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Forum

Risk Management Foundation of the Harvard Medical Institutions

Complementary and Alternative Medicine (CAM)
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About Complementary and Alternative Medicine (CAM)

The Definition

This *Forum* explores the risk management issues associated with what is commonly referred to as "alternative medicine" or "complementary and alternative medicine" (CAM). The Office of Alternative Medicine at the National Institutes of Health defines CAM as:

> 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 in a given historical period.
>
> CAM includes all such practices and ideas self-defined by their users as preventing or treating illnesses 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 or fixed.

The Statistics

According to a national survey on the use of CAM in the United States in 1997:

- Prevalence of the use of CAM increased to 42 percent of U.S. adults, compared with 34 percent in 1990.
- CAM providers totaled 629 million patient encounters; primary care physicians had 386 million encounters.
- Americans paid $21 billion to CAM providers; $12 billion was out-of-pocket.
- More than $15 billion (out-of-pocket) was spent on CAM-related remedies (e.g., vitamins, herbs, books, classes).
- At least 15 million adults took prescription medications concurrently with herbal remedies and/or high dose vitamins.
- Less than 40 percent of patients disclosed their CAM therapies to their physicians.

Source
David M. Eisenberg, M.D., Center for Alternative Medicine Research and Education, Department of Medicine, Beth Israel Deaconess Medical Center

CAM Patients' Most Common Health Complaints

Complaint	Most Common CAM Therapy Sought
Neck, Back Problems	Chiropractic, massage
Anxiety, Depression	Relaxation, spiritual healing
Headaches	Relaxation, chiropractic
Digestive Problems	Relaxation, herbal medicine

Source: Eisenberg DM, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. *Journal of the American Medical Association.* 1998;280:1569-75.

The Agencies Regulating CAM Providers

Chiropractic

Federation of Chiropractic Licensing Boards
Greeley, Colorado
970-356-3500
www.fclb.org/fclb

Massage Therapy

National Certification Board for Therapeutic Massage and Bodywork
McLean, Virginia
800-296-0664
www.ncbtmb.com

Acupuncture

National Certification Commission for Acupuncture and Oriental Medicine
Alexandria, VA
703-548-9004
www.nccaom.org

American Academy of Medical Acupuncture
Los Angeles, California
323-937-5514
www.medicalacupuncture.org

Homeopathy

National Center for Homeopathy
Alexandria, Virginia
703-548-7790
www.homeopathic.org

Naturopathy

American Association of Naturopathic Physicians
Seattle, Washington
206-298-0126
www.naturopathic.org

Why Talk About Alternative Therapies In a Risk Management Publication?

by
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Chances are, the patient sitting across from you in the exam room has or is using a therapy that may impact your care plan for that patient...and you don't know about it. Recent studies have revealed that more than two in five Americans uses some form of complementary or alternative medicine (CAM), from herbs to acupuncture. Most patients receiving CAM do so contemporaneously with the receipt of conventional care, but often do not tell their physicians.[1] In Britain, by comparison, 95 percent of general practitioners said that patients discussed alternative medicine with them.[2]

The 629 million visits to CAM providers exceeded total visits to all primary care providers (386 million) in 1997. The most common therapies sought were chiropractic, massage, and relaxation.[1] In that same year, an estimated 15 million adults took prescription medications concurrently with herbal remedies or high dose vitamins.

Americans' reluctance to discuss CAM with their physicians is compounded by equally hesitant clinicians who may avoid discussing therapies they don't understand or don't consider efficacious. Meanwhile, many patients may be embarrassed to share their CAM pursuits. Recognizing that communication gaps adversely affect medical care and often drive malpractice claims, the absence of communication about CAM is an area of concern for patient relationships, their health, and clinicians' potential liability.

Clearly, some alternative therapies are not grounded in evidenced-based research and are, at best, anecdotal in their outcomes. *Forum* is not investigating the efficacy and adequacy of alternative practices. Rather, the focus of this issue is on what, if any, risks *clinicians* face when dealing with CAM. We are addressing the areas of maintaining therapeutic relationships with patients who request referrals to CAM providers, the availability of alternative therapies offered through managed care companies, and specific risks associated with co-managing patients with CAM providers. We also look at the current status of medical student education in the United States as well as what some practicing physicians are doing to meet consumer requests for CAM. ■

Notes & References

1 Eisenberg DM, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. Journal of the American Medical Association. 1998;280:1569-75.

2 Rampes H, Sharples F, Maragh S. Introducing complementary medicine into the medical curriculum. The Journal of the Royal Society of Medicine. 1997;90(1):19-22.

CRICO[1] Claims Experience and Risk Management Advice re: CAM

Over the past 21 years, the Harvard medical malpractice insurance program has had no claims related to licensed health care providers delivering or *referring to* complementary or alternative medicine (CAM). Beyond that, *Forum* found no published legal decision citing negligent referral as a valid cause of action.

However, several factors suggest that physicians should maintain careful CAM referral protocols. Continuing popular demand, variable treatment and credentialing standards, limited satisfactory research, and an uncertain atmosphere of trust between patients and clinicians regarding CAM are the basis for risk management advice focusing on evaluating the relative risks and benefits of alternative therapy in two situations: 1) initiating a referral to a CAM provider and 2) responding to a patient's request to receive CAM while under a physician's ongoing care. Specifically, a physician making a referral to a CAM practitioner should consider the following:

- Have you done a thorough history and physical on the patient and made a differential diagnosis?
- What is the expected benefit of the referral?
- Is any conventional treatment not being given as a result of the referral?
- What other medical treatment would other physicians provide or recommend?
- Does your clinical judgment lead you to believe that the patient will benefit (or not be harmed)?
- Have you discussed with the patient (known) risks, anticipated results, and other forms of treatment available?
- Did you document your discussions with the patient about potentially assuming the risks associated with the treatment choice?
- Can you verify that the CAM provider is appropriately credentialed (including proper licensing) and is in good standing among peers?
- Have you clarified your role in ongoing care? Will you be sending information to the CAM provider and will you be receiving consultation notes and recommendations from him or her? How will they be incorporated into the overall plan of care?
- Does your patient's managed care organization have referral requirements or does it allow patients direct access to CAM providers?

1 Controlled Risk Insurance Company (CRICO) provides professional liability insurance to health care institutions, their employees, and affiliated physicians.

Medicine that Works

by
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"There cannot be two kinds of medicine: conventional and alternative. There is only medicine that has been adequately tested, and medicine that has not; medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted."[1]

These words, ending a controversial editorial in the *New England Journal of Medicine*, may serve as a first principle for the "one-good-effective-tested" medicine of the future (which I hope will have one good, effective, and simple name as well). Some of us working to create this medicine share a vision. We see that a heterogeneous, increasingly popular group of healers and practitioners are practicing in and out of the health caremainstream with variable successes and failures.

Most of the biomedical "facts" currently taught in medical school will likely be modified or completely discarded in one or two decades.

Well-educated patients and physicians know that even experts and the editors of leading medical journals cannot yet adequately and rigorously answer many questions about what may or may not work in health care. Patients wish physicians would admit this more often, talk to them about it, and most importantly, talk to each other about it.

Mainstream, conventional physicians should talk and work with unconventional complementary and alternative medicine (CAM) practitioners as often as possible for the health and well-being of our patients. We should discuss what we are doing. We should share patient histories, anecdotes, data, outcome studies, theories, principles, and practices. We should work together to decide how to effectively study what we do. Our collaboration should begin wherever we share common ground. Sharing our knowledge of the power of the physician-patient relationship is a good beginning. Respectfully practicing side by side is even better.

Collaborative Practice

The Marino Health Center (MHC) is building a team of board certified, conventionally trained practitioners who work with licensed or otherwise credentialed practitioners of complementary and alternative medicine. The issue of credentials and certification will become more important as time goes on, but our first step is to work together in some formal network to learn about each others' skills. MHC is testing the hypothesis that a variety of practitioners with different credentials can work together as colleagues. Continuity of care and a team approach are assured by making it part of the culture at the center to share and discuss cases informally *and* through formal consultation. MHC also holds two noteworthy weekly meetings. In one, the primary care medical staff meet to discuss cases and approaches to various problems, including decisions about whether a referral to a conventional or CAM practitioner would be appropriate.

The second meeting is more unusual. It is a case conference in which all health care providers at the medical center sit together for an hour to discuss interesting, difficult, or problematic cases that have arisen recently. At the table are acupuncturists, homeopaths, internists, family practitioners, nurse practitioners, surgeons, neurologists, naturopaths, chiropractors, nutritionists, massage therapists, psychotherapists, and exercise physiologists.

On the other hand, the art and science of forming the physician-patient relationship will probably endure for a long time.

Most of us are unaccustomed to seeing people who are trained so differently sitting at the same table—especially when they all carry the same authority when they speak. At this conference the caregivers come together largely as equals in an effort to develop a common language. All are trying to become fluent in this new language and all are studying, talking to, and respectfully challenging each other. Although this conference is at the most elementary level, it is the beginning of a highly rigorous, scientific, evidence-based forum for a comprehensive, integrated form of medical care.

The Enduring Relationships

Most of the biomedical "facts" currently taught in medical school will likely be modified or completely discarded in one or two decades. On the other hand, the art and science of forming the physician-patient relationship will probably endure for a long time. As long as some people become ill and others play the role of health care provider, a relationship will exist in which certain issues will arise over and over again.

Most medical schools now have some form of physician-patient relationship course in which medical students learn lifelong principles of interviewing, interpersonal skills, and sensitivity to subjects such as sexuality, disability, grief, death, loss, chronic illness, and substance abuse. The finest conventional physicians practice and model for

their students the development of this relationship through which all health care is delivered.

While CAM practitioners pay particular attention to the physician-patient relationship, neither they nor conventional practitioners can lay claim to being *more* sensitive to patients' needs, *better* listeners, or *more* interested in their patients as people. CAM practitioners pay attention to the physician-patient relationship differently because they have different models of illness and wellness as well as differing models of mind/body interaction.

It may seem risky for such a diverse group of people to practice together, but what MHC is doing is more integrated than what is actually happening in our society as people shop around for a variety of health care providers.

CAM practitioners often have wide-ranging models of illness and categories of disease that do not fit contemporary conventional categories. CAM providers consider environmental and chemical sensitivities; weaknesses in host defenses; and metabolic, nutritional, and musculoskeletal imbalances that may contribute to disease susceptibility. For this reason, they listen for and juxtapose a variety of symptoms sometimes differently than conventional practitioners. In CAM, more attention may be paid to what would appear trivial or unrelated in a conventional interview.

More than Placebo

Although most practitioners of medicine today take into consideration the interaction of mind and body, until recently their attention went toward measurable biological findings after a cognitive/emotional intervention. Decreased blood pressure readings after a program of meditation and stress reduction, for example, demonstrates this aspect of the mind/body relationship.

CAM practitioners believe in a deeper, more pervasive interaction of mind and body and allow for some of the mystery of this still poorly-understood relationship. Some CAM practitioners listen especially to a patient's beliefs about healing and what types of interventions and treatments make sense to the patient. Some think this is simply enhancing the placebo effect of subsequent treatment recommendations, but it is probably not that simple. The power of believing in whatever treatment one undergoes or in the practitioner who provides it is better termed "belief-in-healing" or the "belief-in-treatment" than the "placebo effect." It touches the core of the physician-patient relationship and could be a rich topic for research and collaboration amongst all practitioners (*see Page 7*).

Focusing on Common Ground

It may seem risky for such a diverse group of people to practice together, but what MHC is doing is more integrated than what is actually happening in our society as people shop around for a variety of health care providers. At the Marino Center, every patient has some degree of conventional and alternative medical assessment and is monitored carefully if any "unconventional or unproven" therapies are provided. The tendency at MHC is to allow for unconventional treatments where reasonable—as long as solid evidence exists about its safety. The principle of "first do no harm" is deeply shared by all.

Focusing on the common ground of the power of the physician-patient relationship, and working collaboratively with a diverse team of providers to give the most appropriate care for patients is exciting and rejuvenating. It may carry a lower risk of adverse events than does a health care system that separates conventional and alternative caregivers from one another, especially since recent research indicates that many patients don't share information about their CAM visits with their physicians. This collaboration can be the foundation for a scientific base from which all caregivers may begin to more systematically scrutinize, evaluate, and improve what they do in the one-good-effective-tested medicine of the future. ■

Reference

1 Angell M and Kassirer JP. Alternative medicine: the risks of untested and unregulated remedies. *New England Journal of Medicine.* 1998;339:839-41.

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Credentialing and Quality Assurance for Harvard Vanguard's *Alternative Paths to Health* Program

by
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In November 1997, Harvard Vanguard Medical Associates launched its *Alternative Paths to Health* program, offering on-site acupuncture, chiropractic, and massage therapy.[1] Now available at eight of Harvard Vanguard's 14 centers, this program provides quality, integrated care to patients already familiar with the benefits of alternative medicine as well as many patients who are new to these modalities. Harvard Vanguard has approached alternative medicine with the same values of quality and integrity applied to all patient care issues.

Provider Selection and Credentialing

Although the alternative medicine providers are not Harvard Vanguard employees, each location uses the same credentialing standards and follows the selection process described below:

1 Acupuncture, massage therapy, and chiropractic candidates are suggested through referrals from staff members, referrals from known alternative clinicians, and through resumes received by Harvard Vanguard.

2 Potential candidates respond to a Request for Proposal (RFP) which contains details about Harvard Vanguard's practice and expectations, and provides Harvard Vanguard with answers about the clinician's practice, experience, and willingness/ability to meet expectations.

3 Candidates who submit a superior response to the RFP go through a series of interviews with managerial and clinical staff members. In addition, Harvard Vanguard clinicians evaluate the candidates' general clinical assessment and patient interaction skills. In some cases, candidates are asked to demonstrate their skills. For example, massage therapy candidates perform massages on staff who can evaluate their quality.

4 For final candidates, professional references are contacted, including at least one expert in the field of practice, e.g., a clinical professor from an accredited school.

5 Final candidates who are offered positions (pending successful completion of the credentialing process) are asked to sign a provider contract and a lease or fee agreement.

Credentialing Standards

The Harvard Vanguard credentialing program for alternative medicine includes the following components:

- Licensure, certification, or registration requirement.
- Minimum malpractice insurance coverage (*See chart, Page 6*).
- Minimum general liability coverage.
- Checking on licensure and disciplinary actions via applicable state and local authorities. These may include the Board of Registration in Medicine, Committee on Acupuncture, the state Board of Chiropractic, or local departments of health.
- Membership in professional organizations.
- Participation in continuing education.

Quality Assurance

Harvard Vanguard applies its rigorous standards for quality to its associated alternative medicine practices. Each alternative medicine program is required to measure quality assurance on a regular basis.

Medical Record Audit

As contracted providers, alternative medicine clinicians are required to maintain their own patient records, separate from the patient's Harvard Vanguard medical record. A key quality measure is the review of these records after the clinician has been practicing for six months. This review is repeated every six months. A random selection of charts is reviewed by Harvard Vanguard staff who have both managerial and clinical expertise.

The key elements reviewed are:

- Documentation of patient demographic information;
- Patient authorization for communication with the primary care team;
- Evidence of communication with the primary care physician or specialist, when patient permission is granted;
- Evidence of SOAP type note taking: subjective, objective, assessment, and plan;
- Evidence that the clinician has explained what to expect during the visit; and
- Documentation of initial treatment plan, evaluation of progress, and summary at conclusion of treatment.

Documentation of any deficiencies found is included in the written summary and discussed with the alternative clinician. Corrective action plans are also included. A follow-up chart review occurs two to three months after any deficiencies are identified.

Patient Satisfaction Survey

A patient survey was developed to gauge patients' satisfaction with their visits as well as gain some information about 1) the nature of their problems, 2) whether they had seen other clinicians about them, and 3) their general well-being. At the time of an alternative care visit, patients are asked to complete the confidential, 20-question survey. The clinician explains that the

survey will be used to help Harvard Vanguard improve the program and enhance services. The responses to the survey give the program managers an indication of the most frequent reasons for visits, the number of visits per patient, how long the patient has suffered with a problem, and the names of other clinicians that the patient has seen. In addition, a number of questions elicit the patient's satisfaction with office hours, the availability of clinicians to speak with them, and the amount of time that clinicians spend with patients. These responses give the program managers specific information to improve program operations. Finally, the last set of questions are taken from the SF-12, a validated survey of patient well-being.[2] These questions are meant to provide a baseline of patient outlook and well-being and are used to correct for attitudinal bias.

Medical Clinician Assessment

The third quality assurance tool that has been implemented is a brief telephone survey of the medical staff at the sites with the *Alternative Paths to Health* program. This survey is directed to internal medicine staff, mental health clinicians, and other clinicians who have shared patients with alternative medicine providers.

The purpose of this phone survey is threefold: 1) to indicate clinician comfort and understanding of alternative medicine; 2) to determine if medical clinicians are referring patients to alternative clinicians; 3) to assess the level of communication and collaboration among the clinicians. Since one of the hallmarks of this Harvard Vanguard program is communication between the medical clinicians and the alternative clinicians, the responses to this tool are critical.

Alternative Clinician Satisfaction Survey

Another important gauge of the quality of the program is the level of satisfaction among the alternative medicine clinicians. To that end, Harvard Vanguard instituted a brief written survey that evaluates the clinicians' views about their practices, their physical spaces, the helpfulness of support staff, and the management of the program. It enables the program manager to work more effectively with the alternative clinicians and enhance the program operations.

Universal Precautions and Confidentiality Training

Two training programs, one on universal precautions and another on patient confidentiality, are required for all staff in the health offices and, therefore, the alternative clinicians are also required to complete this training. Both trainings can be completed by viewing a short video. Universal precautions training and successful completion of testing requirements are repeated annually.

Peer Review

The final quality assurance measure, which is currently in the developmental stage, is a peer review process. Clinicians in each modality will meet, along with an administrative member of the program, and review selected charts and case studies. Elements under review will include documentation, differential diagnosis, treatment options, and outcomes. Eventually, Harvard Vanguard hopes to use this review as a way to generate treatment guidelines and standards of care for use in the alternative medicine program. ■

Notes & References

1 Harvard Vanguard facilities serve members of Harvard Pilgrim Health Care. HPHC members currently have access to, but only limited coverage for, alternative care, including care provided through the *Alternative Paths to Health* program.

2 SF-12 is an abbreviated version of the SF-36 patient well-being survey developed and distributed by QualityMetric, Inc.

Credentialing Standards for Harvard Vanguard's *Alternative Paths to Health* Providers

Modality	License Requirements	Certification Requirements	Registration Requirements	Professional Organizations	Minimum Malpractice Insurance Coverage	Suggested Requirements
Chiropractic	State	Not required	Not required due to license	ACA	$1,000,000/ $3,000,000	Training in CCE accredited institutions ❖ Member of ACA
Acupuncture	State	Not required May be certified by NCAA	Not required due to license	NCCA	$300,000/ $500,000	Training for MDs: 200 hours Training for Non-MDs: 2 years
Massage Therapy	Not required	By NCBTMB (since 1992)	Required by the City or Town Department of Health	AMTA, NCBTMB	$2,000,000	Minimum of 500 hrs. training in a COMTAA accredited, approved, or licensed school ❖ Member of AMTA

ACA: American Chiropractic Association
AMTA: American Massage Therapists Association
CCE: Council on Chiropractic Education
COMTAA: Commission on Massage Training Accreditation/Approval
NCBTMB: National Certification Board for Therapeutic Massage and Bodywork
NCCA: National Commission for the Certification of Acupuncturists

The Importance of the Placebo Effect, or "Remembered Wellness," in Alternative Therapies

by
Herbert Benson, M.D. and Patricia Myers

Dr. Benson is Chief of the Division of Behavioral Medicine at the Beth Israel Deaconess Medical Center, the founding president of the Mind/Body Medical Institute, and an Associate Professor of Medicine at Harvard Medical School.

Consumers of health care are increasingly turning to alternative therapies as adjuncts to mainstream medicine.[1] Alternative therapies may be therapeutic for patients, but the question arises as to what extent such treatments are effective because of their true potency or because of the healing effects of the nonspecific factors of the placebo effect.

The placebo effect plays a role in both mainstream and alternative therapies and has been an inherent part of healing and medicine throughout history.[2] Prior to the development of scientifically proven therapies about 150 years ago, physicians depended almost exclusively on the powers of beliefs, thoughts, and feelings to heal. However, modern medicine has largely disregarded and ridiculed the power of the placebo effect because specific therapies (e.g., insulin, antibiotics, cataract surgery) produce truly awe-inspiring results independent of the placebo effect. Reliance on such belief-related factors diminished.

Beliefs and the Placebo Effect

The pioneering work of Henry Beecher established the power of the placebo. In patients suffering from pain, cough, headaches, seasickness, drug-induced mood changes, and the common cold, a placebo was effective in 35 percent of cases.[3] Since these early findings, the placebo effect has been documented in 50 to 90 percent of cases among patients with conditions that include bronchial asthma, duodenal ulcer, angina pectoris, and herpes simplex.[2,4]

Prior to the development of scientifically proven therapies, physicians depended almost exclusively on the powers of beliefs to heal. However, modern medicine has largely disregarded and ridiculed the power of the placebo effect because specific therapies produce truly awe-inspiring results.

The placebo effect is dependent on three sets of beliefs: 1) the beliefs of the patient, 2) the beliefs of the health care provider (the healer); and 3) the beliefs that ensue from the relationship between the patient and the healer. In 1962, Ikemi and Nakagawa demonstrated the power of patients' beliefs among Japanese students who were allergic to the oil of a lacquer tree which produces a rash similar to that of poison ivy.[5] The students were blindfolded and told that one of their arms would be stroked with lacquer tree leaves while their other arm would be stroked with chestnut tree leaves, to which they were not allergic. Unbeknownst to the students, the researchers switched the leaves so the skin believed by the subjects to have been brushed with the lacquer leaves was actually stroked with chestnut tree leaves. A rash developed on that arm. The skin that was stroked with the leaves of the lacquer tree, but believed to have been stroked with the chestnut tree leaves, developed no rash.

A study of treatments for angina pectoris provides an example of how beliefs of the health care practitioner can affect disease.[6] Therapies used in the past now known to have no therapeutic value included aminophylline, vitamin E, and surgeries such as internal mammary artery ligation and implantation. When physicians believed in and used such therapies, the effects were dramatic. Anginal pain, for example, was relieved in 70 to 90 percent of cases. Not only would the pain be alleviated, but the patients' electrocardiograms and exercise tolerance improved. However, when these therapies were invalidated and no longer believed in by physicians, their rate of effectiveness dropped to 30 percent or lower.

Beliefs that ensue from the relationship between "healers" and patients constitute the third component of the placebo effect. In 1964, researchers at the Massachusetts General Hospital compared two matched groups of patients about to undergo similar surgery.[7] The anesthesiologists visited both groups of patients prior to the operation, but interacted with them differently. They made only cursory remarks to one group whereas they treated the other group with warm, sympathetic attention, detailing the steps of the operation and describing the pain they might expect. Those patients who received the friendlier, more supportive visits were discharged from the hospital an average of 2.7 days sooner and requested only half the amount of pain-alleviating medication sought by patients in the other group.

Remembered Wellness

Some insight into the possible brain mechanism of the placebo effect is provided by a study in which Stephen Kosslyn and his colleagues examined how the brain processes information both real and imagined.[8] Subjects viewed a grid with a letter printed on it. As they viewed it, positron emission tomography (PET) was used to determine which areas of the brain were active. The subjects then looked at the same grid without the letter on it, but were asked to visualize the letter in their mind's eye. On the repeat PET scan, the same area of the brain was stimulated. In

other words, from the brain's perspective visualizing a scene is similar to actually seeing the scene. Thus, the mind/body effects of visualizing a pleasant or aversive scene are akin to actually seeing it.

This process of perception helps to explain the placebo effect. All our thoughts, actions, and memories represent the activation of specific brain connections. Pain in an arm activates specific brain areas that ultimately can result in pain memories. Thinking of injuring that arm can activate those memories and the pain produced. Memories of being without such a pain are likewise retained. Brain connections also form and result in memories of having a skin rash and of not having one. Thus, a sugar pill or an inactive therapy that a patient believes is effective can activate the appropriate brain connections and cause him or her to "remember" what it is like to be without the pain or the rash, thus alleviating the symptom. In other words, thoughts can activate brain connections that can produce or eliminate a symptom.

The term "placebo effect" should be eliminated and replaced with one that is less pejorative and more accurate. We suggest "remembered wellness."

To help eliminate the negative perceptions of such powerful therapies, the term "placebo effect" should be eliminated and replaced with one that is less pejorative and more accurate. We suggest "remembered wellness."[2]

Research on Alternative Therapies

To obtain greater acceptance by the medical communities, alternative interventions need to be scientifically tested in controlled trials. Such research is underway at centers around the country funded through the National Center for Complementary and Alternative Medicine of NIH.[9]

When I began exploring mind/body interactions 30 years ago, many thought I was throwing away a promising career; my work was considered beyond the pale. Since I knew that even the examination of mind/body interactions would be problematic, I maintained two parallel careers for 15 years: one was that of a traditional cardiologist, the other was as a mind/body researcher. As I began conducting studies in mind/body interactions through the study of transcendental meditation, I remained a clinician and became the head of pathophysiological cardiology teaching at the Harvard Medical School.

Mind/body approaches are different from alternative therapies in that mind/body therapies are evidenced-based. With this established scientific base, mind/body approaches are being integrated into mainstream medicine. Relaxation-response therapy, for example, is one mind/body approach that was considered alternative until it was established that it could consistently produce measurable, predictable, and reproducible physiological changes when specific mental instructions are followed. These physiologic changes occur independently of belief.

We founded the Mind/Body Medical Institute 10 years ago to expand upon the evidence-based data that had been collected over several decades at Harvard. Some still question whether the mind can affect the body, but today I believe they are in the minority. One of my colleagues recently commented on the changes that have occurred in mind/body research saying that "Twenty-five years ago only two people believed in mind/body interactions, now only two people don't."

Alternative therapies will gain more acceptance by the medical community if research on the evidence of their effectiveness moves beyond that of belief and the placebo effect. Indeed, once the evidence is in place, such therapies will no longer be considered alternative, but like mind/body medicine will become an integral feature of accepted medicine. ■

Notes & References

1 Eisenberg DM, et al. Trends in alternative medicine use in the United States, 1990-1997: results of a follow-up national survey. *Journal of the American Medical Association*. 1998;280:1569-75.

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4 Benson H. *Timeless Healing: The Power and Biology of Belief*. New York: Scribner, 1996.5 Benson H and McCallie, Jr. DP. Angina pectoris and the placebo effect. *New England Journal of Medicine*. 1979;300:1424-29.

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9 Villaire M. Research tops agenda of September AMPAC meeting. *Alternative Therapies*. 1997;3:22-28.

Educating Future Physicians About Complementary and Alternative Medicine

by
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The panoply of "alternative" therapies includes acupuncture, chiropractic, energy healing, herbal remedies, homeopathy, therapeutic massage, meditation/relaxation, and many more health care practices. This world outside the traditional medicine universe, becoming commonly known as CAM (complementary and alternative medicine), has reached a new level of public awareness. A recent study shows that visits to CAM practitioners increased by more than 47 percent from 1990-1997.[1] Although many insurers and managed care organizations offer a limited amount of coverage, patients paid billions of out-of-pocket dollars for CAM therapies in 1997.[1] Market demand is causing a growing number of insurers and hospitals to assess the benefits of CAM.[2]

Are Medical Schools Keeping up with the Trend?

With so many patients turning to CAM, are future physicians being prepared to be knowledgeable about these therapies? According to a 1996-97 American Medical Association survey, 46 of the 125 United States medical schools offered CAM as part of a required course; two years later, 75 medical schools offered electives, or included these topics in required courses.[3,4] This rate of increase is phenomenal for traditionally very conservative institutions. The fact that this field only came into the consciousness of mainstream medicine in 1993, following publication of the initial national CAM survey, makes its prevalence even more remarkable.[5]

Medical educators are currently engaged in an active dialogue about how, when, and in what form CAM should become a part of the medical curriculum.

Medical educators are currently engaged in an active dialogue about how, when, and in what form CAM should become a part of the medical curriculum. A CAM Special Interest Group has been established under the auspices of the Association of American Medical Colleges and has met for the past two years under the leadership of Patricia Muehsam, M.D., of New York's Mt. Sinai Medical School. Because of the tremendous diversity of what composes CAM, and the great variability of content and format in the existing courses, concerned academicians realize the need for a workable educational model.

Dr. Muehsam and others strongly advocate an integrated approach to the teaching of CAM. For example, in an ideally integrated curriculum, students would learn about herbal remedies in pharmacology courses, as well as about the usual pharmacologic agents; spirituality and mind/body techniques would be taught in psychiatry courses, and orthopedic and rehabilitation courses would include information about chiropractic and body work. This is not to suggest that allopathic physicians be trained to treat patients with these techniques, but rather that they be well-enough informed to discuss them knowledgeably with patients.

Using the Case Study Method

One way to achieve integration of CAM into the fabric of medical education is through the use of problem-based cases. This methodology, widely used in basic science courses in medical schools, can be incorporated into almost any medical curriculum in a variety of ways.

Actual patients and case studies have traditionally been used as vehicles for learning in the clinical years. An important part of the rationale for the more recent use of cases in the early years of medical education is to teach the requisite medical sciences in the context of a patient's story. Thus, while the students are acquiring knowledge about anatomy, histology, physiology, pathology, microbiology, and more, they are thinking about a real patient with a real-life family, occupation, interests, preferences, hopes, and fears, as well as a health problem. Third and fourth year students ponder diagnosis and treatment plans, recognizing that, in real life, most patients come with multiple social, emotional, and physical issues, not with only one clearly defined medical problem.

In the Harvard Medical School (HMS) elective, *Alternative Medicine: Implications for Clinical Practice and Research*, each theme chosen for the course is introduced by a case written from actual patient records. The study of the case proceeds through the following sequence:

- Students read and discuss the case.
- Students read selected relevant materials, including published research studies.
- The patient in the case visits the class.
- The alternative care provider in the case visits the class and answers students' questions.
- Students have an opportunity to experience the treatment.
- Students role-play relevant situations that arise with patients.
- Students and faculty evaluate the educational experience.

Case Example: "My Aching Back"

Frank Richards is a 46-year-old with a strong handshake and a salesman's smile who retired at 42, after having successfully managed and owned four restaurants. He is currently investigating other business opportunities, but is troubled by intermittent, severe low back pain. His medical history is significant for mild hypertension for which he initially tried nonpharmacologic therapy (i.e., salt restriction, aerobic exercise, and relaxation response techniques). Ultimately, he resorted to pharmacotherapy to adequately control his blood pressure. He currently uses Enalapril, 5mg PO q.d. and has a blood pressure of 120/80.[6]

The full case describes Frank's medical history in detail, and his pursuit of relief for his low back pain that eventually leads to treatment by a chiropractor. The case objectives describe what the student is expected to accomplish. Study questions supplement those raised by the students when they meet the patient and a chiropractor in class.

The Experiential Component

Students are offered the opportunity to experience an example of chiropractic adjustment while they are studying the back pain case. While studying other cases, they can sample acupuncture, therapeutic massage, energy healing, and a macrobiotic meal. This experiential component affords students a sense of what the patient experiences with these alternative therapies. From meeting the alternative care provider and experiencing the therapy, students gain an in-depth understanding that they could not acquire by reading and discussion alone.

Other cases in the HMS alternative medicine course are:

- Let Like be Treated by Like (Homeopathy, energy healing)
- An Odyssey of Healing (Macrobiotic diet, herbal remedies, vitamins)
- I'm Using AZT, DDI, and Bactrim, Now What? (acupuncture, guided imagery, psychic healing)[7]

An ongoing criticism of CAM is that the efficacy of many of the therapies is unmeasured. One of the major goals of the HMS alternative medicine course is to promote critical reading of the relevant literature. Each of the above cases is accompanied by extensive, carefully selected readings. Students are taught to critique research design and are required to write a proposal for a study of a CAM therapy as a final project for the course.

Talking to Patients and CAM Providers

Another essential skill for future physicians is the ability to discuss the use of CAM therapies with patients. A session in HMS' required *Commons/Patient Doctor III* course for third-year students focuses on this topic. The fact that studies show that more than 70 percent of patients do not tell their primary care physician about their use of CAM reinforces the need for these sessions.[1,6] Such non-communication raises concern about possible adverse effects, particularly interactions between herbal remedies and prescription medications. It is the physician's obligation to broach the subject in a respectful and non-judgmental manner, ending the "don't ask, don't tell" approach.[8]

In addition to talking with patients about their use of CAM, future physicians need to communicate effectively with their patients' alternative care providers. They should be prepared to discuss plans for responsible co-management with all parties at the table—the patient, the primary care physician, and alternative providers.

Student and Faculty Interest

Student groups at Harvard and many other medical schools have sparked interest in including CAM in the curriculum. Plans for a student-initiated conference are currently under way at Brown University School of Medicine. Innovative CAM offerings have been developed and introduced entirely by student efforts at University of California at Davis, University of Alabama, and Washington University in St. Louis. Interested faculty members have also been responsible for the development of the curricular content at many of the 75 U.S. medical schools who reported including CAM in their courses.[4]

A major conference is being planned for November 1999 by the Center for Bioethics and the Dean's Working Group on Alternative Medicine at the University of Pennsylvania. This conference will feature editors of prominent medical journals, and top academic thinkers in alternative medicine.[9] For both students and faculty, this is only the beginning of the development of an important part of the medical curriculum for the 21st century. ■

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Legal Considerations in Referral to Alternative Medicine

by
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In 1997, American chiropractors, acupuncturists, massage therapists, naturopaths, and various other alternative medicine[1] practitioners received 629 million visits, for which patients paid more than $12 billion in out-of-pocket expenses.[2] This represents a dramatic increase in both use and expenditure through the 1990s. Employers and insurers, including several major managed care organizations such as Oxford Health Plans, Health Net, and Harvard Pilgrim Health Care, have responded to this demand by adding alternative therapies to the benefits they cover (*see Page 5*). Some states have enacted laws that require health insurers to include alternative treatments in the benefits they offer.[3]

Many physicians worry that they will be sued if a patient they refer to an alternative medicine practitioner suffers a poor outcome.

Despite this activity, coordination between conventional and alternative medical care remains poor. While measures to improve communication between physicians (M.D. or D.O.) and alternative medicine practitioners have been proposed,[4] they are hindered by a long-standing professional rivalry, a general lack of knowledge among physicians about the appropriateness and efficacy of alternative medicine, and the fact that many physicians are skeptical about such treatments.

A subset of these doubts and concerns about alternative medicine relates to medical malpractice.[3,5-9] Many physicians worry that they will be sued if a patient they refer to an alternative medicine practitioner suffers a poor outcome. Even when patients have independently chosen alternative treatment, physicians may be reluctant to discover or discuss this care with them for fear that if they know about it, they will be deemed to endorse it.

Liability for Referral to Alternative Medicine

As a general rule, a physician's mere referral of a patient to another physician, *without more*, does not expose the referring physician to liability.[10-12] This rule has been applied by courts throughout the country in cases involving referral among physicians. Yet in certain circumstances—alluded to in the "without more" qualification—the rule does not hold. These exceptional situations in the context of alternative medicine can be divided into two categories:

1 The choice of referral is negligent; or

2 The referring physician is held liable for the treating practitioner's negligence because the referring M.D. supervised the care, jointly-treated the patient, or knew the referred-to practitioner was incompetent.

Negligent Referral

In the first category, the referral itself falls short of the "reasonable" practice standard and is sufficient to form the basis of malpractice, regardless of the quality of care delivered by the practitioner to whom the referral is made. Of course, the law only applies if the patient suffers injury causally related to the substandard referral. But if, for example, an M.D. refers a patient to an alternative medicine practitioner instead of to a more appropriate practitioner, and the referral delays, decreases, or eliminates the opportunity for the patient to receive important care, the referring physician could be held liable.[13, 14]

Available empirical evidence on alternative medicine usage suggests that this type of referral liability may be more a theoretical concern than a practical one: the most commonly used alternative therapies treat minor ailments, or serious conditions for which conventional medicine can offer little in the way of therapeutic benefit.[2] Nonetheless, it does highlight an important reason why physicians who refer to alternative medicine practitioners should keep up to date with scientific findings about the efficacy of various alternative therapies. As knowledge about the appropriateness of alternative therapies expands, courts may determine that physicians act negligently when they refer patients for particular therapies that they know, or should know, offer no practical benefit to the patient.[15]

Vicarious Liability

The second category of exceptions is when the referring physician is considered partially or wholly responsible for referring the patient to a practitioner whose treatment negligently injures the patient. Under several situations the courts may impute liability in this way; all involve "vicarious liability" (liability of a person or organization for the negligence of an employed individual or agent).

First, when Dr. A refers a patient to Dr. B, and then exerts authority over the way Dr. B treats that patient, Dr. A may be held liable for Dr. B's negligent acts. To find vicarious liability, the law must determine whether Dr. B is Dr. A's agent. The question of whether an agency relationship exists, and hence whether vicarious liability may be appropriate for that reason, depends on the level of actual or apparent control maintained by the referring physician. Courts have generally been reluctant to find that one physician controls another, setting a fairly high threshold for plaintiffs who attempt to establish liability on this basis.[16-19]

Second, vicarious liability may be extended to the referring physician if the care given appears to be a joint undertaking. Cases that have bound defendants together in this manner have looked for a fairly high degree of unity in the practitioners' approach to treatment.[20,21] In fact, joint undertakings typically involve practitioners who act in concert, concurrently administering treatment to a patient, rather than being separated by the referral process.

Under current health care arrangements, this kind of situation is unlikely to arise between physicians and alternative medicine practitioners. However, it could emerge as a possibility if the providers are employed by the same hospital or health plan, and collaborate closely in providing patient care. This level of collaboration could also exist if physicians and alternative medicine practitioners render care in a jointly owned or operated clinic, or in "integrated" units within a hospital.

Courts may determine that physicians act negligently when they refer patients for particular therapies that they know, or should know, offer no practical benefit to the patient.

A situation in which the referring physician knows, or should know, that the referred-to practitioner is incompetent may bridge negligent referral and vicarious liability.[22-24] For example, if a physician is aware that a particular acupuncturist uses unsterilized needles, or that he has recently been the subject of serious disciplinary action by his professional board, then the physician may be considered negligent if a patient she refers to that acupuncturist suffers iatrogenic injury.

While the physician's liability in the above scenario is certainly a consideration, the courts have been far more active in holding institutions vicariously accountable in this area. The obligation hospitals and managed care organizations (MCOs) have to be diligent in selecting and evaluating health care professionals will extend to their relationship with alternative medicine practitioners.[25-27] Therefore, the MCO that credentials an incompetent acupuncturist may face liability as a corporation when a physician refers a patient to this practitioner for treatment, especially when it has established incentives or guidelines to facilitate this referral.

Continued on next page

Exploring Case Law Related to Alternative Treatments

by
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A review of some of the most characteristic examples among the relatively few legal cases related to alternative treatment highlights the issues that have caused liability for providers of traditional medicine. In turn, those issues identify appropriate loss prevention measures to consider when encountering patients who are concurrently consulting with, or planning to see, providers of alternative treatment.

Older cases (10 or more years ago) include decisions in which physicians' licenses were revoked for providing alternative treatment to their patients whether or not harm was done, e.g.:

- In *re George A. Guess, M.D.*, 327 N.C. 46, 393 S.E.2d 833 (1990), a physician's license was revoked for integrating homeopathy into his treatment of a patient even though the patient was not injured.
- In *Sletten v. Briggs* 448 N.W. 2d 607 (N.D. 1989), the physician's license was revoked for failing to stop treating a patient with chelation therapy who had been diagnosed with atherosclerosis and hypertension.

More recently, the courts have generally found for the patient if the provider's treatment delayed more conventional treatment and the patient suffered significant harm. However, in the cases cited below, the courts also found that: if the evidence indicated the patient had sufficient information about the risks and benefits for the prescribed treatment—and still chose to proceed with that treatment—the patient was assuming some of the risk.

***Charrell v. Gonzales* 673 N.Y.S.2d 685 (1998)**
A case recently decided by the New York Court of Appeals involved a patient who declined conventional chemotherapy and radiation therapy for cancer treatment. Instead she chose alternative treatment from the defendant M.D. which included nutritional supplements and coffee enemas. The cancer metastasized to her spine before she was successfully treated with radiation therapy. Unfortunately, she developed retinopathy associated with the cancer and is now blind in both eyes.

The court found for the plaintiff, noting that the physician's deviation from accepted medical practice was the proximate cause of the plaintiff's injuries. The court held that the physician failed to appropriately inform the patient with respect to the risks of the treatment and the alternatives he offered.

The court, however, also found that the patient assumed some of the risk, noting that she was "a well-educated person, who...did a significant amount of investigation regarding the treatment being offered by the defendant and hence became quite knowledgeable on the subject."

***Schneider v. Revici* 817 F.2d 996 (N.Y. 1992)**
In another case decided by the New York Appeals Court from 1992, a woman with a breast mass declined her physician's recommendation to see a surgeon and have a biopsy. Instead, she told him that she wanted to be treated without surgery. She sought out Dr. Revici, a physician who claimed to treat cancer patients with "non-toxic," non-invasive methods that had not been adopted by the medical community. His unconventional therapy included ingestion of mineral compounds and monitoring urine: steps he said would shrink and eliminate the tumor. The patient claimed that Dr. Revici never advised her to get a biopsy, or to have the tumor removed even after 14 months of treatment (at which point, the cancer had spread to her lymph nodes and the tumor had significantly increased in size. Revici argued that the patient had signed a detailed consent form (which he was unable to produce at trial).

While examples of physician liability in this area are few, some specific loss prevention strategies are appropriate to list: 1) maintaining a collaborative relationship with patients to encourage and foster joint decision making about all types of treatments; 2) careful documentation of conversations detailing discussions of risks and benefits of all proposed treatments; and 3) encouraging patients to report back concerning their experience with other forms of treatment, so that ongoing collaboration is maintained.

Importance of Licensure

The above observations assume that courts are not prepared to make presumptive judgments about the competence of alternative medicine practitioners based solely on their idiosyncratic approaches to health care. Should such generic dismissal of a given therapy receive legal viability, it would have serious legal ramifications. It would allow liability of the referring physician to be inferred in a much wider range of cases —not merely those in which there is knowledge about a *particular* practitioner's incompetence.

The courts do not yet appear to have considered this important issue directly. A review of litigation brought against alternative care practitioners shows that the courts assess the conduct of individuals who are appropriately licensed and regulated by state authorities as they would any health care professional (*see Page 12*). Alternative care practitioners are generally held to standards of care that are enunciated by their professional peers. Courts assess malpractice claims against *licensed* alternative medicine practitioners according to standards set by the particular "school" itself. Presumptions of *inherent* incompetence are not generally made—a comforting result for physicians who are concerned about liability for referring their patients for alternative therapies. Most importantly, it highlights the importance of ensuring that any alternative practitioner to whom a referral is made is licensed.

Conclusion

Opening a professional dialogue between physicians and alternative medicine practitioners is crucial to better health care for those patients who choose alternative medicine. This need can be expected to grow with alternative medicine use, particularly as health insurers include alternative therapies in the benefits they offer. The larger solution lies with better education for physicians about alternative medicine, and more comprehensive outcome studies and randomized trials assessing the efficacy and relative safety of alternative therapies. However, clarification of medical liability issues should help remove a significant obstacle to integration and continuity of patient care.

Physicians who currently refer to alternative medicine practitioners, or who are contemplating doing so, should not be unduly concerned about the potential liability implications of their conduct. The same common sense considerations applicable to other referrals are a reasonable guide regarding acceptable practice. More specifically, it may be useful to ask the following questions.

1 Is there good evidence to suggest that the therapies a patient will receive as a result of the referral will offer no benefit or will subject the patient to unreasonable risks?

2 Do I have any special knowledge or experience to concern me that this *particular* practitioner could be incompetent?

3 Is the practitioner licensed in my state? (Some added comfort can also be derived from knowing that the practitioner carries his or her own malpractice insurance.) and

4 Will this be the usual kind of referral (i.e., basically at arm's-length, without ongoing and intrusive supervision of the patient's management)?

"No" answers to the first two questions and "yes" answers to the last two should remove many of the physician's concerns that the referral decision will be construed as negligent. This conclusion holds even if the patient suffers an injury caused by the alternative medicine practitioner's negligence. The alternative medicine practitioner should be held accountable for his or her autonomous actions, and be judged according to standards set by his or her fellow-practitioners. ■

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