimes even fatal with prolonged use (Apelland et al, 1999; Hawkey, 1996; McCarthy, 1998). Indeed, a recent study by Lazarou and colleagues (1998) found that deaths from adverse reactions to allopathic drugs were between the fourth and sixth leading cause of death in this country.

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As a result of patients' growing frustration with diminished contact with their doctors and the slow pace of development of effective and less toxic treatments for a host of chronic conditions, in the 1970s and 1980s many people begin experimenting with a variety of non-allopathic, or "unconventional," medical therapies. Initially, many of these unconventional therapies were mainly provided as alternative treatments to allopathic health care. Hence, these non-allopathic therapies became known collectively

as "alternative medicine." However, as Americans began to increasingly use the two systems of medicine—allopathic medicine and alternative medicine--side by side, essentially to complement one another, the term "complementary medicine" emerged to describe this system of medicine.

Yet, even this terminology was imprecise because it did not take into account that fact that although many alternative therapies were being used to complement allopathic medical care, some were being used *instead* of allopathic medical care. Thus, over the past several years, the terminology has been refined to acknowledge this dichotomy. The phrase “complementary and alternative medicine,” or CAM, has been adopted to best describe this system of medicine (see Part II for a more detailed discussion of CAM).

The Rise in Popularity of CAM

Little was known about the detailed landscape of CAM usage until the early 1990s, when David Eisenberg and his colleagues (Eisenberg et al., 1993) published the results of a national survey showing that 34% of the American adult population used at least one of 16 different alternative therapies in the previous year. By the latter 1990s, Eisenberg et al. (1998) and Astin (1998) documented further increases in the use of alternative therapies, with both of these national studies reporting that approximately 40% of the general population had used some form of CAM therapy in the previous year. The most frequently used CAM therapies in these surveys were: relaxation techniques, chiropractic, massage, life-style/diet, and exercise/movement. Furthermore, the two

Eisenberg, et al.(1993, 1998) surveys consistently found that Americans paid more visits to alternative medicine practitioners than to conventional primary care physicians. In 1997, Americans spent approximately \$21.2 billion on CAM professional services and \$27 billion overall, a 45.2% increase since 1990 (Eisenberg et al, 1998) (See Part II for a more detailed discussion of these and other surveys).

One disturbing finding that has emerged from surveys of CAM use, however, is that many users do not routinely report their use of these therapies to their allopathic physicians (Eisenberg et al., 1993, 1998), a situation has the potential for a great deal of harm (Eisenberg, 1997). Nowhere is this problem more acute than in the dramatic rise in the use of herbs and nutritional supplements in recent years. Studies have found that supposedly "gentle" herbal remedies, in fact, contained powerful prescription drugs (Catlin et al., 1993) or toxic metals such as mercury (Kang-Yum and Oransky, 1992; McKinney, 1999) or lead (Bayly et al., 1995) and have caused serious injuries. Other studies have demonstrated that even uncontaminated herbs and nutritional substances pose health risk, particularly in regard to interactions with allopathic medications (Kirk, 1995; Miller, 1998). This topic is discussed in greater detail in the following section.

Evidence for the Safety and Efficacy of CAM

Studies documenting the rise of interest in and use of CAM by patients, were a major impetus for the Federal government to begin to take a serious look at both safety and efficacy of many CAM therapies. As a result, Congress established the Office of

Alternative Medicine (OAM) at the National Institutes of Health (NIH) in the ~~early~~ 1990s. In 1998, Congress elevated the OAM to the status of a national center for coordinating research in CAM throughout the United States. To date, this National Center for Complementary and Alternative Medicine, or NCCAM, has funded the establishment of 14 research centers to explore the safety and efficacy of a wide range of CAM therapies for a host of conditions.

As a result of these and other research efforts in the U.S. as well as Europe, and Asia, there is preliminary but growing evidence that some CAM therapies are effective treatments for a variety of conditions. Indeed, to date more research on CAM exists than is commonly recognized. For example, the library of the Cochrane Collaboration, an international effort to develop an evidence base for a wide variety of medical therapies both allopathic and CAM, lists over 4000 randomized trials for CAM therapies. Furthermore, there are a growing number of systematic reviews of this literature, many confirming that CAM approaches do have some medical benefit for specific conditions. There is preliminary, but convincing evidence for the effectiveness of CAM approaches in the treatment of a number of conditions, including back pain (Van Tulder et al, 1999), headache (Melchart et al., 1999) depression (Linde and Mulrow, 2000), arthritis (Little and Parsons, 2001; Towheed et al, 2001), neurologic conditions (Soares and McGrath, 2000; Olin and Schneider, 2001), and heart disease (Hooper et al, 2001).

In addition, an NIH Consensus Development Panel held in 1997 (NIH Consensus Statement, 1997) concluded that acupuncture ^{is} a plausible treatment option for treating

several conditions, including post-operative nausea and vomiting, acute dental pain, headaches, temporomandibular joint dysfunction, fibromyalgia, and depression. Furthermore, there is growing scientific consensus that a variety of so-called “mind-body” techniques, such as meditation and guided imagery, are effective both in the management of painful conditions and the relief of stress and anxiety (Berman and Swyers, 1999; Broderick, 2000; NIH Technology Assessment Panel, 1996).

Although most of these literature reviews have concluded that larger, more rigorous studies are needed, it is important to note that definitive evidence for the efficacy of many allopathic therapies is lacking as well. For example, a recent review of 121 literature reviews of allopathic medicine in the Cochrane Collaboration Registry found that 21% reported "evidence of no effect," 22% reported "insufficient evidence," 21% reported "evidence of positive effect," and 7% reported "evidence of a harmful effects" (Ezzo et al, 1998). This finding is consistent with literature reviews of conventional treatments for back pain (Deyo, 1993; Turner et al, 1992), most of which have not been definitively proven effective despite their widespread use.

Nevertheless, most CAM therapies that are currently being used by consumers have not been adequately studied (Clinical practice guidelines in complementary and alternative medicine, 1997; Ernst and Fugh-Berman A, 1999). Furthermore, even among those where there is evidence of efficacy, not enough is yet known about their safety. For example, it was recently discovered that St. John's Wort (*hypericum*), an herb that has been shown effective in treating mild to moderate depression (Philipp et al, 1999), can

interfere with the action of an important anti-HIV drug, indinavir (Piscitelli et al, 2000). Preliminary evidence also indicates that St. John's Wort lowers the therapeutic activity of some types of oral contraceptives (Baede-van Dijk. et al, 2000) and cyclosporin A, a drug used to prevent the rejection of transplanted organs (Ruschitzka et al, 2000). One study noted that St. John's Wort also may increase an individual's sensitivity to sunlight (Woelk et al., 1994).

There also are numerous case reports of other CAM therapies causing significant adverse effects, including cases of spinal cord injury (Kida et al, 1988; Kishikawa et al, 1990; Ilhan et al, 1995), pneumothorax (Gray et al, 1992; Vilke and Wulfert, 1997) and various types of infections (Chen et al, 1997; Grange, 1990; Kirschenbaum and Rizzo, 1997; Matsumura et al, 1998). caused by acupuncture. In addition, inappropriate application of chiropractic manipulation has been reported to cause vascular problems (Balblanc et al, 1998; Jumper and Horton, 1996) and even brain stem damage (Mueller and Saks, 1976). The majority of the adverse consequences from acupuncture in the U.S. have been attributed to unlicensed or poorly trained practitioners (Safety Record of Acupuncture, 1993)

Thus, CAM therapies are not necessarily harmless. However, because they tend to be less invasive and more potent than allopathic modalities, CAM therapies tend to pose significantly less risk for harming health than do allopathic medicines. For example, even though Americans made pay more visits to CAM practitioners than to allopathic practitioners (Eisenberg, 1993, 1993), malpractice claims against allopathic practitioners

occur more frequently and typically involve more severe injury than claims against CAM physicians (Studdert et al, 1998). These findings illustrate vividly the need to rigorously evaluate both widely used CAM and allopathic treatments for safety and efficacy.

Therefore, there is an urgent need for physicians and patients to become more knowledgeable about the potential benefits and harms of CAM treatments. Such steps are not likely to proceed, however, until there is greater cooperation and collaboration between the conventional medicine and CAM communities (Berman et al, 2000). Recently, there has been a major effort to increase allopathic physicians' awareness and understanding of CAM through educational programs. However, there is a great deal of variability in the content of these programs. A recent survey of 117 U.S. medical schools found that 64% offered an elective course in CAM or included information about CAM in a regular course, only 31% were part of a required course (Wetzel et al, 1998). Topics included chiropractic, acupuncture, homeopathy, herbal therapies, and mind-body techniques. Although, some institutions are developing educational programs for practicing physicians to give them an understanding of the theory, practice, strengths, and weaknesses about the major CAM modalities (Weil, 2000), there is not yet any requirement for most practicing physicians to obtain training in understanding CAM.

The White House Commission on Complementary and Alternative Medicine Policy

To address a number of major uncertainties in the access and delivery of CAM as well as research and education, the White House Commission on Complementary and

Alternative Medicine Policy (WHCCAMP) was established in March, 2000, by Executive Order 13147 of the President of the United States. The Commission's primary focus is to provide a report by March 2002, through the Secretary of Health and Human Services, to the President on legislative and administrative recommendations for assuring that public policy maximizes the potential benefits to Americans of CAM therapies.

Specifically, ~~according~~^{recent}, the recommendations of the Commission are to address the following:

- (a) the education and training of health care practitioners in CAM
- (b) coordinated research to increase knowledge about CAM products;
- (c) the provision of health care professionals with reliable and useful information about complementary and alternative medicine practices and products;
- (d) guidance of appropriate access to and delivery of complementary and alternative medicine.

To accomplish its mission, the Commission ~~took~~^{recent} testimony from the public through a series of town hall meetings. The purpose of these town hall meetings was for the Commission to listen to testimony from individuals and organizations interested in the

subject of federal policy regarding CAM. Specifically, the town hall meetings were focused around four primary areas with several questions to be posed under each area:

- I. Coordinated Research and Development to Increase Knowledge of Complementary and Alternative Medicine Practices and Interventions
- II. Guidance for Access to, Delivery of, and Reimbursement for Complementary and Alternative Medicine Practices and Interventions
- III. Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine
- IV. ~~IV~~ Delivery of Reliable and Useful Information on Complementary and Alternative Medicine to Health Care Professionals and the Public

In addition to the Town Hall meetings, the Commission solicited expert testimony from clinicians, researchers, educators, regulatory officials, policymakers, and consumers related to the four areas. The Commission asked these expert witnesses to provide recommendations as well a documentation to support the basis of their recommendations. The Commission also conducted a number of site visits to see first-hand how various medical institutions are dealing with the issues related to integrating CAM into clinical practice.

The Commission Report: Purpose and Scope

This Report, therefore, represents the culmination of extensive public and expert testimony and the examination hundreds of pages of written testimony and peer-reviewed research that was either submitted to the Commission or that the Commission requested as part of its deliberations.

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How To Use The Report

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PART II: GUIDING PRINCIPLES AND PERSPECTIVES OF CAM INTERVENTIONS AND PRACTICES

Introduction

The purpose of this part of the report is to provide an overview of the field of complementary and alternative medicine, or CAM. Specifically, it examines the evolution of the definition and how the term is used today. It also examines trends in CAM usage, who uses CAM therapies, what types of CAM modalities are used most frequently and for which condition, and the reasons many people give for using these modalities and approaches and their level of satisfaction. Finally, it examines the paradigm, or worldview, that is common to many CAM systems of medicine and the obstacles that are inherent in attempting to integrate CAM and allopathic approaches with such different worldviews and languages.

What Is CAM?

Ever since the use of medical treatments that fall outside of what is considered mainstream, or conventional, medicine became an internationally recognized phenomenon, various groups have attempted to develop labels and definitions for these therapies. However, as more is learned about what types of therapies are being used, who is using them, and how they are used, the trend has been to broaden these definitions to incorporate new knowledge. The result has been a blurring of the lines between what has

traditionally been considered conventional and what it considered to be non-conventional medicine.

Initially terms such as “unscientific” “unorthodox” or “unconventional,” were used to describe treatments for which there was not a scientific rationale for how they might work nor any studies of their safety and efficacy (Brody, 1980; Cassileth et al, 1984; Eisenberg et al, 1993). Because many in the medical community perceived that these therapies, such as acupuncture and homeopathy, were being used as alternatives to standard, allopathic health care, they became known collectively as "alternative medicine" in the late 1980s (Furnham and Smith, 1988; Murray and Shepherd, 1988).

However, in the early 1990's a variety of surveys began to demonstrate that people were increasingly using the two systems of medicine—conventional medicine and alternative medicine--side by side, essentially to complement one another (see *Who Uses CAM and What Are They Using?*, below). As a result, the term "complementary medicine" emerged first in Europe and adopted in this country not long afterwards to describe this “other” system of medicine (Ernst, 1995; Joyce, 1994). Yet, even this terminology was unsatisfactory for many because it did not take into account that fact that although many alternative therapies were being used to complement conventional medical care, some were being used *instead* of conventional medical care. Thus, since the mid-1990s, the phrase “complementary and alternative medicine” has been adopted in the U.S. and Europe to acknowledge this dichotomy.

In an attempt to develop a definition of CAM, a panel sponsored by the Office of Alternative Medicine of the National Institutes of Health (currently known as the National Center for Complementary and Alternative Medicine, or NCCAM), defined CAM as “a broad domain of medical or healing systems that are outside the range of those that are intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp and fixed” (Panel on Definition and Description, 1997).

The Complementary Medicine Field Group of the international Cochrane Collaboration (see Part I) has adopted this definition. However, Cochrane has further broadened the scope of CAM to include “all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture of a given historical period. Boundaries within CAM and between the CAM domain and the domain of the dominant system are not always sharp and fixed” (Zolman and Vickers, 1999).

These latter two definitions incorporate a larger worldview than earlier definitions by acknowledging that many health care practices that are considered “complementary” or “alternative” in the United States, such as herbal medicine, are often the main system of treatment in many developing countries (Bannerman et al., 1983; WHO, 1978) and in

many ethnic communities in this country (Berman et al, 1999). These definitions also acknowledge that the boundaries between CAM and biomedicine are constantly changing and are likely to evolve even further in the years to come as therapies that are now considered CAM become integrated into mainstream medicine, while new, untested therapies appear on the horizon to take their place.

The NCCAM at the NIH has offered an even more expansive definition of CAM as both “those healthcare and medical practices that are not currently an integral part of conventional medicine” and “those treatments and healthcare practices not taught widely in medical schools, not generally used in hospitals, and not usually reimbursed by medical insurance companies” (NCCAM, 2000). This definition potentially includes many approaches to healthcare, including behavioral medicine, preventive medicine, and culturally centered medicine, which are generally accepted as important to overall health care by the conventional medical community but which are not traditionally available in hospitals nor usually reimbursed by medical insurance companies (see *CAM's Focus on Health, Wellness, and Disease Prevention*, below).

Thus, the terminology used to describe unconventional approaches to health and illness has evolved significantly over the past 15 years. Indeed, it began with a rather narrow focus on therapies for which there is a lack of scientific understanding and/or proof of safety and efficacy to a much broader concept of CAM. Indeed, CAM now includes some therapies where there is both a general understanding of how they work in addition to significant evidence of proof safety and efficacy. However, many of these

therapies have become associated with CAM because, for various reasons, they have been marginalized or underutilized by conventional medicine as critical ingredients to the delivery of high-quality health care.

Rather than attempt to define CAM as what it is not, for the purposes of this report, the Commission has chosen to focus on what it is. Therefore, the Commission has developed a list of common modalities and systems of medicine that are illustrative of the types of CAM treatments and approaches that are encompassed by this report (See Table 1 below).

[Note: This section will be completed after receiving feedback from the Committee on CAM criteria, coordinated by Wayne Jonas].

Trends in CAM Usage

Table 1: Common CAM Therapies and Systems of Medicine		
Acupuncture	Chiropractic	Naturopathy
Acupressure	(Sacral) Cranial Osteopathy	Nutritional Therapy
Alexander Technique	Environmental Medicine	Osteopathy
Applied Kinesiology	Herbal Medicine	Reflexology
Anthroposophic Medicine	Homeopathy	Relaxation and Visualization
Aromatherapy	Hypnosis	Shiatsu
Autogenic Training	Imagery	Spiritual Healing
Ayurvedic Medicine	Magnets	Therapeutic Touch
Energy Medicine	Massage and Bodywork	Traditional Chinese Medicine
	Meditation	Yoga
Adapted from Zollman C, Vickers A. What is complementary medicine? BMJ 1999;319:693-696		

As mentioned in Part I, the use of (CAM) has risen dramatically over the past decade. Between 1990 and 1997, the number of consumers using CAM therapies rose

significantly, from 33.8% to 42.1%. (Eisenberg et al.,1998). Some (46.3%) saw a CAM practitioner, but the remaining 53.7% were unsupervised in their use of CAM. During that same time period, the number of people who sought advice from both physicians and practitioners of CAM rose from 8.3% to 13.7%. Surprisingly, only about 40% reported CAM use to their physician, even though 96% had seen their doctor within the past year.

Consequently, expenditures on CAM by Americans have risen dramatically as well, from almost \$14 billion in 1990 (Eisenberg et al, 1993) to an estimated \$21 billion to \$33 billion in 1997 (Eisenberg et al, 1998). The use of herbs was one of the fastest growing categories, with Americans spending an estimated \$663 million on medicinal botanicals alone in 1998, compared to \$94 million in 1990.

This same survey found that more than 58% of those who used CAM paid out-of-pocket for these treatments and services. As mentioned, total estimated expenses were \$21.2—32.7 billion, which is on par with the estimated \$29.3 billion out-of-pocket expenses for all United States physician visits (Eisenberg et al, 1998).

Who Uses CAM and What Are They Using?

What are the demographics of CAM usage in the U.S. In 1997, John Astin, Ph.D., then at the Stanford Center for Research in Disease Prevention, asked this question in a nationally representative survey of more than 1,000 randomly selected individuals. This study found people who used CAM therapies were more likely to be college educated

(50.6%), aged 35—49 (50.1%), of Caucasian descent (77%), have incomes greater than \$50,000 (48.1%), and live in the western United States (501%). The most common medical condition reported among the surveyed subjects was back problems at 24%. Neck problems were associated with the highest use of CAM (57% of patients). The Eisenberg et al surveys (1993, 1998) also have documented that people with chronic pain conditions, including arthritis and headache, and psychological problem (insomnia, depression, and anxiety) are some of the highest users of CAM therapies.

The CAM modalities that patients choose appear to match the medical conditions reported. Eisenberg et al (1998) found, for example, that relaxation techniques, which commonly are used for patients with chronic pain and/or mental conditions, were the most common alternative therapy. Other modalities, such as massage, chiropractic and acupuncture, also are used for chronic pain. People also are turning increasingly to dietary supplements as treatment modalities. Herbal therapies were the second most common therapy with 12.1% of those surveyed reporting use in 1997, up significantly from 2.5% in 1990 (Eisenberge et al, 1998).

The following gives a more detailed overview studies of the prevalence of CAM usage in specific patient populations, including: 1) arthritis, 2) back pain, 3) cancer, and 4) HIV:

Arthritis

A number of surveys of clinic-based populations taken over the past decade suggest that patients with arthritis and other rheumatologic conditions are frequent users of complementary/alternative medical (CAM) therapies (Boisset and Fitzcharles, 1994; Cronan et al, 1989; Pioro-Boisset et al., 1996; Vecchio, 1994). In fact, these surveys have found that as many as 8 out of 10 rheumatology patients that use clinical services also use CAM therapies to treat their condition. A recent survey by Rao et al. (1999) of patients at a rheumatology clinic revealed a 63% CAM utilization rate, with an average use of 2.5 CAM therapies per patient. This study also found that severity of symptoms predicted the degree of CAM usage. Patients diagnosed with rheumatoid arthritis were more likely to use CAM (38%) compared with those who had osteoarthritis (23%) and fibromyalgia (19%). Half of the patients who tried dietary supplements or vitamins reported some benefit. Only half told their physicians about their use of CAM therapies, however.

Chronic Pain

According to a number of surveys, chronic sufferers are some of the most frequent users of CAM. Indeed, in a national survey, Paramore (1997) found that back neck and shoulder pain were the most frequently cited reasons for visiting a CAM practitioner. In another national survey, Astin (1998) found that the CAM therapies of choice for chronic pain sufferers were exercise, chiropractic, massage, and relaxation techniques. Similarly, in both of their national surveys, Eisenberg and colleagues (1993, 1998) found that CAM therapies were used most frequently by individuals with chronic conditions, including back problems, anxiety, depression, and headaches. In a small survey of people with disabilities, Krauss and colleagues (2000) found that CAM therapies were chosen more often than

allopathic therapies by those with physical disabilities for pain (51.8% versus 33.9%), depression (33.9% versus 25%), anxiety (42.1% versus 13.1%), insomnia 32.3% vs 16.1%), and headaches (51.4% vs 18.9%).

Cancer

Cancer patients also are high users of CAM. A recent study by Burstein and colleagues (1999) found that almost 40% of 480 women with stage I or II breast cancer participated in some form of CAM prior to surgery, whereas only about 30% did after surgery. Use of healing and psychological therapies was highest before surgery but tapered off throughout the first year. After 12 months, approximately 50% of women reported new use of both psychological and healing modalities, whereas 45% reported continued use. The use of CAM treatments was not associated with cancer staging or method of treatment. Other studies have reported use of CAM therapies among cancer patients greater than 80% (Bennett and Lengacher, 1999; Richardson et al, 2000). A study of cancer patients enrolled in clinical trials at the National Institutes of Health found that 63% used at least one CAM therapy, with an average use of two therapies per patient (Sparber et al, 2000). Men were significantly less likely to use CAM than women, who were more likely to use numerous therapies. The cancer patients' primary reasons for CAM use included treatment-related medical conditions, such as depression, anxiety, and insomnia. The most frequently reported therapies were spiritual, relaxation, imagery, exercise, lifestyle diet (e.g., macrobiotic, vegetarian), and nutritional supplementation. Patients unanimously believed that these CAM treatments helped to improve their quality of life through more effective coping with stress, decreasing the discomforts of treatment and illness, and giving them a

sense of control. Lippert and colleagues (1999) found a similar pattern of CAM usage among men with prostate cancer. This study found that 42% of those surveyed used vitamins, prayer or religious practices, and herbs to treat their condition. The probability of CAM use was independent of treatment modality, but only 17% to 30% reported the use of CAM to their physicians.

Human Immunodeficiency Virus (HIV)

Studies similarly have found that HIV patients are frequent users of CAM. For example, Fairfield and colleagues (1998) surveyed 180 HIV-infected individuals and found more than two-thirds (67.8%) used herbs, vitamins, or dietary supplements. Eighty-one percent of those who used supplements said these remedies were "extremely" or "quite a bit" helpful. Almost half (45.0%) of this group had visited a CAM provider. In fact, they visited a CAM practitioner an average of 12 times per year, compared to only 7 visits per year to their conventional physician or nurse practitioner. The CAM practitioners they visited most often were massage therapists, acupuncturists or acupressurists. Two-thirds (66%) of those who saw a CAM provider said the provider was extremely or quite helpful. Approximately 24% reported using marijuana to treat weight loss, nausea, and vomiting in the previous year and most (87%) said marijuana said it was extremely or quite helpful. Ominously, 16% of these patients surveyed said they had stopped traditional drug therapy.

Ostrow and colleagues (1997) surveyed 657 HIV-positive individuals in a Canadian clinic population and found that approximately 40% had used some form of CAM, with

most using dietary supplements (30%), followed by herbal and other medicinal therapies (22%), tactile therapies (e.g., massage) (22%) had used tactile, and mental relaxation techniques (20%). CAM use was independently associated with younger median age, higher income, and greater physical pain. Interestingly, a slightly earlier study by Singh et al (1996) of CAM use among a population of HIV-positive individuals receiving treatment at a Veterans Affairs medical center Pittsburgh, PA, found that older patients were more likely to use CAM than younger patients, suggesting potential geographic differences in CAM acceptability.

Ethnic Differences in CAM Usage

In addition to the type of illness one has, individual cultural upbringing and ethnicity can influence the type of CAM used. For example, in a study of CAM usage among Mexican-Americans living in the Texas Rio Grand Valley, Keegan (1996) found that 44% of respondents had used a CAM practitioner one or more times during the previous year. In contrast to the national sample surveys, however, the most commonly sought therapies, respectively, for this population were: herbal medicine, spiritual healing and prayer, massage, relaxation techniques, and visits to a curandero (Mexican folk healer). Additionally, in a sample of 104 non-Mexican-American Hispanics adults with diabetes, Zaldivar and Smolowitz (1994) found that 17% of patients reported using herbs to treat their diabetes.

Similar to Hispanics, the Native American populations appear to display a different pattern of CAM usage than the general population. Kim and Kwok (1998) found, for example, in a cross-sectional interview of 300 Navajo patients at an Indian Health Service (IHS) hospital that 62% had gone to native healers and 39% visited them regularly. The factor associated with the least amount of visits was Pentecostal faith. The Navajo were more likely to rely on IHS medical therapy, either alone or with native healers, for physical conditions such as diabetes mellitus, arthritis, abdominal pain, depression, and anxiety. They sought native healers exclusively for traditional issues (family problems, blessings, “bad luck” or “sickness”). Ironically cost was the biggest barrier to seeking a native healer. Native healer costs are approximately 21% of the average Navajo income, whereas care at an IHS clinic or hospital is free.

In a similar study of 150 Native American patients utilizing an urban Indian Health Service clinic in Milwaukee, Wisconsin, Marbella and colleagues found that almost 40% of the patients saw a healer regularly, and of those who do not, most (86.0%) said they would consider seeing one in the future. The most frequently visited healers were herbalists, spiritual healers, and medicine men. Sweat lodge ceremonies, spiritual healing, and herbal remedies were the most common treatments. Not surprisingly, more than a third of the patients seeing healers received different advice from their physicians and healers. Among the patients seeing a healer, the rating of the healer's advice was higher than the physician's advice 61.4% of the time. Only 14.8% of the patients seeing healers tell their physician about their use.

These data suggest that members of minority populations may use CAM therapies differently than the general population. In Mexican-American and Native American populations, in particular, people may rely on those therapies that are more familiar to them or more aligned with their cultural identities. Indeed, these studies suggest that CAM treatments in ethnic populations may be rendered most frequently by traditional healers from the individual's native culture. These studies also raise some serious issues as to the rift between ethnic cultural values and access to native healers. In areas where native healers are available, Mexican-Americans and Native Americans frequent them. Income, not belief systems, prohibits interaction, however (Marbella et al., 1998). Some IHS facilities have addressed this gap by incorporating sweat lodges, or similar spaces, into their facilities and employing native healers (refs?).

Why Do Patients Seek CAM and How is It Used?

It is not surprising that people with chronic painful conditions and psychological disorders, such as anxiety and depression, are frequent users of CAM, because such disorders are complex in origin and, thus, are not easily treated by conventional medicine. Patients experiencing chronic pain often obtain only limited relief from drugs or other medical treatment. Similarly, medicine offers numerous modalities for treating depression and anxiety, but patients may be reluctant to seek medical help, may lack insight into their condition, or may prefer to self-treat. For example, in a survey of 100 patients with panic disorder or agoraphobia, rather than seek conventional medical care, 32% preferred to self-medicate using herbs (Bandelow et al, 1995).

In the Rao et al (1999) survey of rheumatology clinic patients mentioned above, the most common reasons for CAM usage were to alleviate pain and ease their rheumatic condition. Interestingly, 50% of respondents reported turning to CAM because they perceived their drugs as ineffective. Additionally, when Elder and colleagues (1997) interviewed 113 patients at a family practice, the top reason to seek CAM therapies was that they believed they would work. Those who chose to reveal use stated that their physicians accepted their use and respected the patient's desire to have more control over their health.

Although it is not surprising that individuals with chronic, debilitating conditions that are not easily treated by conventional medicine are frequent CAM users, what is surprising is how CAM is being used in relation to conventional medicine. Indeed, until recently, the prevailing view was that people who use CAM therapies were forgoing effective conventional treatments and thus worsening their illnesses (Dwyer, 1993) primarily because they had turned their backs on science (Skrabenak, 1984; 1988)

However, recent surveys designed to test these hypotheses have found an entirely different picture. In the Astin (1998) survey, only 4.4% of subjects relied primarily on CAM. On the other hand, Astin did find an association between CAM usage and cultural beliefs—specifically, a commitment to environmentalism and feminism, and an interest in spirituality and personal growth psychology. Additionally, the Astin study and others (Fliaison, Huchner, & Marchand, 1999; Wagner et al., 1999) have found that a holistic health philosophy, a strong internal locus of control, and transformational life experiences

also are associated with CAM usage. Furthermore, similar to the Eisenberg and colleagues' (1998) study, CAM users tended to have a high prevalence of back problems, chronic pain, or anxiety.

Patient Communication with their About CAM Physicians

Why don't many patients tell their health care providers that they are using CAM? In the South Carolina survey (Oldendick et al, 2000), physicians were unaware of CAM use in 57% of their patients using CAM. Patients were least likely to report hypnosis or biofeedback (12.1%), or healing therapies (21.3%). Only 25.8% reported their use of herbal medicine and similar preparations to their physicians, increasing their risk for adverse reactions.

In a survey of health food store customers, Eliason and colleagues (1999) found that these individuals were motivated to pursue wellness and wanted to take responsibility for their health. Although they welcomed a partnership with their physician, they generally believed that their physicians were closed-minded and had little knowledge about dietary supplements. These consumers, therefore, had decided to assess the effectiveness of dietary supplements through personal study and subjective experimentation.

There have been similar findings in patients with cancer. For example, in a survey of women with breast cancer, Adler and Fosket (1999) found that the majority of women

(55—85%) use CAM therapies but did not divulge this use to their physicians due to assumed disinterest. Other reasons that the women gave for not divulging CAM use to their physicians included anticipated negative physician response, perceived physician unwillingness and inability to help, irrelevance, the disparate healing strategies between CAM and conventional medicine, and the anticipation that discussion would be too one-sided (i.e., the physician would do all the talking).

These findings are particularly troubling in light of the fact that more and more physicians appear to be open-minded about CAM. For example, in the Consumer Reports survey of more than 46,000 patients using CAM, 60% eventually reported CAM use to their physicians (Consumer Reports, 2000). According to these patients, 55% of physicians expressed approval, with 40% expressing neutrality, and 5% expressing disapproval.

Additionally, in their survey of South Carolina adults, Oldendick and colleagues (2000) found that physicians were most likely to recommend biofeedback or hypnosis (39.3%), self help groups (33.4%), or lifestyle and dietary changes (33.2%). However, only 15.2% of physicians recommended herbal medicine remedies.

In an extensive review of 25 surveys of beliefs of conventional physicians with regard to 5 of the more prominent CAM therapies, Astin and colleagues (1998) found that about half of physicians believed in the efficacy of acupuncture, (51%), chiropractic (53%), and/or massage (48%). However, only 13% believed in using herbal therapies. Approximately

40% had referred patients to either an acupuncturist or chiropractic practitioner, whereas 20% referred patients for massage therapy.

Patient Satisfaction With CAM

How does patient satisfaction with CAM therapies compare to conventional therapies? In their survey of 1584 South Carolinian adults, Oldendick and colleagues (2000) found that approximately 68% perceived their therapy to be effective or very effective, depending on the specific modality. Those working with spiritual healers were most likely to report satisfaction (79%), whereas those participating in weight loss programs reported the least satisfaction (44.9%). People involved in herbal medicines, folklore remedies, vitamins, and homeopathy reported a 62% satisfaction rate.

In the Consumer Reports' (2000) survey mentioned above, 23% of those trying herbs and dietary supplements reported feeling much better. This rate was comparable with levels of satisfaction found with both mind-body techniques and over-the-counter drugs, but was inferior to satisfaction with prescription drugs (50%). Satisfaction levels varied widely depending on medical condition and therapy. Patients with some of the difficult-to-manage medical conditions, including back pain, neck pain, and fibromyalgia, reported CAM therapies to be comparable with standard medical care.

World View of Major CAM Traditions

CAM therapies may differ from conventional medicine not only in their methods but also in some of their underlying philosophies. The way that many CAM disciplines define health, illness, and the healing process can depart significantly from the beliefs that underlie the practice of allopathic medicine. It is essential to consider the different paradigms from which conventional medicine and CAM approach healthcare as these have implications for research and integration (see below).

Most of the world's traditional healing systems—Traditional Chinese Medicine (TCM), Indian Ayurvedic Medicine, Persian Urami, and Native American Medicine—are based on the assumption that we humans are connected to one another, to the earth, and the spiritual world in many more ways than science has yet uncovered. Disease, in these systems of medicine, is an imbalance within our bodies as well as between the way we live and the natural, social, and spiritual world (Gordon, 1996).

Even CAM modalities that are not directly evolved from these traditional systems of medicine, such as chiropractors and homeopaths, have adopted such beliefs as well as the notion that the body had the innate ability to heal itself. According to this philosophy, which is referred to as *vis medicatrix naturae* (the healing power of nature), the body's self-healing mechanism can be speeded up, sometimes to an astonishing degree, by the proper stimuli. Thus, many CAM practitioners employ therapies designed to stimulate the patient's constitution to fight on its own behalf, on the assumption that this emphasis on

enhancing the natural healing process is the most appropriate foundation of any medical therapy (House of Lords, 2000).

CAM's Focus on Wellness and Disease Prevention

Many CAM therapies emphasize "wellness" as not only being the absence of disease but also with attributes such as good energy (vitalism), happiness, and a sense of wellbeing as being more central goals of intervention (House of Lords, 2000). Moreover the emphasis of much of CAM is often on strengthening the whole organism rather than directly attacking the pathology (such as an infection or tumor). CAM therapies use different vocabularies to understand these emphases, with treatment concepts such as detoxification and tonification, and with different cultural concepts of "energy" as recuperative forces in the body (notably in forms of medicine originating in Asia) (House of Lords, 2000).

Most CAM therapies also apply a non-Cartesian view of health, making less distinction between the body, mind, and spirit as distinct sources of disease. The language used in CAM often tends to imply that all these dimensions of the human condition should be viewed in the same therapeutic frame. This is different from the conventional medical approach, which often involves prescribing a standard drug and a similar treatment regime for patients with the same underlying pathology.

Another unifying thread that runs through many CAM approaches is a focus not only on restoring balance to those who are sick but also in addressing the underlying causes of the imbalances that have made them sick in the first place. CAM therapies also take a highly individualistic approach to treatment, in which patients may receive a combination of treatments specifically tailored to their needs. Therefore, many CAM practitioners often prescribe a package of care, which could include modification of lifestyle, dietary change, and exercise (House of Lords, 2000). For example, a chiropractor, in addition to providing a spinal adjustment, may also offer advice on diet and exercise, provide guidance on breathing and relaxation, and prescribe nutritional supplements.

As noted earlier in this chapter, an emphasis on disease prevention and wellness is not the sole domain of CAM. In fact, conventional medicine has a long tradition of being concerned with maintaining health and preventing disease. Unfortunately, however, medical schools, for the most part, have not placed a great deal of emphasis on preventive medicine and education on wellness. In fact, a recent survey by Garr and colleagues (2000) of 144 allopathic and osteopathic medical schools found a greater emphasis on teaching and evaluating medical students' knowledge in the areas of clinical preventive services and quantitative methods, and less emphasis on the community dimensions of medical practice and health services organization and delivery. More revealing, however, was the finding that fewer than half of all respondents were satisfied with the quality of their assessment of student achievement in any of the four domains of prevention

education. More than 30% of the medical schools expressed a desire to receive assistance with designing curricula and/ or evaluation methods in prevention education.

In addition, given the prevalence of nutritionally related chronic diseases in American society, it would seem imperative that the training of physicians should include a focus on the relationship of diet to disease. Yet, despite scientific data, public interest, US government reports, society studies, and congressional mandates, according to a recent report by the National Education Consortium (1997), the teaching of nutrition in medical schools and residency programs remains “woefully inadequate.” Indeed, most medical schools do not have faculty trained specifically in nutrition (Cooksey et al, 2000), and faculty resistance to changing medical school curricula is a major barrier to overcome in the effort to expand such education (Armstrong & Koffman, 1998).

Therefore, a core emphasis on wellness and disease prevention appears to be a significant difference between a number of CAM systems of medicine and allopathic medicine, at least in terms of medical education.

Obstacles Integration of CAM Approaches and Treatments into Allopathic Medicine

As the popularity and the evidence base for CAM has grown, so has interest and belief in CAM among allopathic physicians and medical institutions. Astin et al (1998),

for example, conducted a comprehensive review of 25 surveys of physician practices and beliefs with regard to five of the more prominent CAM therapies—acupuncture, chiropractic, homeopathy, herbal medicine, and massage--and found that about half of the surveyed physicians in these studies believed in the efficacy of these CAM therapies. Surprisingly, a significant proportion were both making referrals to CAM practitioners as well as offering some of the CAM treatments in their own practice.

This increasing acceptance of CAM among allopathic physicians has fueled a movement to “integrate” those CAM modalities with the best evidence of effectiveness with the best of allopathic medicine. This integrative medicine movement seeks to sort through all of the evidence about all healing systems and try to extract and integrate those ideas and practices that are useful, safe, and cost effective. The ultimate goal is to merge them into a new, more comprehensive, compassionate, and effective model of care that includes both the precision and power of biomedicine and the wisdom of other healing traditions (Gordon, 1996). According to some (Weil 2000), such an integrated system of medicine would have a strong evidence base but also would sensitive to consumer demand.

However, there is significant debate in the allopathic medicine community on how this new model of care would be implemented. One of the models of integration, which is being tested at a small but growing number of allopathic medical institutions, is to have allopathic and CAM practitioners working side-by-side, collaborating both in the diagnosis and treatment of patient conditions (Muscat, 2000). While promising, this

model of integration faces significant obstacles. Indeed, as mentioned, allopathic medicine and CAM practitioners often have entirely different worldviews regarding health and disease and, thus, employ a completely different vocabulary and grammar. Most allopathic practitioners have little understanding of CAM diagnostic terms, such as Qi (the Chinese term for vital energy) or doshas (the Ayurvedic term for mind-body type). Sometimes familiar terms are used but with a different meaning: acupuncturists may talk of "taking the pulse," but they will be assessing characteristics such as "wiriness" or "slipperiness," which have no Western equivalent. It is important not to interpret terms used in CAM too literally and to understand that they are sometimes used metaphorically or as a shorthand for signs, symptoms, and syndromes that are not recognized in conventional medicine.

By the same token, few CAM practitioners have a thorough understanding the theories and terms associated with allopathic medicine. Indeed, few CAM disciplines have significant exposure to fields such as pathophysiology, epidemiology, molecular biology, and other sciences that allopathic physicians receive training in during the medical school apprenticeships. In such a climate, basic communication, much less collaboration, is almost impossible (Caspi et al, 2000).

Furthermore, conflicts in integration are likely to arise because CAM and allopathic practitioners often have very different methods of assessing and diagnosing patients. Thus, TCM practitioner may describe a patient's condition as deficiency in "liver Qi." A homeopath may describe the same condition as a "pulsatilla constitution."

Whereas, the allopathic physician may describe the patients illness as "a peptic ulcer." Confusingly, there is little correlation between the different diagnostic systems: some patients with deficient liver Qi do not have ulcers, and some ulcer patients do not have deficient liver Qi but another traditional Chinese diagnosis. This could potentially cause significant problems if a CAM practitioner and allopathic doctor, working side by side, were both trying to diagnose and treatment the same patient (House of Lords, 2000).

CAM practitioners also are not generally concerned with understanding the basic scientific mechanism of their particular therapy. Instead, their knowledge base is often derived from a tradition of clinical observation. Sometimes traditional teachings are handed down in a way that discourages questioning and evolution of practice, or encourages reliance on their own and others' individual anecdotal clinical and intuitive experience.

Therefore, even for those CAM therapies proven to be safe and effective, it should be stressed, however, that the lack of a shared worldview is not necessarily an insurmountable barrier to effective integration. For example, doctors have work closely alongside hospital chaplains and social workers for decades, each regarding the others as valued members of the healthcare team.

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Long-Term Trends in the Use of Complementary and Alternative Medical Therapies in the United States

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Background: Although recent research has shown that many people in the United States use complementary and alternative medical (CAM) therapies, little is known about time trends in use.

Objective: To present data on time trends in CAM therapy use in the United States over the past half-century.

Design: Nationally representative telephone survey of 2055 respondents that obtained information on current use, lifetime use, and age at first use for 20 CAM therapies.

Setting: The 48 contiguous U.S. states.

Participants: Household residents 18 years of age and older.

Measurement: Retrospective self-reports of age at first use for each of 20 CAM therapies.

Results: Previously reported analyses of these data showed that more than one third of the U.S. population was currently using CAM therapy in the year of the interview (1997). Subsequent

analyses of lifetime use and age at onset showed that 67.6% of respondents had used at least one CAM therapy in their lifetime. Lifetime use steadily increased with age across three age cohorts: Approximately 3 of every 10 respondents in the pre-baby boom cohort, 5 of 10 in the baby boom cohort, and 7 of 10 in the post-baby boom cohort reported using some type of CAM therapy by age 33 years. Of respondents who ever used a CAM therapy, nearly half continued to use many years later. A wide range of individual CAM therapies increased in use over time, and the growth was similar across all major sociodemographic sectors of the study sample.

Conclusions: Use of CAM therapies by a large proportion of the study sample is the result of a secular trend that began at least a half century ago. This trend suggests a continuing demand for CAM therapies that will affect health care delivery for the foreseeable future.

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Community surveys done over the past decade have documented that a substantial proportion of Americans use complementary and alternative medical (CAM) therapies (1-4), which have been defined as "interventions neither taught widely in medical schools nor generally available in U.S. hospitals" (1). Many managed care organizations have responded to this evidence by providing insurance coverage for some CAM therapies (5). Furthermore, most U.S. medical schools have begun offering courses on CAM therapies (6).

These responses imply that CAM therapies are perceived to be a force to be reckoned with for some time to come. Yet, little is known about the likelihood that this will be the case. The prevailing assumption is that CAM therapies were used by a fairly narrow segment of the population until the 1970s, at which time the ideology associated with the youth counterculture led to a rapid dissemination and use of CAM therapies that has persisted through the present (7). However, lack of rigorous trend data from epidemiologic surveys have precluded evaluating this assumption rigorously or project-

ing the future growth of CAM therapies on the basis of evidence of past trends.

In the current report, we present nationally representative trend data of this sort from a prevalence study. The data came from retrospective self-reports of a nationally representative sample of the U.S. general population in a 1997-1998 telephone survey (4) about age at first use of 20 representative CAM therapies. In our analysis, we studied trends by examining between-cohort differences in rates of initiation of CAM therapy use (8). In the absence of prospective data, which do not exist, our results represent, to our knowledge, the most accurate information currently available on U.S. trends in CAM therapy use over the past half-century.

METHODS

Sample

The telephone survey was conducted between November 1997 and February 1998 in a nationally representative household sample. Random-digit dialing was

used to select households, and a random-selection method was used to select one respondent 18 years of age or older for interview in each sample household. Eligibility was limited to English speakers without cognitive or physical impairment that would prevent interview completion. The average administration time was 30 minutes. A \$20 financial incentive for participation was offered. The Beth Israel Deaconess Committee on Clinical Investigations, Boston, Massachusetts, approved the survey methods.

Of the initial sample of 9750 telephone numbers, 26% did not work, 17% were not assigned to households, and 9% were unavailable despite six attempted follow-up contacts. Of the remaining households, 481 were ineligible because of language barrier or cognitive or physical incapacity. Of the 4167 total eligible respondents, 1720 (41.3%) completed the interview on initial request. Of a random subsample of 1066 persons who initially declined and were offered an increased stipend (\$50), 335 agreed to participate. In all, 2055 interviews were completed. After we extrapolated the conversion rate to all persons who had initially declined and weighted the data for the undersampling of those who participated after initially declining, the weighted overall response rate among eligible respondents was 60%.

The data were weighted for three factors: 1) probability of selection within household as well as geographic variation in cooperation (by region of the country and urbanicity [local population density]), 2) nonresponse, and 3) post-stratification for aggregate discrepancies between the sample distributions and Census population distributions on a variety of sociodemographic variables (9, 10). More details on the sample design have been presented elsewhere (4). Age data were missing for 6 respondents; our analyses are limited to the remaining 2049 respondents.

Measures

The interview was described to respondents as a survey by investigators from Harvard Medical School about the health care practices of Americans. Interviewers made no mention of CAM therapies. The first substantive questions concerned perceived health, functional impairment due to health problems, interactions with physicians, and history of chronic medical conditions. Interviewers then queried respondents about their lifetime and recent use of 20 CAM therapies—acupunc-

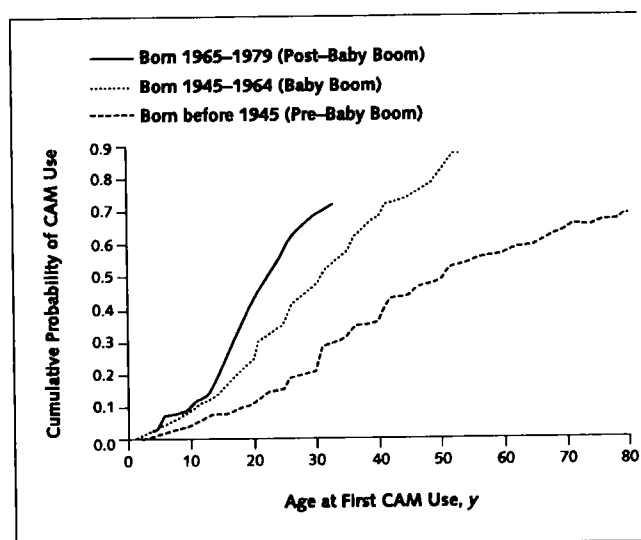
ture, aromatherapy, biofeedback, chiropractic care, commercial diet programs, energy healing (for example, laying on of hands), folk remedy, herbal medicine, homeopathy, hypnosis, imagery, lifestyle diet (such as vegetarianism or macrobiotics), massage, megavitamin therapy, naturopathy, osteopathy, relaxation techniques, self-help group, spiritual healing by others, and yoga. Users of each therapy were asked their age at first use as well as details about the conditions for which the therapy was initiated. The final set of questions dealt with sociodemographic issues.

Cohorts were aggregated into three subsamples: pre-baby boom (respondents ≥ 54 years of age at interview, born before 1945); baby boom (34 to 53 years of age at interview, born 1945–1964); and post-baby boom (18 to 33 years of age at interview, born 1965–1979). For sociodemographic variables, we used two categories for sex (male or female), four for race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, or other), four for education (less than high school, high school graduate, some college, or college graduate), four for U.S. region (northeast, midwest, south, or west), and four for urbanicity (residence in a large city, small city, suburb, town/rural).

Statistical Analysis

All analyses were performed with weighted data by using SAS statistical software (11). To assess differences in trends among cohorts, the Kaplan–Meier (12) method was used to generate a graphic representation of the cumulative lifetime prevalences of CAM therapy use according to cohort. The significance of historical changes in lifetime use was estimated by using discrete-time survival analysis (13), a method of survival analysis appropriate for data in which events are recorded only at discrete time points (for example, in yearly increments). Discrete-time survival analysis was operationalized as a logistic regression with person-year as the unit of analysis and first use of CAM therapy as the outcome variable. The predictors of primary interest were a series of dummy variables for decades of historical time, and covariates included sociodemographic and dummy variables adjusted for the baseline hazard rate of each year of a person's life. This model results in an intercept for each time period, and the odds ratios (ORs) can be interpreted as the relative risk for the annual risk for use

Figure. Weighted Kaplan–Meier estimates of age of first use of any complementary and alternative medical (CAM) therapy among lifetime users according to cohort.



Intercohort differences are significant at the 0.001 level.

of alternative therapy. Subsample models were estimated to study sociodemographic variation in trends. Disaggregated models were estimated to study trends in the use of particular CAM therapies.

To adjust for the design effects introduced by weighting of the data, the method of jackknife repeated replications (14) was used to estimate standard errors (SEs). For this method, we used user-written macros in SAS statistical software. For this process, 50 random primary sampling units were created with two random half-samples in each unit for a total of 100 random replicates. Jackknife repeated replication is a method that uses simulations of coefficient distributions in subsamples to generate empirical estimates of SEs and significance tests. The ratios of the coefficients to these adjusted SEs are used to compute the 95% CIs of the ORs. Tests for the significance of sets of predictors taken together were computed by using the Wald chi-square test from coefficient variance–covariance matrices based on the jackknife repeated replications simulations.

Table 1. Trends in Relative Risk for First Use of 20 Specific Complementary and Alternative Medical Therapies, according to Decade*

Therapy	1930s–1950s		1960s		1970s	
	% person-year†	RR	% person-year†	RR (95% CI)	% person-year†	RR (95% CI)
Acupuncture	0.0‡	1.0	0.1	4.3 (0.7–27.3)	0.2	7.3 (1.6–33.7)§
Aromatherapy	0.0	–	0.0	1.0 (referent)	0.2	3.5 (0.9–14.1)
Biofeedback	0.0‡	1.0	0.0‡	2.0 (0.2–21.2)	0.3	18.7 (4.4–79.3)§
Chiropractic care	0.8	1.0	0.1	1.3 (0.9–2.1)	1.5	1.7 (1.2–2.5)§
Commercial diet programs	0.1	1.0	0.4	7.0 (2.6–18.3)§	0.5	8.9 (3.4–23.3)§
Energy healing	0.0‡	1.0	0.0‡	1.9 (0.3–14.4)	0.3	9.8 (2.8–34.7)§
Folk remedy	0.1	1.0	0.1	0.5 (0.1–2.1)	0.2	2.2 (0.8–6.1)
Herbal medicine	0.1	1.0	0.1	1.6 (0.2–14.5)	0.5	8.3 (1.1–64.5)§
Homeopathy	0.0	1.0	0.0‡	1.0 (referent)	0.2	4.3 (1.0–17.8)§
Hypnosis	0.1	1.0	0.2	0.9 (0.3–2.8)	0.4	2.7 (1.3–5.6)§
Imagery	0.0‡	1.0	0.0‡	3.4 (0.6–18.3)	0.3	22.5 (5.4–93.8)§
Lifestyle diet	0.0‡	1.0	0.2	5.0 (1.3–18.4)§	0.3	10.7 (3.0–38.1)§
Massage	0.2	1.0	0.4	2.4 (1.1–5.2)§	0.4	2.7 (1.1–6.4)§
Megavitamins	0.0‡	1.0	0.2	7.8 (3.5–17.3)§	0.3	9.5 (3.6–25.6)§
Naturopathy	0.0	–	0.0	1.0 (referent)	0.0‡	1.5 (0.1–17.7)
Osteopathy	0.1	1.0	0.1	1.3 (0.4–3.8)	0.1	1.7 (0.5–5.7)
Relaxation techniques	0.2	1.0	0.3	2.3 (1.1–4.7)§	1.2	5.8 (2.9–11.3)§
Self-help group	0.2	1.0	0.1	7.1 (3.0–16.8)§	0.4	21.6 (14.9–31.3)§
Spiritual healing by others	0.1	1.0	0.1	1.7 (0.4–6.8)	0.5	5.6 (1.7–19.3)§
Yoga	0.1	1.0	0.2	2.6 (0.5–12.9)	0.4	5.7 (1.4–23.6)§
Any Therapy	1.4	1.0	2.1	1.7 (1.2–2.5)§	3.9	2.7 (2.0–3.7)§

* Relative risk was approximated by exponentiating logistic regression coefficients. RR = risk ratio.

† Indicates percentage of person-years between the ages of 20 and 40 in which a therapy was first used.

‡ Actual value is a nonzero value < 0.1%.

§ Significant at the 0.05 level by using a two-sided test.

RESULTS

Differences in Aggregate Use Trends among Cohorts

At the time of interview, 67.6% of all respondents had used at least one CAM therapy at some time in their lives. The **Figure** presents Kaplan–Meier age-of-onset curves showing trends in each cohort in the cumulative probabilities of use according to age. Of note are the dramatic differences in use among cohorts. This is seen most clearly by focusing on cumulative probabilities of use for age 33 years, the oldest age represented in all three cohorts. Approximately 3 of every 10 respondents in the pre–baby boom cohort used some type of CAM therapy by the age of 33 years compared with 5 of 10 in the baby boom cohort and 7 of 10 in the post–baby boom cohort.

Historical Trends in Aggregate Use

The aggregate data in the **Figure** are presented in a different format in the bottom row of **Table 1**, where the risk ratios are shown from a discrete-time survival

model that estimated the effects of historical time in predicting age at first use of CAM therapy among respondents after adjustment for person-year and socio-demographic variables. The contrast category is first use before 1960. Consistent with the pattern in the **Figure**, the results of the model for the outcome of any therapy show monotonically increasing risk ratios in each decade from the 1960s through the 1990s.

Possible demographic subsample differences in time trends were examined by estimating separate subsample models that were identical to the discrete-time survival model for any therapy and by evaluating the statistical significance of differences in trends across subsamples. No statistically significant (0.05 level in two-sided tests) differences in trends were found for sex, race/ethnicity, education level, region of the country, or urbanicity.

Trends in the Use of Specific Therapies

Table 1 also shows the risk ratios to estimate first use of each of the 20 CAM therapies assessed. All trends are statistically significant except for those for folk remedy, naturopathy, and osteopathy; thus, in the United States over the past half-century, use of most kinds of CAM therapy has grown.

The data in **Table 1** can be transformed to yield information on changes over historical periods of time rather than across cohorts. Data resulting from this transformation (results not shown) yield interesting insights into variations in the timing of societal adoption of the different therapies. Use of all but 4 of the therapies increased in the 1960s compared with pre-1960, and the increase was with a risk ratio of 2.0 or greater for 11 of these therapies. In the 1960s, growth in the use of 4 therapies increased markedly—commercial diet programs, lifestyle diet therapy, megavitamin therapy, and self-help groups. Increased use of all 4 of these therapies is consistent with the largely increased national interest that was seen at that time in fitness and health as a result of a fitness campaign initiated by President Kennedy in the early 1960s (15).

Our analysis also shows markedly increased growth in the use of alternative therapies in the 1970s as well; use of all the therapies increased in this decade compared with use in the 1960s, and this increase was substantial for 4 of the therapies (biofeedback, energy healing, herbal medicine, and imagery). In addition, 8 of the

Table 1—Continued

1980s		1990s		P Value
% person-year†	RR (95% CI)	% person-year†	RR (95% CI)	
0.2	11.6 (2.7–49.2)§	0.3	14.3 (3.4–58.9)§	<0.001
0.1	4.9 (1.3–18.2)§	0.9	32.4 (9.8–107.5)§	<0.001
0.2	12.7 (2.9–56.2)§	0.1	9.2 (2.2–38.0)§	<0.001
2.0	2.6 (1.8–3.7)§	2.9	3.5 (2.4–5.2)§	<0.001
0.6	9.5 (3.5–26.0)§	0.6	14.0 (5.4–36.3)§	<0.001
0.2	8.4 (2.1–33.0)§	0.5	28.7 (8.6–95.7)§	<0.001
0.1	1.5 (0.6–3.7)	0.1	1.4 (0.5–4.0)	>0.2
0.6	10.2 (1.4–75.9)§	1.3	27.9 (3.7–210.4)§	<0.001
0.3	8.3 (2.1–31.9)§	0.2	10.7 (2.9–39.7)§	0.001
0.5	3.5 (1.6–7.7)§	0.2	2.3 (1.2–4.3)§	0.001
0.5	40.2 (10.1–160.1)§	0.3	31.5 (8.5–117.0)§	<0.001
0.3	10.6 (3.0–37.3)§	0.3	14.9 (3.7–59.9)§	0.002
0.9	5.7 (2.6–12.7)§	1.9	13.0 (6.1–27.8)§	<0.001
0.3	15.6 (5.3–46.0)§	0.5	23.7 (9.2–60.9)§	<0.001
0.1	3.8 (1.7–8.8)§	0.1	4.2 (1.9–9.3)§	>0.2
0.1	0.9 (0.3–2.3)	0.1	0.6 (0.2–1.8)	>0.2
1.0	6.5 (3.2–13.1)§	1.4	7.8 (3.8–16.0)§	<0.001
0.8	39.3 (29.0–53.3)§	0.5	30.8 (22.3–42.5)§	0.002
0.4	4.5 (1.4–13.9)§	0.4	6.7 (2.2–20.1)§	<0.001
0.2	2.8 (0.7–11.7)§	0.4	5.5 (1.4–21.1)§	0.003
4.3	3.3 (2.4–4.5)§	6.1	5.4 (3.9–7.6)§	<0.001

Table 2. Persistence of Use among Lifetime Users, according to Time since Onset of Initial Use

Years Since First Onset of Use	Current Use of All Complementary and Alternative Medical Therapy in Lifetime Users $\pm$ SE,* %†
1–4 y	60.2 $\pm$ 1.7
5–10 y	47.0 $\pm$ 1.6
11–20 y	48.8 $\pm$ 1.5
$\geq$ 21 y	45.7 $\pm$ 1.5

* Standard error of the percentage estimate.

† Percentage of lifetime users who continue to use currently.

20 assessed therapies had their largest rate of growth during the transition from the 1960s to the 1970s (biofeedback, energy healing, folk remedy, herbal medicine, homeopathy, hypnosis, imagery, and spiritual healing by others).

The 1980s saw more modest growth in the use of CAM therapies. Use of 14 of the therapies increased compared with the 1970s, but only 2 (massage and naturopathy) had risk ratios that were markedly greater than in the 1970s. Only yoga became significantly less popular over this time period. Overall, a modest level of growth continued in the 1990s, with 16 therapies having increased use compared with the 1980s, but only 5 of these had markedly greater risk ratios than in the 1980s (aromatherapy, energy healing, herbal medicine, massage, and yoga). Aromatherapy had the most dramatic growth during this period. Although the risk ratios for use of some of the therapies during the 1990s were lower than in the 1980s, none of these declines was statistically significant.

Next, we examined the hypothesis that observed differences in trends among cohorts were primarily due to increased use of selected CAM therapies considered mainstream (as opposed to alternative). To test this hypothesis, we repeated our cohort analyses by fitting the Kaplan-Meier age-of-onset curves to two additional definitions of alternative therapy that excluded possibly mainstream therapies. The intermediate definition excluded biofeedback, commercial diet programs, hypnosis, lifestyle diet, massage, osteopathy, and relaxation techniques from the definitions used in this report; the narrow definition also excluded imagery and megavitamin therapy. The differences in trends between cohorts remained significant ($P < 0.001$) for all definitions.

Persistence of Use

Table 2 presents data on the percentage of therapies used in the past 12 months by lifetime users, who were classified according to the number of years since first use. The unit of analysis for this table is person-therapies. Of the 2049 survey respondents, 1386 reported lifetime use of at least 1 CAM therapy, with an average of 3.03 therapies used by users, for a total of 4199 person-therapies. Continued use of a specific therapy in the 12 months before the interview was 47% among therapies begun 5 to 10 years before the interview, 48.8% for therapies begun 11 to 20 years previously, and 45.7% for therapies begun more than 20 years earlier. The lack of significant difference among prevalence rates suggests that slightly fewer than half of lifetime users continued to use CAM therapies in any given year throughout their life course.

DISCUSSION

The results reported here suggest that the lifetime prevalence of CAM therapy use in the United States has increased steadily since the 1950s. This increase appears not to be concentrated in a single population sector or decade. Furthermore, the trend is seen for several therapies, although variation can be seen in the timing of the introduction of different therapies between the 1960s and 1990s. We also found powerful cohort effects that are substantial and consistent across cohorts. The post-baby boom respondents had a higher rate of lifetime use by age 33 years than the pre-baby boom respondents had by age 79 years.

These consistent and pervasive results should dispel any suggestion (16) that use has increased for only singular complementary or alternative modalities or that the use of CAM therapies is a passing fad associated with one particular generation or fringe segment of the population. On the basis of the plausible assumption that demand for CAM therapies, similar to that for conventional health care, is sensitive to how much patients must pay out of pocket (17), it seems likely that the proportion of people using CAM therapies will increase as insurance coverage for these treatments expands in the future.

Although limitations in our data do not allow examination of persistence of use over time, we found that 50% of all CAM therapy use that had been initiated at

least 5 years before the interview had persisted at the time of the interview. This finding is consistent with the finding of a previous report (18) that most CAM therapies are used, at least in part, to prevent future illness or to maintain health and vitality as part of lifestyle choices linked to the perceived value of disease prevention and health promotion. It seems reasonable to assume that individuals' interest in prevention will probably persist throughout their lifetime, and this factor may help explain the high rate of persistent use documented in Table 2.

Our results are limited by the restriction of the sampling frame to people who spoke English and who lived in households with telephones, as well as by the relatively low response rate (60%) and the use of a financial incentive (4). Furthermore, we have no data on the accuracy of self-reports on recollection of lifetime use or age at first use of a therapy. Recall bias is a possibility, and the degree of bias might be related to respondent age. Although we could not correct for these limitations, such adjustments might have made the estimated trends less pronounced.

A second potential confounding element of this study is the constant flux in the labels for and the very existence of particular CAM therapies. These may not necessarily have remained stable throughout the examined periods. For example, some unconventional medical professions, such as "drugless practitioners" and "sanipractors," which were licensed in some states in the 1930s, have since disappeared (19).

Our finding of a pervasive increase in the use of 20 CAM therapies over the past half-century warrants reflection on these trends in a historical context. History does not work statistically, and the role of chance makes prediction even more difficult. Specific historic events (such as the invention of the polio vaccination or the discovery of a link between acupuncture and endorphins) and general secular trends (such as confidence in medical progress) are all likely to influence the use or abandonment of CAM therapies. In the future, episodes of conventional or CAM practices associated with dramatic positive developments or adverse events may tip prevalence patterns in one direction or another. Also, from a historical perspective, our data may not represent a consistent trend of increased use of CAM therapies but rather a distinct peak in a longer trend of constant fluctuation in CAM therapy use. For example, survey data

from the 1920s and 1930s have revealed high rates of unconventional therapy use (20), and government statistics from 1900 document large numbers of registered unconventional practitioners (21). Our data may, in fact, be demonstrating a resurgence in CAM use after a period of diminished use during the 1940s and 1950s.

The trend of increased CAM therapy use across all cohorts since 1950, coupled with the strong persistence of use, suggests a continuing increased demand for CAM therapies that will affect all facets of health care delivery over the next 25 years. Evaluations of efficacy and effectiveness by medical researchers and treating physicians' discussions with patients hold the promise of minimizing adverse effects and maximizing the usefulness of those CAM therapies that prove effective.

From Harvard Medical School and Center for Alternative Medicine Research and Education, Beth Israel Deaconess Medical Center, Boston, Massachusetts.

Acknowledgment: The authors thank the staff of DataStat, Inc., Ann Arbor, Michigan, for assistance with telephone data collection.

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When any person is dangerously ill, a tla-quill-augh is consulted, and the price of his services fixed, without his ever seeing the patient. As soon, therefore, as this preliminary part of the business is arranged, the price agreed upon is forthwith sent to his abode, and he repairs to the sick person and begins his operations. He is always paid beforehand—that payment being according to the quality of the sick person; and it is believed that the more is given the sooner and the better will be the case. It is no wonder, therefore, that they should be liberal on such occasions; but if the patient dies the fee is all returned again.

When the tla-quill-augh enters the wigwam or lodge, he views the patient with an air of affected gravity, such as we see some of our own doctors assume on entering the dwelling of a sick person, and tells the bystanders, with a shake of the head and a groan, that the case is a very bad one, and that without him the patient would have surely died.

Alexander Ross

Adventures of the First Settlers on the Oregon or Columbia River, 1810-1813
Corvallis, OR: Oregon State Univ Pr; 2000:287-88

Submitted by:

Andrew Frank, MD
Portland, OR 97210

Submissions from readers are welcomed. If the quotation is published, the sender's name will be acknowledged. Please include a complete citation (along with page number on which the quotation was found), as done for any reference.—*The Editor*

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The Powerful Placebo and the Wizard of Oz

Some myths really ought to be true. We react with surprise and pleasure when we encounter them and then believe them when they neatly and comfortably help to explain some confusing aspect of our world. Thereafter, evidence against them is unwelcome and not to be trusted. But some such myths are flawed and misleading.

John Snow has been widely credited with stopping a cholera epidemic in 1854. He noticed that the disease was prevalent among Londoners who drank from a well supplied by one water company but not among those who drank from the well of another company, and he removed the handle of the offending pump. Alas, the record shows that the number of new cases of cholera had already decreased sharply, and Snow's insight (though important for establishing the cause of cholera) had little effect as the epidemic completed its course. (1)

Studies of five workers at Western Electric's Hawthorne plant in Illinois were cited for decades as having shown that productivity increased each time the investigators changed the working conditions, including the last change -- back to the original conditions. This "Hawthorne effect" was said to show how a research setting itself could change behavior. Again, though, the records belie this simple and appealing story; the last working conditions differed from the original conditions in several important ways, including the addition of a break for rest and tea as well as the progressive transformation of the workers who were being studied from passive subjects into active study participants. (2)

The potential benefits of placebos as treatments for diseases have rarely been questioned since Beecher reported in 1955 that they could relieve symptoms and otherwise contribute to the well-being of patients. (3) Many readers will remember the Wizard of Oz, who was powerful because others thought he was powerful -- until they found that the curtain hid a very ordinary man. (4) Is the placebo powerful because we have not looked behind the curtain? The question is involuted; layers of meaning surround the words "powerful" and "because." In this issue of the Journal, Hrobjartsson and Gotzsche (5) help to remove at least one layer of the mystery. They conducted a systematic review of clinical trials in which patients were randomly assigned to either placebo or no treatment. They found little evidence in general that placebos had powerful clinical effects.

The basic problem is that the patient who has had a bad day with cancer or emphysema or a headache does not need a placebo to feel better the next day. Is the improvement in patients given a placebo a result of the placebo itself, of natural fluctuations in the progression of the disease, or of how the patient responds to the symptoms? The primary comparison in a placebo-controlled trial is usually of the placebo with a possibly active therapy, not with no treatment. This design cannot distinguish an effect of placebo from the natural course of the

disease, regression to the mean (the tendency for random increases or decreases to be followed by observations closer to the average), or the effects of other factors.

Clinical trials generally include blinding to improve objectivity in the assessment of outcomes if the patient or the observer might otherwise be able to tell which treatment was being given. Effective blinding may require the use of a placebo. Some trials include a placebo for other reasons, such as to strengthen the bond between the patient and the study. Some studies do not include a placebo at all. Few, however, include both a placebo and a nonplacebo (untreated) group for which outcomes can be compared directly. It is remarkable that Hrobjartsson and Gotzsche found 114 randomized clinical trials that included both a placebo group and an untreated group and in which other treatment, if any, was held constant.

Placebo is surprisingly hard to define precisely. These authors defined placebo in operational terms as an intervention labeled as such in the report of a clinical trial. They report only the main outcome of each trial, so no patients were counted more than once. When the original report did not specify the main outcome, the reviewers selected the outcome they considered most relevant to patients. The placebos they reviewed were pharmacologic (e.g., tablet), physical (e.g., manipulation), or psychological (e.g., conversation).

In all, data from about 7500 patients with 40 different clinical conditions were included in the comparison of placebo with no treatment. Binary outcomes and continuous outcomes, both subjective and objective, were examined separately. Statistical tests of the pooled data showed no significant effect on subjective or objective binary outcomes or continuous objective outcomes. There was a significant effect of placebo with respect to pain, but the difference as compared with no treatment appeared to diminish with increasing sample size. This finding suggests that the observed effect may be a product of publication bias or other bias in reporting. Even this possible effect of placebo was small, an average of 6.5 mm on a 100-mm visual-analogue scale (an effect the authors state is approximately one third that of nonsteroidal antiinflammatory drugs as compared with placebo in double-blind trials).

These results held across numerous types of trials. For example, the results did not depend on whether physicians were aware of the treatment assignments, whether standard treatments were also given, whether determining the effect of placebo was an explicit objective of the study, or who specified the main outcome (the original investigators or Hrobjartsson and Gotzsche).

Hrobjartsson and Gotzsche conclude that there is no justification for the use of placebos outside the setting of clinical trials. Their findings are impressive, but is their conclusion too sweeping? First, they did find some evidence of an effect in the important subgroup of trials in which the main outcome was pain. Second, despite the large sample, the statistical power to examine many subgroups of interest was low. Their data may have failed to demonstrate a small but clinically useful benefit of placebo for some patients and for some outcomes other than pain. Third, they found statistical evidence of heterogeneity of results in studies with binary outcomes. The results could not be heterogeneous unless at least one trial differed from the others, which would require a real (though unidentified) effect. Fourth, they studied patients in randomized clinical trials, many of which focused on serious conditions whose clinical consequences may have overshadowed small but useful effects of

placebo. Fifth, they noted that the low methodologic quality of some trials might explain a lack of effect, though they found no association between dimensions of trial quality and significant effects of placebo.

Finally, there is that pesky, utterly unscientific feeling that some things just ought to be true. Perhaps most important is that the research setting, with its generally intense methods of observation and precise measurement of outcomes, may obscure a real effect of placebo that would be evident in nonresearch settings. However, it is not clear how one could study and compare the effects of placebo in research and nonresearch settings, since that would of course require a research study.

Few physicians would argue against using innocuous means that might relieve their patients' symptoms or reverse the course of illness. Unfortunately, placebos may not be entirely innocuous. They may divert patients from seeking more effective treatments, they may mask symptoms that need attention, they add to the cost of treatment, and they may have unexpected physiological effects. (3) There may also be some reason for concern that regular reminders of illness (in the form of placebos) may make a person less rather than more comfortable. The deception that is inherent in the use of placebos troubles some physicians as well as ethicists. This deception may damage the doctor-patient relationship in subtle ways. There is thus reason for caution about the casual acceptance of the notion that placebos cannot hurt.

Overall, the uncompromising condemnation of placebos advocated by Hrobjartsson and Gotzsche seems to me just a bit too sweeping. In particular, the evidence that placebos might contribute to pain relief may merit their continued therapeutic use when there is reason to think that a patient may benefit. The Wizard of Oz did give each of the travelers something of great value -- a heart, a brain, courage, hope. It was Toto the dog, unimpressed by all the magical trappings, who ran behind the curtain and brought down the whole scheme. However, I believe there should be a sharp reduction in the prescription of placebos and careful justification for each continued use. Future studies may show either that placebos have benefits not yet documented or that the appearance of small benefits -- for example, for pain relief -- is, in fact, illusory. At present, I would not want to prescribe or receive a placebo without some reason that was far more specific than weak evidence of some general "placebo effect."

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Groft, Stephen (NCCAM)

From: Chang, Michele (NCCAM)
Sent: Thursday, May 24, 2001 10:33 AM
To: Groft, Stephen (NCCAM)
Subject: FW: Organizing the Public Records Files:

As we discussed, I think we really need Palladian for the database entry work. I think Joan (with my help) can do the rest of the hardcopy filing and organizing.

Thanks.

-----Original Message-----

From: Holly Dodge [mailto:hdodge@mail.palladianpartners.com]
Sent: Tuesday, April 17, 2001 5:35 PM
To: Chang, Michele (NCCAM); Groft, Stephen (NCCAM)
Cc: Jean Kazares (E-mail)
Subject: Organizing the Public Records Files:

Michele,

I got your voice message and since you indicated that you would be leaving by 5 pm, I thought I would respond in writing. Your voice message suggested we could send someone to your office tomorrow. That is not realistic given the scope of the project. We need to plan first. I have listed the steps to the plan as we discussed on April 6th, below.

About the project of organizing the Public Records Files:
When we discussed this project at our recent meeting my notes show that we discussed the following plan.

Step One: You move your office.

- You would purchase banker boxes or some kind of sturdy boxes in the quantity of at least one per meeting. (We could get you boxes if necessary -- arranging for files is in the contract.)
- While you pack to move your offices, you would pack one or more boxes per meeting, keeping the meetings separate. We discussed putting the "official records" notebooks in the meeting boxes. This came up because you said that there were at least 2 of the staff for each meeting that had collected all the speaker notes and presentations.
- The meeting boxes would be labeled with the name and date of the meeting.
- In your new office space, you would put these boxes with their labels clearly visible, on the shelving in the storage area/ work room you will have.

Step Two: We plan for the organization of the records.

- We need to discuss and decide what you want to be able to do with the records once they are organized.
- How do you want to be able to retrieve the information and how are you going to use it in the future?
- In what format will the records be stored? Paper files -- an index? Computer files -- access database? excel spreadsheet?
- What information is contained in the record? How much detail is needed? What fields are filled in? What relationship do the records of what people said have to their contact information?
- We understand that the general topics (they are listed in the executive order) will be one general organizing feature. You would want to know what general topic each speaker addressed.
- We talked about numbering the speakers #1 til the end. The first meeting would be #1 to #20, second meeting #21 to #37, and etc.
- We also talked about numbering the speakers within a meeting or within a topic. If this is the choice, this would be a different system than straight numbering. The big question here is whether being able to identify

the meeting they spoke at is important.

-- We need to plan together in order for this process to be smooth. We can not just jump in.

-- We would meet with you, come up with a plan, prepare a plan description for you to review and approve. Then we can go to step three.

Step Three: We have a staff person come over to your new office space and do the task.

-- Jean would bring the staff person to your office for an orientation meeting that would lay out the details decided in step 2.

-- Jean would make sure the staff person knew where things were and what the desired product is supposed to be.

-- Jean would make sure that the staff person had the tools needed to do the job -- hanging files, manila files, file labels, access to a computer and printer for creating the labels, or possibly a blank database to enter in the information belonging in the records.

-- The staff person would then work through the boxes, one at a time. She would follow the rules, ask appropriate questions, and provide you with the product decided upon in Step 2.

-- Jean would provide oversight, would be available by phone, and would go on site to verify the project was done correctly.

Holly Dodge

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