



Safety Issues in Complementary & Alternative Health Care

The Convergence
of Complementary,
Alternative &
Conventional
Health Care:

**Educational Resources
for Health
Professionals**

This publication is one in a series of educational resource materials on complementary and alternative health care issues published by the Program on Integrative Medicine, University of North Carolina at Chapel Hill, entitled:

The Convergence of Complementary, Alternative & Conventional Health Care: Educational Resources for Health Professionals

Titles in the series include:

Understanding the Convergence of Complementary, Alternative & Conventional Care in the United States

Concepts of Healing & Models of Care

Evidence-Based Medicine & Complementary & Alternative Therapies

Assessing the Effectiveness of Complementary & Alternative Medicine

Safety Issues in Complementary & Alternative Medicine

Evaluating Information Sources for Complementary & Alternative Health Care

Information Sources for Complementary & Alternative Therapies

Integrating Complementary & Alternative Therapies With Conventional Care

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Safety Issues in Complementary & Alternative Health Care

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THE CONVERGENCE OF COMPLEMENTARY, ALTERNATIVE & CONVENTIONAL HEALTH CARE

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Safety Issues in Complementary & Alternative Health Care is one publication in a series entitled *The Convergence of Complementary, Alternative & Conventional Health Care*, developed as an educational resource for health professionals by the Program on Integrative Medicine, University of North Carolina at Chapel Hill, with support from the National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health.

This series responds to the many questions raised as conventional health care practitioners encounter widespread and increasing use of complementary and alternative therapies. Each publication in the series highlights one or more of the key issues facing health professionals today—including assessing information, safety, and efficacy; appreciating alternative healing concepts; and effectively integrating conventional, complementary, and alternative health care.

Safety Issues in Complementary & Alternative Health Care explores issues related to the safe use of complementary and alternative therapies, the comparative risks of complementary and conventional care, and the specific safety concerns that emerge when conventional and complementary and alternative health care practices converge.

Safety Issues in Complementary & Alternative Health Care

foreword

Not many years ago, the use of complementary and alternative therapies in the United States was assumed to be an infrequent occurrence. Consequently, conventional health care practitioners had little knowledge of these practices and even less understanding of safety considerations related to their use. But research in the 1990s revealed extensive and rapidly growing use by Americans of a wide range of complementary and alternative therapies. In fact, a large percentage of patients receiving conventional medical care now also use complementary and alternative care.

For the conventional practitioner, this finding raised two immediate questions: “How safe are these therapies?” and “What risks are involved when patients combine the use conventional and complementary therapies?”

Safety Issues in Complementary and Alternative Health Care was written in response to these questions. Ironically, this task was undertaken at the same time that research was revealing serious safety issues confronting conventional medicine. Thus, the following discussion examines complementary and alternative medicine’s safety not in isolation, but in the context of a conventional medical system that itself poses high risks to patients, and is increasingly interacting with a variety of complementary and alternative therapies.

The primary purpose of this publication is to assist health care providers—alternative as well as conventional—to understand the safety issues that arise when their practices meet.

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Specifically, the objectives are to assist readers to:

- understand the risks and safety issues that arise from the convergence of conventional, complementary and alternative medicine;
- identify safety problems specific to complementary and alternative medicine;
- be aware of issues related to credentialing and professional monitoring of complementary and alternative health care providers; and
- communicate effectively about these safety issues with patients.

Finally, a note about the terminology used in this publication. In recent years, the term “CAM” has come into common usage to describe, in the words of the National Center for Complementary and Alternative Medicine, “*a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.*” Despite its convenient brevity, the acronym CAM has some unfortunate implications. It suggests, for example, a homogeneity among the practices included under the umbrella term—something that is not at all true. It also implies a clear and complete distinction between conventional and CAM systems of care. That also is inaccurate. Therefore the term CAM is used sparingly, and only as shorthand for that “group of diverse medical and health care systems. . .” where the emphasis is on the word “diverse.”

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Safety Issues in Complementary & Alternative Health Care

*“You medical people will have more lives to answer for
in the other world than even we generals.”*

—Napoleon Bonaparte

One cannot examine the safety of complementary and alternative therapies in isolation. They are components of a larger, complex system of health care and their safety must be considered along with that of all health care services and products.

A widespread public belief is that non-mainstream therapies pose a higher risk than conventional treatments. In fact, adverse effects of complementary and alternative therapies are relatively infrequent compared to those of conventional medicine. The perception persists, nonetheless.

Paradoxically, the public’s assumption that the safety of conventional medicine is assured by regulations and the education and training of health professionals also may be a misperception (*see box, below*). Certainly the incidence of deaths resulting from medical error and adverse pharmaceutical effects should raise serious questions about the safety of conventional medical care. In addition, new research continually uncovers dangers of accepted treatments that were once thought to be highly safe and beneficial. A case in point is the widely publicized study of over 16,000 postmenopausal women concluding that hormone replacement therapy (Prempro®) significantly increases the risks of coronary artery disease, stroke, and pulmonary embolism after five years of treatment (Writing Group for the Women’s Health Initiative Investigators, 2002). These findings contrast dramatically with the guidelines and clinical practice in treating menopause over the last 15 to 20 years: that this therapy protected women from these same health risks. Thus, to fully appreciate the safety issues related to complementary and alternative medicine, it is important to take a balanced view of the risks and safety of all forms of medical treatment.

Equally important is the understanding of the safety implications of a health care system where complementary and conventional practices intertwine. It is clear that not only are many

NUMBER OF DEATHS BY SELECTED CAUSE IN 1999

Medical errors	44,000
Medication errors	7,000
Motor vehicle accidents	43,458
Breast cancer	43,297
AIDS	16,516
Workplace injuries	6,000

SOURCE: Kohn, Corrigan, & Donaldson (Eds.), 2000

FACTORS IN COMBINATION AFFECTING TREATMENT OUTCOMES & SAFETY

PATIENT FACTORS

- Age, gender, race
- Severity of disease/illness
- Course of illness (speed of progression or variability)
- Individual responses to the intervention or medication
- Other clinical factors or co-morbidities
- Ability to pay for care

CLINICAL FACTORS

- Known adverse effects of the intervention/medication
- The delivery system of treatment
- Relative effectiveness of the treatment
- Clinician's level of knowledge, expertise, skill, and fallibility

people using complementary and alternative therapies, but most do so *in combination with* conventional care (Eisenberg, et al., 2001). Different systems of health care do not simply co-exist, but interact—usually without guidance from their respective health care providers. This complexity is compounded by widespread product marketing on the part of both pharmaceutical *and* complementary and alternative companies directly to the public through the television and Internet.

Risk and safety issues in health care may thus be examined from three perspectives. First, there are the issues of safety in conventional medicine; second, there are safety issues particularly relevant to complementary and alternative therapies; and, third, there are the issues arising from overlapping care that patients may receive from both types of practitioners.

defining safety, assessing risk

It would be helpful in day-to-day clinical practice if it were possible to define a standard level of acceptable risk or safety threshold for all medications, herbal and nutritional products, and procedures, including surgery. This is an unrealistic goal, because an assessment of risk and safety depends on *combinations* of many factors (*see box, above left*). Patient factors that affect outcomes include age, gender, race, the severity of the disease, its course and

progression, the individual patient's response to the intervention, and the patient's ability to pay for care. These combine with a variety of clinical factors, including known adverse effects of the intervention, the delivery system of treatment, the relative effectiveness of the treatment, and the clinician's expertise.

For example, the *Physician's Desk Reference* contains a vast array of pharmaceuticals—both single agents and combination products—that are associated with a wide range of side effects occurring in from less than 1 percent to 15 percent of patients. Therefore, advising the patient is necessarily a highly individualized and complex exercise for the health professional. In conventional medicine, effectiveness and safety of treatment are closely linked as part of the formation of standards of care over time (Cohen & Eisenberg, 2002). Although these standards are continually evolving, when counseling the patient or family, the clinician must always consider whether the test or treatment is:

- Effective and relatively safe (for example: a conventional hypertensive medication; acupuncture for pain or nausea; massage for low back pain; saw palmetto for benign prostatic hypertrophy).
- Effective, but with some potential or recognized adverse outcome (for example: antibiotics causing allergy; *ginkgo biloba* causing increased bleeding tendency; St John's wort or kava kava affecting liver function).
- Effectiveness is unclear (insufficient evidence) but relatively safe (for example: short course of steroids for acute low-back pain; Echinacea for viral influenza; mind-body techniques for anxiety).

- Effectiveness and safety are unclear or questionable (for example: hormone replacement therapy for menopause (Writing Group for the Women's Health Initiative Investigators, 2002); surgery for chronic low-back pain; *Panax ginseng* for multiple sclerosis).
- Ineffective with potential or established harmful effects (for example: chaparral).

Good clinical judgment requires knowing the toxicity, quality, and cost of the procedure or product; careful monitoring of the diagnostic test or treatment; and assessing the benefits versus the risks. The clinician's responsibilities also include communicating openly about management options, demonstrating professional competence, and ensuring ethical behavior.

Potential harm to patients comes not only from direct risks, but also from 1) financial loss due to payment for ineffective treatments, 2) indirect damage due to delay in diagnosis or treatment, or 3) misunderstandings due to biased or incomplete information. All can lead to undesired outcomes. A well-informed clinician with good listening and communication skills can help patients avoid adverse effects.

the safety of conventional health care

In conventional medicine, safety is generally assured by societal agreements that the federal government is responsible for monitoring the development and safety of pharmaceuticals and new technical procedures, and that professional organizations and other government agencies will oversee medical training and safe and ethical medical practice. The main agency in the government responsible for safety is the Food and Drug Administration (FDA). Health professional societies and training organizations are responsible for the ethics and competence of practitioners, and hospitals are responsible for the safety of patients and professionals working within their confines. Certifying boards operate in all states to regulate various health practices while protecting the welfare of the public. State medical boards, for example, have been required to license and monitor the quality of conventional medical practitioners since 1912. Nurses have been licensed under state nursing boards since 1903, and nurse practitioner licensing went into effect in North Carolina in 1974.

Although widespread, these monitoring systems are not always effective or adequate, and failure of practitioners to comply with standards and regulations often goes unreported. Recent studies have shown that HMOs and hospitals rarely report incompetent physicians as required by law and that the quality of conventional health care needs substantial improvement (Chassin & Galvin, 1998; McCormick, Himmelstein, Woolhandler, Wolfe, & Bor, 2002).

There have been recent improvements. As of January 2001, federal law requires that Medicare patients be allowed access to their medical records if there are complaints about their care (*New York Times*, Jan. 1, 2001). Additionally, information on disciplinary action against physicians can now be requested through the Federation of State Medical Boards website (www.docinfo.org). Information on incompetent physicians is also maintained in the National Practitioner Databank; similar information is available from the Board of Nursing (www.ncbon.com) about impaired nurses.

Still, despite the many mechanisms developed to protect the public and insure quality of care, problems remain. In fact, there is evidence that some patients have turned to complementary and alternative therapies because they fear the toxicity or side effects of modern drugs and treat-

HIGH-RISK MEDICINE

The organization of conventional medicine, coupled with its emphasis on pharmacological care, creates a high-risk system. Recent examples of the dangers include:

- Wolfe et al, estimated there were 103,000 serious gastrointestinal complications and 16,500 deaths related to NSAIDs in patients with arthritis, costing over \$2 billion annually (Wolfe, Lichtenstein, & Singh, 1999).
- The Kellogg Foundation examined 30,195 patients in the United States and reported a 3.7 percent medical error rate.
- A 1998 JAMA meta-analysis of 39 prospective studies reported adverse drug reactions (ADR) occurring in 6.7 percent of hospitalized patients. The authors estimated that, in 1994, 10,600 fatal adverse drug reactions occurred (Lazarou, Pomeranz, & Corey, 1998).

A 1999 Institute of Medicine study estimated that 225,000 iatrogenic deaths occur each year in the United States. Of these, 12,000 deaths are associated with unnecessary surgery. The study also reported that of 106,000 adverse effects of correctly prescribed drugs, 50 percent were preventable (Kohn, Corrigan, & Donaldson, (Eds.), 2000).

pharmaceutical industry, health care practitioners and hospitals, medical schools, and governing agencies—including the NIH and the FDA. Because of these entangled relationships, health care providers are enmeshed in the pharmaceutical industry's efforts to research and promote its established and emerging products. For example, there is good evidence that systematic reviews and meta-analyses of therapeutic interventions (often funded by pharmaceutical companies) focus mainly on reporting effectiveness data and give little information on safety (Ernst & Pittler, 2001) This practice tends to downplay safety issues in favor of boosting the marketing of the drug (Angell, 2000a&b; Angell, 2004).

Analyses of the types of adverse effects in conventional medical care occurring in western countries reveal significant problems in many areas, including operative errors, medication errors, and adverse pharmaceutical effects (Alberti, 2001). Indeed, medical errors (*see box*) are the third leading cause of death after heart disease and cancer (Kohn, Corrigan, & Donaldson, 2000).

This is not a problem confined to the United States. Worldwide, there is increasing awareness of the dangers of conventional medical practice occurring in hospitals, pharmacies, physicians' offices, nursing homes, and home care programs. The Australian government reports, for

ments and because they mistrust medical providers and their institutions or means of providing care (Astin, 1998).

the iceberg of safety problems

The structure of the health care system itself leads to safety problems. Research shows, for example, that improved health outcomes correlate with well-organized primary care; but the United States has a poorly developed primary care system (Starfield, 2000). The reliance on health insurance as the principal way of regulating access and the constant changes in those delivery systems create numerous safety and quality assurance problems. Social and income inequalities result in delayed, inadequate, and discriminatory patient care. Additionally, the structure of the delivery system results in discontinuous and poorly coordinated care by generalists and specialists and poor communication among practitioners. The particularly high reliance on technology, tests and procedures often leads to indiscriminate and costly treatment—with the accompanying potential harms, such as unjustified procedures and treatment arising from false-positive results (Starfield, 2000; Fisher & Welch, 1999).

Perhaps most significant is the power and influence of what might be called the “medical-industrial complex.” This term describes the pervasive and dominating relationships between the

example, that preventable medical errors in hospitals are responsible for 11 percent of all deaths in Australia. In the United Kingdom, medical errors are the third most frequent cause of death, with one in 14 patients suffering adverse events such as drug reactions and diagnostic or surgical errors (“Medical Error,” 2000; *Sunday Times* (UK), Dec. 19, 1999).

pharmaceutical safety

While there has been important progress in recent decades in developing reliable, effective medications, the emphasis on and enthusiasm for effectiveness has often overshadowed issues of safety. Thus, despite federal drug regulations, use of clinical trials, and the application of chemotherapeutic principles, there remain serious issues of safety related to pharmaceutical products and their applications.

In clinical settings, safety concerns include prescription and dosage errors, patient compliance, side effects, polypharmacy, and drug interactions. For example, 69 percent of medical injuries were judged to be due to errors in management while 19.4 percent were due to dosage errors in writing or preparing prescriptions (Bates, et al., 1995).

A number of factors contribute to these problems. It appears, for example, that clinicians often are not sufficiently aware of the potential side effects of the vast array of available drugs. In their busy practices, they neither have nor take the time to read about them in detail. Furthermore, a practitioner cannot always rely on the medical literature to clarify the risks. A few examples illustrate the magnitude and complexity of the problem.

- In a study of outpatient prescriptions, involving 11 ambulatory clinics in Boston, patients reported an 18 percent complication rate (although this was recorded in only 3 percent of clinic charts). Significant correlates of these complications were failure to explain side effects and situations where patients had multiple medical problems (Gandhi, et al., 2000).
- In 2000, the FDA used a fast-track process to get alosetron (Lotronex)—used to treat irritable bowel syndrome in women—approved and into pharmacies quickly. Clinical trials had shown that ischemic colitis occurred in 1 of 970 patients. After the drug entered the market, a number of patients taking this drug were hospitalized for severe constipation, bleeding, and ischemic colitis, some requiring surgery. Over all, the drug produced a therapeutic gain of only 10-15 percent over controls. It is of note that the drug was pulled from the market and is now being re-released.
- Seventy-five percent of U.S. patients receive a prescription for a pharmaceutical product from a doctor, nurse practitioner, or physician’s assistant. One in five patients experiences side effects, mainly from antibiotics, antidepressants, and anti-inflammatory drugs. And, in 20 percent of cases, the adverse effects last more than three months (Gandhi, et al., 2000).
- Three out of four adverse drug reactions are dose-related. This is largely because manufacturers develop dosage levels to prove significant effects, although there are many patients who respond well to lower dosages. For example, the recommended dose of hydrochlorothiazide has dropped over the years from 100 mg per day to 6.25 mg. People who are sensitive to caffeine, alcohol, and over-the-counter antihistamines often respond well to smaller doses of medicines (*Pharmacist’s Letter*, 2001).

As these examples reveal, many medical safety problems relate to pharmaceuticals in spite of an apparently rigorous evaluation and testing process monitored and regulated by the FDA. The

STAGES OF FDA DRUG APPROVAL PROCESS

Phase 1: Establish pharmacological actions and safe dosage range.

Phase 2: Conduct controlled studies in animals and volunteers to assess effectiveness and safety.

Phase 3: Conduct clinical trials testing larger numbers of patients in clinical settings who have the condition the drug is intended to treat.

Phase 4: Conduct “post-marketing surveillance” studies after FDA approval and marketing of the drug. This important stage may reveal adverse effects not shown in Phase 3. Many thousands of people are monitored while taking the drug—both actively (using survey and clinical evaluations) and passively (by voluntary reporting of adverse effects).

Fast-track drugs: This is an accelerated approval process for drugs for patients with serious diseases who are not able to receive effective therapy.

problem may lie partially in the sheer size of the agency’s responsibility. The FDA monitors about one trillion dollars worth of products annually and, in the last 10 years, more than 500 products have been approved for public use.

In the past, bringing a drug to market involved four stages of clinical evaluation required by the FDA. In 1997, the Food and Drug Modernization Act (FDMA) streamlined the drug approval process to help get drugs to market. Thus, only one clinical trial and surrogate end points were deemed enough to move a new drug through the approval process to market. This change has been severely criticized for lowering the standards of approval. Of the products approved this way in 1998, several were eventually removed from the market because of adverse effects—including mibefradil for hypertension, dexfenfluramine for obesity, and terfenadine for allergies (Lipsky & Sharp, 2001).

the risks & safety of complementary & alternative medicine

The evidence shows that conventional medicine has major problems in terms of patient safety and that the causes and solutions are complex. However, there also are issues of safety in the practice of complementary and alternative medicine

about which the public and clinicians should be aware. We know, for example, that health food store staff readily give consumers information, but that this information is often incorrect or misleading and staff often advocate unproven products (Gotay & Dumitriu, 2000). As more and more people use botanicals and nutraceuticals alone as well as in combination with other supplements and conventional drug therapies, health professionals need to know about adverse effects and interactions that can occur. They also need to know where to seek this information.

Four major kinds of issues are related to the safety of complementary and alternative therapies. The first are those resulting from the unique regulatory status of CAM products and practitioners. For example, because herbs and supplements are regulated as food rather than medicine, they lack the mandated efficacy and safety assurance mechanisms that are required of pharmaceuticals. A second area of concern relates to the many different approaches to testing and diagnosing illness taken by complementary and alternative practitioners. The variety in the underlying theories of illness makes standardization of clinical practices much more difficult. Third, issues of clinical competence are raised by the substantial variability in the training and/or standards of practice of these practitioners. Finally, there are a number of safety issues related to the standardization and biological efficacy of specific products and techniques.

general safety problems in CAM

In the early 1900s, state licensing laws came into effect to regulate the training and practice of conventional medicine and protect the public from fraud and abuse. These regulations, in conjunction with the rise of biomedicine and the pharmaceutical industry, essentially marginalized other healing systems, often making them illegal.

Legislation also played an important role, setting the stage for the environment in which complementary and alternative therapies are practiced today. In 1906, the Pure Food and Drugs Act was introduced because of widespread food production scandals and deaths from bacterial contamination (Nadakavukaren, 2000). At that time, the act required only truthful labeling of products. Subsequently, the 1938 federal Food, Drug and Cosmetic Act (FDC Act) required drugs to be tested for safety (composition, quality, labeling, and directions for use), but effectiveness of drugs was not addressed (Lewis & Strom, 2002; Burdock, 2000).

In 1962, the Kefauver-Harris Amendments to the 1938 FDC Act required for the first time that stringent testing be used to prove that drugs were effective (Kauffman, 1995). (Homeopathic remedies have been exempted from safety testing since 1938, perhaps because the remedies contain minimal amounts of biologically active compounds.) However, in 1994—partly in response to lobbying by the dietary supplement industry and partly because of personal belief in the reported health benefits of supplements—members of Congress passed the 1994 Dietary Supplement Health and Education Act (DSHEA) (Burdock, 2000; Lewis & Strom 2002; Dietary Supplement Act of 1994, 1995).

Dietary supplements under DSHEA are clearly defined and include “an herb or other botanical” as well as vitamins, minerals, metabolic extracts, and amino acids. Manufacturers of dietary supplements must provide the FDA with evidence the product is “reasonably expected to be safe” (Lewis & Strom, 2002). The requirements for determining safety are not as stringent as are those for food additives and pharmaceutical drugs. Herbal product manufacturers need not submit results of clinical trials to substantiate safety claims; in fact, herbal substances in common use prior to the enactment of the bill are “grandfathered;” i.e., they are marketed lawfully without FDA approval (Burdock, 2000). Thus, under current law, it is the government’s responsibility to show that an herb or supplement is unsafe (Burdock, 2000). Only then are vendors forced to stop selling their product. Manufacturers now strive to follow the FDA’s Good Manufacturing Practices (GMPs) and report this on their labels.

In contrast, the German government regulates herbal products and pharmaceuticals in a similar manner in terms of safety and efficacy. The standards for approval of herbal ‘drugs’ are more lenient than those for pharmaceuticals, however (Blumenthal, 1998). The limited regulation of complementary and alternative products and treatments and the increasing number of patients who use CAM and conventional medicine concurrently, has led to a number of broad safety concerns that deserve special attention, including labeling and mislabeling, misrepresentation, misapplication, misdiagnosis, substitution, interactions, double-dosing, and adverse effect reporting.

labeling & mislabeling

Since 1999, federal regulations require that food and dietary labels be more comprehensive, showing all ingredients and the daily reference value in the label box. Minerals must be uniformly listed and herbs and herbal extracts must be listed with their common name and Latin name.

Labeling problems often have to do with the “other ingredients” noted on the label. These usually consist of additives that help construct the product delivery vehicle—fillers (to add bulk), binders (for tablets), lubricants (to help manufacturing), coatings (to aid swallowing), and colorings. Some of these products can cause allergies or biological effects or reduce absorption—and are often given disguised names. For example, “glaze” (natural, confectioners, pharmaceutical) is a euphemism for shellac. As in conventional medicine, potential reactions may occur with food colorings, various gums, preservatives such as benzoates and propionates, and lubricants (stearates, vegetable and castor oil). The supplier may have added other ingredients without informing the purchaser.

Mislabeled occurs when the product does not contain the items listed on the label, or contains ingredients with incorrect quantities/concentrations. For example, studies have shown that the amount of ginseng in most commercial ginseng products is highly variable and is generally less than indicated on the label (Cui, Garle, Eneroth, & Bjorkhem, 1994; Feifer, Fleshner, & Klotz, 2002). Magnets may not deliver the magnetic field strength (gauss) claimed by the manufacturer. Labeling also often fails to identify pharmaceuticals and toxic agents (heavy metals and pesticides) contained in herbal products (Straus, 2002).

In response to labeling concerns, since March of 2003, the FDA has drafted Current Good Manufacturing Practices (cGMPs) to “ensure that the identity, purity, quality, strength, and composition of dietary supplements are accurately reflected on the product label” (FDA, 2003b). These new guidelines should significantly improve the quality of dietary supplements, although they will not address underlying issues of the safety of the botanical ingredient (Kroll, 2003).

misrepresentation

Therapies or products may claim effectiveness using treatments and diagnostic procedures that have yet to be conclusively demonstrated. Such misrepresentation may not cause harm and the products or treatments may be quite safe. However, the use of these treatments may be unnecessary and costly while delaying access to existing effective care. An example of such an unproven treatment would be the use of acupuncture to treat diabetes, possibly distracting the patient from seeking conventional care.

misapplication

It is likely that inappropriate self-dosing by consumers has led to problems of toxicity or adverse interactions with other medications, but this issue has not been studied systematically. Misapplication may occur because of inadequate training or experience on the part of the practitioner. It is not uncommon for complementary and alternative practitioners to expand the scope of their practice to include other healing systems. Many chiropractors, for example, offer acupuncture and nutritional counseling. However, while well credentialed in their own field, they may not have adequate training or certification in the new discipline. The same problem may arise when conventional clinicians begin to use complementary and alternative therapies.

Variability in training and credentialing among some CAM practitioners may contribute to this problem. For example, the education of chiropractors varies according to the training school, either including or excluding study in the use of nutritional supplements and acupuncture. Naturopathic practitioners may be trained by a six-week correspondence course or attend a four-year post-baccalaureate degree program. The possibility of misapplication is clearly much greater for those with less training.

misdiagnosis by the clinician

Risks are incurred when the clinician fails to detect the actual medical problem or assigns the wrong diagnosis to the patient. This is particularly likely when the diagnosis is governed by a very narrow diagnostic paradigm. For example, iridology uses patterns in the iris of the eye, reflexology uses patterns on the soles of the feet, and electro-diagnostic instruments (the neuro-calometer developed by chiropractic in the 1930s) are used by chiropractors to recognize diseased organs.

Of course, diagnostic problems also commonly occur in conventional medicine, either by missing the diagnosis, making the incorrect diagnosis, or “over-diagnosing” the problem (Chassin & Galvin, 1998). Missing the diagnosis—which results from errors of omission, such as not doing an adequate physical examination, failing to do an appropriate test, or misinterpretation of test results—most often occurs in primary care. Over-diagnosing—which results from errors of commission, such as identifying a prolapsed lumbar disc that “requires” surgery, or getting a false positive test for benign prostatic hypertrophy—tends to occur most often in specialist care. Also in conventional medicine, laboratory errors that may lead to invasive testing and treatment by the clinician are quite frequent (Sox, 1996).

substitution for or delay of appropriate therapy

Indirect safety risks may result from the substitution of a more invasive or ineffective therapy for the “appropriate” therapy. (Of course, in medicine there is always uncertainty about what is actually appropriate for an individual patient in a given situation.) This problem is often seen within conventional medicine, as in a surgeon’s being too quick in recommending back surgery, before the patient has explored less invasive therapeutic options. This problem may also arise with respect to CAM therapies: a patient might delay or substitute use of a safe, effective conventional therapy so as to use a riskier or unproven alternative; or, the patient who is receiving appropriate conventional therapy may stop it in spite of health risks, on the recommendation of a CAM practitioner. An example is the case of a middle-aged diabetic woman whose CAM provider recommends that she stop oral hypoglycemic drugs before starting to use a traditional Chinese remedy and whose diabetes consequently goes out of control.

It is important to note that substitution for, or delay of “appropriate” therapy may not necessarily pose a safety risk. In fact, the appropriate treatment for a particular patient may well be a complementary therapy or a combination of CAM and conventional treatment. Moreover, harm may result from conventional providers’ dismissing the use of any complementary or alternative therapy for “lack of evidence of efficacy,” thus dissuading patients from using potentially helpful therapies. It may well be that the evidence for effectiveness exists, but that the clinician is unaware of it. The real issue is one of information transfer and communication. In all fields of medicine, it is essential that communication between clinicians about their respective serious risks may arise when one practitioner’s treatment supersedes another and the respective clinicians are not in communication.

interaction between CAM & conventional medicine

Of particular concern are problematic interactions between conventional medications and dietary supplements. After all, one in six adults taking prescription drugs also takes at least one herbal product (Kaufman, Kelly, Rosenberg, Anderson, & Mitchell, 2002). While some interactions are life threatening, other, more subtle problems may also result. A complementary product or

treatment might counteract a medication, dilute its effects, or enhance its properties, creating an inadvertent “overdose.” And often the effect is not obvious and may thus compound over time. One example occurs in organ transplant therapy when blood levels of cyclosporin and indinavir are significantly decreased when St. John’s wort is started, resulting in rejection of the transplanted organ (*Medical Letter*, 2000). St John’s wort taken for longer than 14 days also alters the metabolism of other conventional medications by affecting liver enzyme function (Wang, Gorski, Huang, Lesko, & Hall, 2001).

double-dosing

Patients often take many different commercial CAM products at the same time. Many herbal and nutritional supplements sold to the public are branded for different health maintenance and prevention purposes, such as “anti-aging,” “menopause,” or “cholesterol defense formula.” Thus, it is fairly easy to take multiple sets of many of the same ingredients—particularly if labels are unclear about the ingredients. The mail-order company Bronson, for example, sells Anti-Aging, a “complete men’s formula that contains 12 vitamins, 8 elemental nutrients, and 5 herbs for prostate, cardiac, and immune health.” Based on this form of marketing, patients may take several doses of the same herb or vitamin and not be aware of the total dosage.

adverse effect reporting

In order to understand the risks of diagnosis or treatment and convey this information to patients, there needs to be some evidence of the frequency and severity with which adverse events occur. With many complementary therapies, adverse events may be difficult to identify. First, one often does not have adequate information about the potential for a specific adverse event. Second, patients who are using complementary therapies and their providers often fail to report abnormal events or symptoms as an adverse event (Blendon, DesRoches, Benson, Brodie, & Altman, 2001). Third, many experts disagree on whether an adverse event has actually occurred. Fourth, aside from the surveillance system put into place at the FDA’s Center for Food Safety and Applied Nutrition (CFSAN) in July, 2003, called the CFSAN Adverse Event Reporting System (CAERS), there is currently no organized state or national system for reporting adverse effects of complementary and alternative therapies (FDA, 2003a). CAERS has its limitations. Although both health professionals and the general public can report serious adverse events to herbal products as well as foods, cosmetics, and vitamins, the FDA does not have anyone on staff with the necessary expertise to evaluate a reaction to an herbal substance (personal communication, Dr. Ken Falci, July 2003).

In any event, a fairly large number of subjects or incidents are needed to establish whether an adverse effect is linked to a particular therapy. Ideally, this information would be gathered through large clinical trials. However, thus far, these have not been undertaken in research on complementary and alternative therapies, and practical constraints make it more likely that surveillance type epidemiological data will be used to indicate effects (Ernst & Pittler, 2001).

International reporting systems do exist, although the classification of adverse effects is in its infancy (Farah, Edwards, Lindquist, Leon, & Shaw, 2000). A study in the United Kingdom showed that about 26 percent of consumers of herbal products do not report minor or serious adverse effects to their physicians or pharmacists, although they would do so for a problem with conventional medication. This suggests that there may be future problems in identifying the adverse effects of complementary and alternative therapies (Barnes, Mills, Abbott, Willoughby, &

Ernst, 1998). Many CAM therapies are considered “natural” and assumed to be without harm (Matthews, Lucier, & Fisher, 1999). This assumption is valid for a number of practices, such as meditation, spiritual healing, and homeopathy. However, some therapies have potential dangers and should be used with caution. Adverse events have even been documented with psychic practices such as voodoo. Chelation therapy and some dietary supplements can be harmful in certain situations. Adverse effects from dietary supplements may be related to the botanical ingredient itself or to contaminants; examples include the introduction of steroids into “natural” imported products for body builders (Wang, Wen, & Shiao, 1997).

diagnosing & testing safety concerns

Because many complementary and alternative practitioners employ diagnostic procedures and testing processes that are quite different from those used by conventional clinicians, there is concern about the accuracy and therefore the safety of these methodologies. For many of these procedures, although there is no research suggesting they are harmful, neither is there research that establishes their efficacy. Thus, questions about their usefulness and risk remain.

diagnostic procedures

In complementary and alternative medicine, certain diagnostic methods are used that are either unrecognized in conventional medicine or have not been validated. The unfamiliarity of these methods per se does not make them unsafe or invalid. Consistency, reliability, face validity, and usefulness in determining outcomes may indicate safe and valid practice. Research suggests that some CAM diagnostic techniques are valid, reliable, and useful, while others are not. For example:

- Traditional Chinese Medicine diagnosis of specific problems is generally consistent and reliable (Zhang, Bausell, Lao, Handwerker, & Berman, 2003). Chiropractic uses X-rays extensively, although it has been shown to be of little value in treatment outcomes (Ernst, 2001a).
- Manual assessment of joint dysfunction has moderate validity and inter-observer reliability (French, Green, & Forbes, 2000; Najm, et al., 2003).
- Reflexology, based on the premise that stimulation of reflexes enhances auto-regulation and thus healing, practices palpation of the feet, guided by charts that show representative organs and parts of the body on the foot surface, and is said to reveal dysfunctional reflexes in the body, with an abnormal feel in one particular area suggesting some dysfunction of the representative organ or a disease state. However, inter-observer reliability studies of reflexology show poor correlations between experienced practitioners (Ernst, 2001a).
- Iridology, based on the belief that organs and body regions are represented at a specific location on the iris of the eye, assesses the patient’s condition by inspection and enlarged photographs of the eye. This system has not been shown to produce clinically useful diagnoses (Ernst, 2001a).

Conventional practice may view variability in diagnosis as invalidating. However, from the perspective of many complementary medicine practitioners, variability in diagnosis may be quite acceptable, since diagnosis is based on the assessment of multiple data sources arising from personal, contextual, and physical factors that may be interpreted differently by different clinicians.

Although certain non-conventional diagnostic techniques may be of relatively little use, they may pose little or no risk to the patient. Even the concern that diagnosis using complementary medicine may delay the implementation of conventional investigation may be unfounded. There are no data to support this fear.

laboratory testing: conventional medicine

In general, risk and safety issues are not a problem in conventional laboratory testing because of the very rigorous quality assurance programs dictated by federal authorities. There are, however, always problems of variability, accuracy, and reliability of test results that must be taken into account by the clinician, especially if the test result seems unusual or does not fit the clinical picture (Sox, 1996).

Variability in test results in conventional laboratories can occur as a result of:

- **Biological variability:** the variability of physiology between patients or in one patient at different times, which involves such factors as gender, race, and age. This is why laboratories provide reference ranges of test results to clinicians.
- **Pre-testing variability:** involving such things as food intake, exercise, stress level, medications, and over-the-counter drugs taken by the patient just before the test.
- **Analytic variability:** the variability of laboratory measurement (materials, equipment, personnel skills, and procedures). This may be due to inaccuracy or imprecision and is minimized by rigorous analytic method monitoring and quality assurance using standards set out by national (American College of Pathologists) and federal laboratory regulations. All affiliated conventional laboratories participate in regular proficiency testing programs.
- **Post-analytic variability** comes from errors in reporting (e.g. transcription, identification) all of which affect a test's sensitivity and specificity.

The American College of Pathologists provides regular reports of error rates and quality assurance programs for laboratories all over the country (Rock, 1994).

non-conventional laboratories

With the growth in the use of complementary and alternative therapies, there has been a parallel increase in the number of laboratories that serve the particular paradigms and philosophies of those practitioners. In general, these approaches are based on the concept that human health and illness are much more susceptible than has been realized to the toxic effects (metal, chemical, radiation) of our environment and to the intake of synthetic products (including foods and drugs). Theoretically, identification of "poisoning" of the body can be rectified by avoiding and removing exposures and with special biological, dietary, and herbal treatments, and by cleansing and chelation (removal from the blood) regimens. These different tests and their interpretation do not escape the quality and accuracy problems identified for conventional lab tests. However, mainstream laboratory science remains skeptical about many of these claims of scientific usefulness, and little research has been done to evaluate the effectiveness of what has been called the "bioterrain approach."

Consequently, conventional clinical laboratories are concerned with four issues in relation to complementary diagnostic testing:

- Some conventional clinicians and a variety of complementary practitioners are using

non-traditional laboratories for special types of testing, such as measuring anti-oxidant defense levels to assess the patient's susceptibility to cancer.

- Many non-conventional laboratories perform tests for which there is, so far, little clear evidence that what is measured relates causally with clinical problems.
- With wider use of herbals and supplements, more incidents of interaction and toxicity may occur and will expand laboratory investigation. Many conventional laboratories may not possess the technology and trained personnel to evaluate these problems.
- There is increasing understanding that some of the substances used in complementary medicine, or their metabolites, interfere analytically with routine conventional laboratory tests.

NON-CONVENTIONAL LABORATORY SERVICES

One example of a non-traditional laboratory certified by the Clinical Laboratory Improvement Act (CLIA) is the Great Smokies Diagnostic Laboratory in Asheville, NC (www.gsdl.com). Its services to over 8,000 clinicians include:

- **Gastrointestinal assessment:** Comprehensive stool analysis, analysis of the ecology of the GI tract, wall integrity, small bowel bacterial overgrowth, presence of yeast, immune function, parasitic activity, intolerances, vaginal health. The usual purpose is to detect GI dysfunction and dysbiosis (incorrect bacterial environment—the leaky gut syndrome).
- **Immunology Assessment:** Comprehensive antibody and allergy assessment on serum (immediate and delayed IgG), for 120 different types of food and many non-food compounds.
- **Nutritional assessment:** Elemental analysis of hair and blood, for 20 elements (such as arsenic, cadmium, nickel copper, tin, amino acids), and 40 essential and metabolic fatty acids—to detect causes of unexplained symptoms, blood deficiencies or deviations from normal laboratory values.
- **Endocrinology assessment:** Sex and regulatory (e.g., thyroid) hormones in men and women. Identifying bone resorption (osteoporosis), usually using blood or salivary secretions.
- **Metabolic assessment:** Body detoxification processes, oxidative stress and antioxidant defense, cardiovascular markers.
- **Toxic element exposure profile:** In-depth assessment of exposures to a variety of industrial and chemical products encountered in daily life (e.g., aluminum, arsenic, barium, bismuth, cadmium, copper, lead, mercury, nickel), usually tested on hair, blood, and urine. Some clinicians and many patients believe that this type of toxicity may play a role in attention deficit disorder, Alzheimer's, Parkinson's, weakened immunity states, increased cancer risk, and gastrointestinal dysfunction.
- **Hair testing:** This has become a common test for these laboratories. It is used to assess nutritional status and toxic element exposure based on the organic substances trapped in the hair, and has been internationally approved as a reliable method of monitoring biological exposures if careful collection and analytic procedures are followed. For example, in a recent batch of hair analyses at the Great Smokies Diagnostic Laboratory, the laboratory technician noticed a high level of uranium from a sample from Simpsonville, SC. This level was 50 times higher than considered safe for humans. It was discovered that the town drew water from an area rich in natural uranium, and high levels were confirmed in other inhabitants. The town is now connected to the main Greenville water lines (Asheville Citizen, July 30, 2001).

NURSING AND COMPLEMENTARY THERAPIES IN NORTH CAROLINA

Many licensed nurses in North Carolina practice a variety of complementary therapies with their patients. These include massage, therapeutic touch, Reiki, and craniosacral therapy. The North Carolina Board of Nursing “considers it not in conflict with nursing law for nurses with the knowledge and skill to do the various complementary therapies as long as they are in compliance with related state laws.” Thus, nurses must be licensed in the modality (e.g., massage, acupuncture) where licensing is required.

Where complementary practices are less well defined and regulated, the Board examines cases referred to it individually, to determine if any nursing law has been violated (e.g., abuse, boundary violation) and if the nurse can demonstrate that he or she has the knowledge and skill to practice the therapy (e.g., craniosacral therapy).

The North Carolina Board of Nursing’s policy statement on complementary therapies is posted on its website:

www.ncbon.com/prac-rnfaq.asp

Non-conventional laboratories specialize in functional assessment and in the identification of a variety of environmental “toxins,” bacterial or fungal imbalances, and food and organism allergies (www.yorkallergyusa.com, accessed December 2004; Great Smokies Diagnostic Laboratories, www.gsdl.com, accessed May 2004). These are extensively used by naturopaths and clinicians practicing holistic or ecological medicine and provide testing not offered in conventional laboratories. The kinds of conditions for which these tests are done include: acne, asthma, cystitis, dental caries, depression, autism, ADHD, seizure disorders, candidiasis, irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, and postmenopausal problems. Most of these services are not reimbursable by insurance and may cost several hundreds of dollars (Ernst & Hentschel, 1995).

If a patient is having tests performed through a non-conventional laboratory, reliability of results can be increased by checking that the laboratory is in compliance with the Clinical Laboratory Improvement Act (CLIA) 1988 and that it is licensed by the state. The laboratory should be conducting regular proficiency tests against a national standard. This means that the laboratories are regularly inspected and certified. Of about 200 non-conventional laboratories studied recently, 80 percent were not participating in the CLIA program. (For a full report see CLIA Regulation of Unestablished Laboratory Tests at <http://oig.hhs.gov/oei/reports/oei-05-00-00250.pdf>, accessed December 2004.)

The kinds of testing services performed at non-conventional laboratories are shown in the box on page

13. Several factors have an important impact on the outcome of the tests, including sample collection and results interpretation. Samples must be collected carefully. Hair specimens, for example, are often contaminated from sweat, environmental agents, and cosmetics; other samples may be affected by daily fluctuations in metabolism. Finally, as with many conventional tests, interpreting results is a complicated process; slightly abnormal results and false positives may be unclear and difficult to interpret.

ensuring clinical competence

State medical licensing laws were implemented in the early 1900s to protect the public from abuse, fraud, and mistreatment. These laws were linked to the process of ensuring reasonable and ethical standards of practice. This was necessary because the quality of medical practice was highly variable and the medical system was in disarray. For example, in those days it was possible to obtain a

mail order medical degree after only six weeks of home study for a cost of \$200. The licensing laws also served to ensure that only those with specific training from certain medical schools could legally practice. All others who practiced as healers could be prosecuted and jailed for practicing medicine without a license. Only religious healers were exempted.

Thus, the licensing laws created a medical guild that not only “protected the public” but also protected their own entrenched discipline, and thereby reduced public choice in seeking other kinds of care. In fact, the American Medical Association (AMA), between 1930 and 1970, aggressively tried to suppress or prosecute “unlicensed” or alternative practitioners such as chiropractors. In 1987, the AMA was convicted by a federal court ruling of unreasonable restraint of trade and violating anti-trust laws (*Wilks v. AMA*).

The competence of conventional physicians, nurses, and pharmacists is now generally assumed and accepted by the public and government agencies. It is based on a standard of rigorous and well-tested training, continuing education requirements, re-certification exams, the monitoring of practice by professional boards, and the control and punishment of “bad apples” by professional organizations. How well this system actually works is unclear, but evidence of problems can be found in the substantial numbers of complaints, malpractice suits, and disciplinary actions that occur annually (North Carolina Medical Board, www.ncmedboard.org).

Recent changes in the delivery of health care have resulted in proposals for regulatory reform for all health professionals to provide a more flexible scope of practice (Pew Foundation, 1995). Although regulation of health professionals was designed to protect the public, it can create barriers to access for patients and cause professional “turf” problems (Reinhardt, 1996).

credentialing practitioners of complementary & alternative medicine

In the United States, formal recognition of clinical competence may be a problem for those practitioners of complementary and alternative therapies who have not completed approved training programs and national board exams in their discipline or who practice where there is no state licensure. The standards of competence and responsibility also relate to the degree of autonomy or supervision under which these clinicians practice. For example, an autonomous CAM practitioner should be expected to have a reasonable amount of medical knowledge to recognize medical conditions or early warning symptoms (Ernst, 1995; Eisenberg, et al., 2002).

Today, most professional organizations for complementary and alternative modalities have requirements for membership that include training, defined supervision, and testing. Licensing of complementary and alternative practitioners, through multidisciplinary or single-discipline state boards, has evolved slowly over the past few years and is in a continual state of flux. In states where licensing boards exist to monitor adequacy of training and quality of practice (for example: chiropractic, acupuncture, homeopathy, and naturopathy), the practitioners can practice legally, therefore offering the public some assurance of the competence of local complementary and alternative care providers.

In those states without licensing, the ability to monitor training, competence, and fraud is curtailed, and these practitioners may be subject to criminal prosecution. Referrals to effective and safe complementary and alternative clinicians may therefore depend more on local reputation and personal knowledge than on ascertaining licensing status. To find out whether a certain discipline is licensed in the state, it is necessary to call the State Medical Board or Health Department, or study the website appropriate to the discipline. Most complementary disciplines have national organizations of practitioners and many have referral services.

A good resource for quality information about herbal and nutritional products is the website

www.consumerlab.com

which regularly compares and assesses the quality of products on the U.S. market. Although much of the information is proprietary, a year's subscription to the site is modest.

Another excellent source of reliable information regarding dietary supplements is the Natural Medicines Comprehensive Database at

<http://www.naturaldatabase.com>

Although more expensive, the site provides invaluable information to the clinician faced with the necessity of providing counseling to patients using botanicals or other dietary supplements.

This variability in the legal standing of complementary practitioners creates uncertainty for all concerned and prevents a more integrative approach to health care. Referrals between conventional and complementary care providers may have malpractice implications in the event of a lawsuit (Cohen, 2000). Ethics regarding the boundary between conventional, complementary and alternative medicine are unclear (Ernst, 2001b). To what degree should conventional practitioners be obligated to offer non-conventional treatment options to patients? If conventional practitioners offer complementary therapies or referral to a CAM practitioner, they must have some understanding of the therapy's benefits and risks, and of the competence of the practitioner. This understanding should be reflected in their documentation of rationale and intended benefits.

The establishment of legal and regulatory standards for complementary and alternative medicine is still in its early stages. Conventional clinicians who practice non-conventional, complementary therapies may be at some risk related to the scope of their practice, and also may be subjected to disciplinary action by state medical boards based on prevailing norms. Malpractice rates are significantly lower for licensed practitioners of complementary and alternative medicine compared to conventional generalist clinicians.

ensuring product safety: herbs & nutritional supplements

The majority of safety issues in complementary and alternative care arise from the inappropriate or indiscriminate use of botanicals and nutraceuticals. Patients often believe that organic or natural products are inherently safe, and safety is therefore not a concern (Matthews, et al., 1999). Another belief that may pose risks for those who self-treat is that more is better and can produce a speedier beneficial effect.

Safety of supplements thus relates to three issues: first, the possibility of interactions between herbs and conventional medications; second, the possibility of toxicity from supplements or contaminants (which may be difficult to detect); and third, the possibility that non-conventional laboratories may theoretically cause "harm" through high cost to the client, or through using unreliable methods for testing that have not been proven to affect health outcomes.

Herbals and supplements, like other biological agents, act at multiple sites in the body, producing many effects; some of these effects are not normally detectable on routine clinical or toxicology testing. Many conventional laboratories fail to successfully identify the active agents of these herbals because of ignorance of their metabolism and/or not knowing where to look for the evidence (e.g., urine, liver, or blood). The one exception is that toxicity screening can usually reveal contamination of herbal products by heavy metals.

Similarly, it may be useful to monitor certain laboratory values while patients are taking an herbal remedy or supplement, because of potential adverse effects. Details of such monitoring

protocols are available in the book, *Complementary and Alternative Medicine* (Fetrow & Avila, 1999).

Interference with analysis of laboratory tests also occurs. For example:

- Digoxin measurement is affected by Siberian ginseng, Chan su, milkweed, uzara root, and lily-of-the-valley. Chan-su (from secretions of toads) is a major component of the traditional Chinese remedies Liu-Shen-Wan and Kyushin. These substances may increase or decrease true level of digoxin.
- Ephedra (Ma Huang) may affect workplace and athletic urine testing for performance enhancers (cross reacts with amphetamine antibodies).
- Creatine supplements affect creatinine testing.
- Herbal weight loss products interfere with catecholamine testing.

risks with herbal products

Herbal products, although derived from natural substances, are the forerunners of synthetic pharmaceuticals. Like medications, they have biological actions, which is why many herbal products are regulated as drugs in Europe (Mills & Bone, 2000).

Many herbal therapies are quite safe and fall into the realm of foods. Examples include many of the western “tonic” herbs traditionally consumed as teas, such as nettles and red clover. Other herbs, termed “heroics” have a history of adverse effects well known to traditional herbalists and have been employed specifically because of their toxic properties (Mills & Bone, 2000). An example is the use of bloodroot as an escharotic for treating skin cancers as popularized by Frederick Mohs, MD (Alleger, 1999).

A number of problems can occur when taking herbal or nutritional supplements. Reactions to therapy can be immediate or delayed, often as a result of a main pharmacological action. Between 1997 and 1998, for example, 140 adverse events (hypertension, arrhythmias, stroke, seizures, and death) were reportedly caused by dietary supplements containing ephedra (Ma Huang), usually in combination with caffeine. These products are widely used for weight reduction and enhancement of physical activity (Haller & Benowitz, 2000). Three billion doses of ephedra were sold in 1999, giving an adverse reporting rate of 10 per billion. More recently it was reported that there were 12,000 complaints to the company making Metabolife 365 (containing ephedra) with the result that the FDA stopped the public sale of ephedra (Marcus & Grollman, 2002).

Unpredictable reactions also can be associated with short- or long-term therapy. Some adverse events have only been recognized recently, perhaps in part because of differences in the way herbal supplements are now used. In addition, lack of knowledge about the proper dosing of herbs may lead consumers to take herbal supplements inappropriately. For example, liver damage has been documented as being associated with the extended use of chaparral or kava kava, herbs traditionally taken short-term. Other unpredictable toxicities occur from accidental or purposeful substitution of one substance with another, such as digitalis toxicity from the contamination of plantain with digitalis glycosides (Escher, Desmeules, Glostra, & Mentha, 2001).

In general, however, the epidemiology of adverse events from herbs is not well known. The FDA's CAERS system for reporting adverse events to food, dietary supplements, and cosmetics is just getting off the ground (FDA, 2003a). In Sweden, a European adverse-event reporting system collects data from 55 countries (Farah, et al., 2000). Adverse-event reporting systems are limited in their ability to define the true incidence of reactions to herbal products or drugs due to their inability to define the denominator (the number of consumers using the herbal product or

drug in question). The systems perform best in capturing acute, serious events (Rodriguez, Staffa & Graham, 2001).

contamination

Herbal products pose a risk from contamination with pesticides, heavy metals (cadmium, mercury), pharmaceuticals, and micro-organisms (Slifman, et al., 1998). For example, a study of herbal stores in California showed that 35 out of 251 products had unacceptably high levels of mercury (Talaly & Talaly, 2001). In Canada, Hua Fo, a Chinese herbal product claimed to enhance sexual function, was recently found to contain Viagra (http://www.hc-sc.gc.ca/english/protection/warnings/2002/2002_09e.htm, accessed December 2004). In February 2002, the California state health department found that PC-SPES (an eight-herb traditional Chinese remedy used for prostate hypertrophy and lowering prostate-specific antigen levels) was contaminated with diethylstilbestrol (feminizing hormone) and warfarin (anti-coagulant) (Straus, 2002).

potency & bioavailability

The strength and bioavailability of herbal supplements may be different from traditional herbal preparations as a result of manufacturers using different extraction processes. This leads to potential alterations in potency for the active compounds or the extraction of new compounds, with their corresponding effects (DeSmet, 1999). Also, seasonal variation in growing conditions and harvesting can affect the potency of a product (Valli & Giardina 2002).

dosing

Dosing recommendations for herbs lack uniformity and vary depending how the herb is prepared or on the manufacturer's recommendations. For example, random testing of Traditional Chinese Medicine products in Britain showed continued evidence of banned substances (mercury, arsenic) in products (www.mca.gov.uk, accessed December 2004).

allergies

Herbs also may produce allergic reactions. These may be allergies either to the herb itself or to excipients—the delivery vehicle in which the product is placed, such as lanolin, propylene glycol, and binders and fillers in capsules or tablets.

direct toxicity

Also of concern is toxicity of compounds in the herb. For example, aristolochia fangchi, a Chinese herb used in weight reduction treatments, contains nephrotoxic aristolochic acid, which can provoke genitourinary cancers. The incidence of adverse effects to St John's wort is 1-3 percent, photosensitivity being the most frequent problem (Schultz, 2000).

herbal remedies & surgery

A special risk posed by herbal products is their possible impact on surgical safety. It is particularly important to identify whether patients are taking certain herbal remedies when they are evaluated for surgery involving anesthesia, as the interaction between many herbals and anesthesia can be dangerous. Worrisome is a 1998 study of cardiothoracic surgery patients, showing that,

while the overall CAM use rate was 44 percent (excluding prayer and vitamins), only 17 percent had discussed this usage with their surgeons (Liu, et al., 2000).

Seven herbs—accounting for a large fraction of all preparations sold in the US—have been identified as having potential pharmacological effects relevant to surgical procedures:

- **Ephedra:** sympathicomimetic effects, may affect hemodynamic state
- **Garlic:** inhibits platelet aggregation and may increase bleeding tendency
- **Ginkgo:** may increase bleeding tendency
- **Ginseng:** lowers blood glucose and may increase bleeding
- **Kava:** may increase sedative effect of anesthetic and affect liver function
- **St. John's wort:** affects metabolism of steroids, warfarin, calcium channel blockers, digoxin, and many other drugs
- **Valerian:** increases sedative effect of anesthetic

Although there is still relatively little research proving adverse effects related to surgery and anesthesia, recommendations are to discontinue use of these supplements five to seven days before surgery (Ang-Lee, Moss, & Yuan, 2001).

non-herbal “nutraceuticals”

Non-herbal nutraceuticals include vitamins, minerals, phytonutrients, and animal extract and tissue products. Examples include: blue-green algae, bee pollen, glandular extracts, and protein powder. Product quality, including purity, is again an issue, but the main safety problems are:

- **Excessive dosage:** Some patients believe that more is better and knowingly ingest too much vitamin A or calcium, for example.
- **Allergies** to fish or animal protein are not unusual, and may occur from bee sting or dried (animal) cell therapy.
- Meats, liver extracts, and ghee (Indian butter) may harbor **micro-organisms** such as salmonella or *Clostridium tetani*.
- **Toxic metals** (such as arsenic, cadmium, lead, and mercury) or other contaminants can be purposefully or accidentally added to traditional and homeopathic preparations and cosmetics. For example, L-tryptophan has been advocated for sleeping problems but a contaminant caused cases of eosinophilia/myalgia syndrome, resulting in the product being pulled from the market. Recently it was reported that Ayurvedic formulations contained substantial variations of arsenic (0.0027 ppm to 1675 ppm) (Itankar, Sakharkar, & Chandewar, et al., 2001).
- **Diets and vitamins:** Over-zealous use of unbalanced diets can lead to nutritional deficiencies, to changes in physiological function, and changes in responses to conventional medications. Excessive beta-carotene causes yellow skin; too much vitamin D leads to hypercalcemia and GI problems; and substantial vitamin E doses cause a coagulopathy.
- **Contamination of combination products** with undeclared substances: A study by Consumer Lab found that up to 10 percent of mineral supplements in the USA were contaminated with lead; calcium was contaminated with an antibiotic; Chinese diet pills contained fenfluramine; there were excessive amounts of Vitamin A in Metabolife bars; and nettle products were contaminated with lead (www.consumerlab.com/recalls.asp, accessed December 2004).

safety of three commonly used complementary therapies

In addition to an understanding of safety issues related to CAM products, conventional practitioners should be aware of the risks—if any—posed by other commonly used complementary and alternative therapies. Three types of CAM therapies—manual therapies, acupuncture, and homeopathy—are highlighted below, because of their widespread use. Of the manual therapies, chiropractic and osteopathy are among the most widely and regularly used by Americans. For example, 11 to 16 percent of the population visits a chiropractor, while 25 percent of patients with low-back pain do so (Eisenberg, et al., 1998). About 30 percent of all visits to CAM practitioners are to chiropractors; and about 65 percent of physicians refer to chiropractors (Meeker & Haldeman, 2002). Acupuncture is becoming increasingly popular in the U.S. In 1997, for example, Americans made more than five million visits for acupuncture treatment (Eisenberg, et al., 1998). Homeopathy, in common use worldwide, is used less frequently in the U.S., with approximately two million visits made to homeopaths in 1997 (Eisenberg, et al., 1998). Although there may be some risks associated with these therapies, they appear—over-all—to be relatively safe.

manual therapy

Manual therapies involving manipulation of joints and the spine have been practiced for centuries and have evolved into the disciplines of chiropractic and osteopathy. There are now many educational programs with osteopathic training requiring four years of medical school with additional postdoctoral training in manipulation. Osteopathic physicians are now part of mainstream medicine. In addition, a number of short courses in manual therapy—ranging from a half-day to two weeks—are offered to conventional primary care physicians by the American Academy of Physicians and schools of osteopathy. Limited manual therapy is also taught in physical therapy.

Adverse events from manipulation may occur, but most are mild, usually causing localized discomfort, headache, or fatigue (16 percent of visits). A recent meta-analysis of five prospective studies showed that about 50 percent of patients receiving manipulation experienced mild transient reactions (Ernst, 2001c). Other adverse effects can arise out of misdiagnosis (missing cancer or metastases) or manipulating joints that are either severely inflamed or affected by other serious diseases (rheumatoid arthritis, bone infection, dislocations, myelopathy). However, no serious complications have been noted in over 70 controlled trials (Meeker & Haldeman, 2002).

Of the serious problems that do occur, most have involved cervical spine manipulation. Assendelft and colleagues reviewed the world's literature (mostly single-case reports) over the past 30 years and identified a total of 295 reported complications of spinal manipulation, most performed by chiropractors (61 percent) (Assendelft, Bouter, & Knipschild, 1996). There were 39 fatalities over a 30-year period. In 165 of the 295 cases, vertebrobasilar strokes from cervical manipulation occurred. In 61 cases of low-back pain there was deterioration of a herniated disk or progression to cauda equina syndrome. A more recent self-report survey of 323 British neurologists found 74 percent reporting complications of manual therapy within 24 hours of receiving chiropractic treatment and identified 35 cases with serious complications (Stevinson, Honan, Cooke, & Ernst, 2000). The reported incidence of complications varies from 1:2,500 manipulative procedures to 1:1 million (Klougart, Leboeuf-Yde, & Rasmussen, 1996). Unfortunately, few long-term prospective studies have been done to clarify this issue (Ernst, 2001c). In addition to the direct effects of manipulation, indirect effects include the excessive use of X-rays in evaluating spinal problems and prolonged manipulation treatment beyond recommended national guidelines.

To put these numbers in context, one should consider the adverse effects of NSAID use for low-back pain and neck pain. Gastrointestinal symptoms occur in 3 percent to 20 percent of patients. The odds ratio for gastrointestinal perforation (often asymptomatic) is 3.7 for aspirin, 6.7 for other NSAIDs, and 1.0 for placebo (Aronson, 1996).

acupuncture

Most adverse effects from acupuncture are mild and transient. Aggravation of symptoms occurs in about 13 percent of patients (Rampes & James, 1995). Other adverse effects include fainting, increased pain, nausea, and vomiting. Infections, including Hepatitis B and C and bacterial infections, have rarely been reported, and, when they occur, most bacterial infections have responded to antibiotic therapy. The use of disposable needles has eliminated most of these problems. Needle punctures causing hematomas and injury to the lungs (pneumothorax) have been reported (Ernst & White, 1997). Electromagnetic acupuncture needle stimulation should not be used if the patient has a cardiac pacemaker. A recent review of case reports of the adverse effects of acupuncture identified only 202 incidents in 35 years, from 22 countries. Adverse effects have declined in recent years because of clean needle techniques and more rigorous training (Lao, Hamilton, Fu, & Berman, 2003; White, Hayhoe, Hart, & Ernst, 2001).

homeopathy

Homeopathy is based on the use of highly dilute solutions of natural substances. Clinical practice is generally safe: there are no major reports of adverse effects and little evidence of direct toxic effects of homeopathic remedies. One small survey showed that about 10 percent of patients taking homeopathic remedies reported some adverse effect, which was frequently an aggravation of the symptoms being treated, often perceived by the homeopath as a positive response to therapy (Ernst, 2001a).

The indirect risks of homeopathy are the suggested potential “neglect” effects where conventional medical care may be withdrawn or access to it delayed by the long-term use of homeopathic remedies (since some of these remedies are reported to take several months to produce an outcome) (Ernst & Hahn, 1998). The example of delayed conventional care that is most often cited is the issue of recommending against orthodox vaccinations for infectious disease. All of these concerns, however, are based on anecdotal recording, and not substantiated by research. Further, these potential adverse effects are more likely if the practitioner is not well trained or is from another discipline and only “dabbling” in homeopathy.

safety, pediatrics & complementary medicine

Increasing numbers of children and adolescents are using complementary therapies and nutritional supplements (Gardiner, Conboy, & Kemper, 2000). Typically, youngsters using complementary and alternative therapies suffer from chronic, usually recurrent conditions such as acne, asthma, sleep problems, attention deficit hyperactivity disorders, premenstrual syndrome, obesity, and urinary infections. In particular, chiropractic care for families has expanded, so that in 1993, children made an estimated 20 million visits to chiropractors. Nearly a third of all visits to homeopaths and naturopaths are by children and adolescents (Lee & Kemper, 2000).

Other than the safety issues already discussed, two main issues cause concern to conventional pediatricians. First, a number of homeopathic, naturopathic, and chiropractic practitioners (probably about 10-15 percent) believe the risks of immunization outweigh the benefits, and will advise families against the practice (Ernst & White, 1995). Secondly, it is theoretically possible (though not substantiated) that children with acute illnesses might receive delayed appropriate treatment if the complementary and alternative practitioners persist with their approach too long.

shared safety issues: conventional & complementary medicine

The recent final report of the White House Commission on Complementary and Alternative Medicine (March 2002) advises clinicians and patients to “become more knowledgeable about the potential benefits and harms of CAM approaches” and urges “physicians and other health professionals [to] make significant efforts to open lines of communication with their patients about their use of CAM. . . .” The reason for this recommendation is simple. Although not integrated with conventional care, complementary and alternative therapies form a major component of the contemporary health care system and the uncoordinated, ill-informed blending of these systems poses safety risks.

In general, risks arise as the result of incomplete knowledge on the part of the clinician, leading to errors in decision-making and therapy. Among the possible problems:

- Health professionals are unaware that the patient is being treated by other conventional or complementary and alternative care providers.
- Health professionals are not fully aware of the medications, herbal and/or nutritional supplements taken by the patient.
- There is a lack of communication between health professionals, possibly leading to conflicting diagnoses, advice, and therapy.
- There is a lack of respect between clinicians, based on biases, poor esteem, ignorance of training and skills, and concern about legal and financial risks.

These misunderstandings may result, at least, in reduced benefit to patients or, at worst, in serious errors in treatment decisions. It should be noted that some of these problems are just as frequent within the conventional health care system, either between different specialties or between primary and specialist care. However, they are likely to be compounded in instances involving complementary and alternative treatment. A number of risks specific to the CAM-conventional care overlap may arise for patients, including:

- Disagreement regarding diagnosis.
- Lack of knowledge of interactions between herbs, supplements, and conventional medications.
- Potential for unnecessary health care costs due to duplication of tests and clinical management.
- Lack of laboratory and clinical methods to evaluate effects of CAM biological products.

communicating about risk & safety of complementary & alternative medicine

Perhaps the clinician's most useful tool to address problems caused by the convergence of complementary and conventional medicine is effective communication. The practitioner who wishes to improve communication skills should reflect on the following questions: Why is my patient seeking an alternative therapy? Is it my job to discuss the effectiveness and safety of the therapy with the patient? What is my appropriate approach to this request? Do I listen well? Do I know of any reliable sources of information on the therapy's safety and efficacy? Are there adequate studies (any studies?) or texts to tell me about the efficacy of this particular modality?

The conventional practitioner should advise patients to be wary of any practitioner who is overtly hostile to or ignorant of conventional medical practice or who cannot supply a reasonable explanation for his/her clinical method. Other red flags include practitioners who claim to be persecuted by conventional medicine; who ask for an up-front lump sum payment to cover a period of treatment; who schedule frequent return visits without justification; or who offer the likelihood of remarkable and quick results. Any of these cues may suggest that the practitioner involved may not have the patient's best interests at heart.

While this advice applies to complementary and alternative care providers, it should be noted that the same cautions apply to conventional practitioners. Patients should be wary of conventional clinicians who do not communicate clearly or adequately with their patients; who urge extensive testing or therapy without providing sensible and clear reasons; who appear uninterested in the patients or are rushed; who schedule frequent return visits without good justification; and who prescribe medications without explaining their action, expected outcome, or adverse effects.

guidelines for discussing CAM

When talking with patients about complementary and alternative treatments, there are certain principles that should guide the conventional practitioner:

- Respect the patient's autonomy.
- Make no assumptions about CAM use, with respect to ethnicity, age, and social status.
- Inquire about and be open to hearing about CAM use.
- Be sensitive that the patient may expect the clinician's disapproval or disinterest.
- Be aware that the patient may not be asking for the clinician's endorsement or belief in a particular CAM treatment, but just wanting facts, including a good diagnostic workup.
- Advise the patient to weigh carefully any decisions to abandon useful conventional therapy.
- Inform and advise the patient about any therapies, whether CAM or conventional, that may cause harm.
- Recognize that the patient's choice in therapy can be empowering.
- Reflect on the ethical duty to facilitate patients' requests for referrals.
- Be sure that patient is provided with clear treatment goals, reasonable timelines, and careful monitoring.

Similarly, the following guidelines are useful in maintaining a responsible, evidence-based approach to complementary and alternative therapies (Eisenberg, 1997).

- Listen to the patient for a full two minutes—this is the average time a patient needs to explain or report symptoms and state expectations of treatment and outcome.
- Use patient-centered communication to gain trust and complete information.
- Use good clinical skills to obtain as clear a diagnosis as possible.
- Assess patient preferences and expectations.
- Review safety and effectiveness.
- Know where to look for reliable information on complementary and alternative medicine.
- Know something about the specific effect of the complementary/alternative modality.
- Do not use or recommend complementary and alternative therapies without adequate knowledge of their proposed mechanism of action.
- Learn the magnitude of effect and what possible harm (or good) may be caused by the complementary/alternative modality.
- Identify suitable licensed practitioners of the complementary/alternative modalities being discussed.

evaluating risks & benefits

Patients should be aware of the risks and benefits of any therapy. The effectiveness of treatment must be considered in the context of patient safety as well as costs. The risk:benefit ratio, which is often discussed, is the ratio of the chance that an adverse event will occur at a certain dose of a substance to the chance that a beneficial effect will occur. The lower the risk:benefit ratio, the more desirable the treatment. A risk to benefit ratio of zero is ideal (Huxtable, 1998).

For example, if the herb comfrey causes liver disease in a very small portion of the people who take it orally and they receive no recognizable benefit from the herb (low risk, low cost), then it should not be used. On the other hand, cancer patients who receive conventional chemotherapy (high cost, high risk) but suffer side effects including hair loss, nausea and vomiting, mouth ulceration, and low blood counts can also experience great benefit from the drugs, making the risks acceptable for many patients.

When there are only few data on effectiveness, risk:benefit ratios often cannot be considered or discussed. On the other hand, there may be adverse events as well as costs that should be reviewed with the patient. The chart below (based on estimates from the literature) illustrates how

COST-RISK ASSESSMENT FOR DIFFERENT CAM THERAPIES

	minimal risk	medium risk	moderate risk
Low Cost	Mind-body therapy Aspirin	Ginkgo	Fasting Ephedra
Medium Cost	Acupuncture Aromatherapy	Colonic irrigation Chiropractic	Chelation therapy Chaparral
High Cost	Clinical ecology (Multiple lab tests)	Mud therapy	Insulin therapy for breast cancer

a clinician with some general knowledge of complementary and alternative therapies might think through the pros and cons in terms of costs and risks for a patient asking for advice about using those therapies. This chart, however, gives no indication of

Many factors affect how patients receive risk:benefit information. These include:

PATIENT FACTORS

- Duration of consultation
- Body language
- Verbal cues
- Communication process
- Social alignment with the clinician (gender, race, language skills)
- Understanding
- Age
- Intellectual ability to analyze explanations and simple statistics
- Reading ability to study informational materials and handouts

CLINICIAN FACTORS

- Duration of consultation
- Body language
- Verbal cues
- Communication skill
- Social alignment with the patient (gender, race, language skills)
- Knowledge of topic (accuracy, up-to-date, comprehensiveness)
- Practice style in encounter
- Access to/use of informational materials
- Delegation of task to others such as a nurse or caregiver

effectiveness, which would also need to be factored into the assessment. Because the evidence is still largely incomplete, useful risk:benefit assessments often are difficult to make (Ernst, 2002).

It is up to the patient and caregiver to address the issues of effectiveness and safety that relate particularly to the age, gender, race, and health status of the individual patient. Very low-risk complementary therapies include homeopathy, guided imagery, most types of massage, spiritual healing, hypnosis, and meditation techniques. In general, the following therapies should be monitored: herbal preparations (except teas), patent remedies from the Far East, nutritional supplements, dietary regimens, agents given by injection, intravenous infusions (such as chelation), and cervical spine manipulation.

framing risks & benefits

Discussing risks and benefits can, in reality, be quite complicated and time consuming. This is especially true if a great deal is known about the subject—such as breast cancer; or if the information continues to change—as in the case of the effects of hormone replacement therapy in menopause or the value of mammograms in screening for breast cancer (Mosca, et al., 2001; Writing Group for the Women’s Health Initiative, 2002). It would seem obvious that the style or approach in which a clinician presents information to patients and their families can affect the way health decisions are made. This is known as “framing” of information.

Most studies of how the risk:benefits are “framed” have been done in research laboratories and actually show that “framing” styles can substantially affect how people make their decisions (Edwards, Elwyn, Covey, Matthews, & Pill, 2001). Research in clinical settings finds that

these effects are much less obvious than in the laboratory (Edwards, et al., 2001). But we do know that people are more persuaded by positive rather than negative framing. The difference between positive framing and negative framing is demonstrated by the following example:

- **Positive framing:** “With this operation, you will have a 96 percent chance of surviving five years.”
- **Negative framing:** “With this operation, the five-year death rate is 4 percent.”

relative risk

People are more impressed by relative risk reduction than absolute risk reduction, even though the size of the effect is the same. An example of a statement of relative risk might be, “This medication will reduce your risk of a GI bleed by 50 percent.” (For example, from 2 percent to 1 percent of the population taking the drug.) An example of a statement of absolute risk is: “Only 1 percent of the population taking this drug will have a GI bleed.”

In advising patients about the risks and benefits of complementary and alternative therapies, it is best to:

- Reflect on your own biases and try to exclude them from your discussion, unless there is hard evidence to support them.
- Be open about your biases so that the patient can decide whether the discussion is worth pursuing.
- If you do not have the knowledge to offer sensible and reliable professional advice, at least admit your ignorance and help the patient to get information from other sources.
- If you do not have the time to discuss the issue objectively, fairly and thoroughly, admit it to the patient.
- Consider asking patients to get back to you in some way, if they eventually find the information they need, and tell you about the results of their quest.
- Consult with a respected CAM practitioner.

However hard we try, it can be quite difficult to be completely objective about presenting evidence, risks, and benefits to patients or their families.

increasing safety in complementary & alternative medicine

The responsibility for reducing risks associated with the convergence of conventional, complementary, and alternative medicine is a shared one. On the one hand, it appears likely that regulatory agencies will need to assume greater responsibility for assuring standards of quality for CAM products. Almost certainly there will be a need for stiffer, more consistent laws and regulations governing production standards and labeling practices. Additionally, there is a need for an effective and fair system of reporting the adverse effects of complementary and alternative products and services.

Complementary and alternative care professionals, too, have a responsibility to ensure a high level of clinical competence through their training and credentialing programs. But perhaps most important is the need to educate all those involved in the health care system—clinicians, patients, hospitals, labs—about complementary and alternative therapies. Conventional practitioners and institutions have the responsibility of informing themselves about complementary/alter-

INFORMATION SOURCES ON CAM ORGANIZATIONS & LICENSURE

In addition to general guidelines for seeking and assessing CAM practitioners, there are good sources of information to help evaluate caregivers in certain CAM disciplines (accessed, December 2004). Among them are:

ACUPRESSURE. There is no single credentialing agency; practitioners have a good knowledge of Traditional Chinese Medicine. Information resources: The American Association of Oriental Medicine (www.aaom.org; www.acupressure.com).

ACUPUNCTURE. Regulations vary from state to state, covering many different styles of acupuncture. In states with no regulation, acupuncture is technically illegal unless performed by a physician. Standardized tests are administered by the national organization and an acupuncturist must recertify every two years. A board-certified acupuncturist must have at least 1,500 hours of training (however, a physician may take only a short course, and then, by law, will immediately be qualified to practice acupuncture). Information resources: American Academy of Medical Acupuncture (www.medicalacupuncture.org); Non-medical credentialing: www.nccaom.org, www.acupuncturealliance.org

HOLISTIC MEDICINE. Allopathic physicians who use complementary methods and a more nutritional, lifestyle approach to care can be certified by the American Board of Homeotherapeutics. This distinguishes these physicians from those allopaths who expand the scope of their practice to include CAM with minimal training. Information resources: American Holistic Medical Association (www.holisticmedicine.org).

AYURVEDA. No national licensure in the U.S. In India, Ayurveda requires five years of training. A new certificate course has been started by the National Institute of Indian Medicine, based in New York City (www.niam.com).

BIOFEEDBACK. No national licensure and accreditation requirements, but certificate awarded. Information sources: Biofeedback Certification Institute of America (www.bcia.org), and the Association for Applied Psychophysiology and Biofeedback (www.aapb.org).

HOMEOPATHY. Any licensed physician in the U.S. can prescribe homeopathic remedies, and there are no national standards. However, a diploma, through examination, is offered by the American Board of Homeotherapeutics (DHt). The Council for Homeopathic Certification (415-789-7677) also offers an exam, awarding the CCH (certificate in classical homeopathy). Information resources: American Board of Homeotherapeutics. (703-548-7790), and the National Center for Homeopathy (www.homeopathic.org).

NATUROPATHY. There is inconsistent state licensure. Four main naturopathic medical schools are accredited nationally, offering an ND degree. Information resources: American Association of Naturopathic Physicians (www.naturopathic.org).

MASSAGE/BODYWORK. American Massage Therapy Association (www.amtamassage.org) and the National Certification Board for Therapeutic Massage and Bodywork (www.ncbtmb.com).

CHIROPRACTIC. Federation of Chiropractic Licensing Boards (www.fclb.org/index.htm). International Chiropractors Association (www.chiropractic.org).

MIND-BODY THERAPIES. Meditation—Institute of Noetic Sciences (www.noetic.org). International Association of Yoga Therapists (www.iayt.org). Center for Mind-Body Medicine (www.cmbm.org).

CAM TRAINING SCHOOLS & LICENSURE. Search Engine for CAM Training Schools and Licensure: Alternative Medicine Homepage, University of Pittsburgh (<http://www.pitt.edu/~cbw/altm.html>) (accessed, December 2004).

native therapies and their safety issues. CAM professionals have a similar responsibility to become better acquainted with conventional medicine and how their particular disciplines are affected by the dominant medical system.

increasing CAM safety in clinical practice

In order to address issues of safety of complementary and alternative therapies with patients, clinicians need to take the following steps:

- In a non-judgmental way, ask patients if they are taking any herbal remedies or nutritional supplements, using any complementary devices, or seeing a complementary practitioner, and for what conditions, symptoms, or other reasons.
- Record the information in the chart, or ask the patient to bring the products in at the next visit to review these for duplication of ingredients. Other approaches for obtaining this information might include providing a form so patients can fill it out at home.
- Monitor risk level. Check the safety of the therapies and the possible interactions using texts or databases. Many of these sources are listed in this monograph.
- Before laboratory testing for any clinical evaluation, check on the patient's use of complementary therapies.
- If referring to a CAM practitioner, document why the decision was made and what was the discussion with the patient (i.e., it was a shared decision?). Check what services the practitioner offers, and that he/she is licensed (Cohen & Eisenberg, 2002). CAM practitioners welcome referral letters or calls, and will often respond in like manner.
- Before scheduling surgery with anesthesia, inquire about the patient's use of complementary therapies.

summary

The convergence of conventional, complementary, and alternative health care systems raises important questions about safety. Not only must conventional clinicians educate themselves about unfamiliar therapies, but health care providers generally need to understand the implications of the overlapping of multiple systems of care.

The best way to address these safety issues—for clinicians and patients alike—is to be informed. Health care providers need to learn about the various modalities in use, to understand how to find and evaluate information sources, and to share information effectively with patients and colleagues.

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