INTRODUCTION

One of the major popular health movements at the turn of the 21st century is a widespread interest in, and the utilization of, what has been called “alternative,” “complementary,” and now “integrative” medicine. Many people are using these therapies because of a variety of problems in numerous health care settings. Following widespread recognition of this popular trend by the medical and scientific communities, there has been a corresponding movement among medical practitioners, administrators, academicians, and scientists to incorporate these modalities into their existing spheres of research, practice, and teaching. These popular and professional movements are now leading the private sector, through health systems and insurers, and the public sectors of state and federal governments to invest more deeply and broadly in integrative medicine from the standpoint of public health and health care practice.

The dimensions of the phenomenon are impressive. In recent years, the American public has paid more visits to alternative practitioners than to primary care physicians. The use of herbal remedies and dietary supplements is now supported by a $30 billion dollar industry in the U.S. Even more notable is the fact that American consumers have paid for most of the costs of these products and services on their own and, until recently, have received only limited, if any, insurance reimbursement or tax benefits—unlike reimbursements in other areas of health care. The out-of-pocket costs that patients have paid for alternative care exceed their out-of-pocket co-payments and deductibles under traditional insurance-covered health care.

These observations are critical for further studies of health care utilization with regard to the roles of third-party payers in providing health care. It is significant that one last bastion of traditional fee-for-service medicine resides among alternative practitioners and clients, who currently receive no insurance reimbursement or third-party payment. Further, the workforce supplying alternative and complementary care is strikingly smaller than the current workforce of approximately 600,000 practicing physicians (see “Therapeutic Access and Availability,” page 667). With these observations in mind, greater efforts are required to support further studies on health care utilization and evidence-based medicine to comprehend the implications of this movement for health care in 21st century America.

In this article, I describe the nomenclatures and philosophies that relate to the therapeutic paradigms in practice. I then review the various therapeutic modalities that are classified under integrative medicine, their practitioners, and the related issues of therapeutic access and availability, with some models of integration (in contrast to maintenance of pluralism). After explaining issues related to the need and potential for evaluation of effectiveness and cost-effectiveness, I discuss the special requirements for pharmacy practice, professional education, and public policy efforts in integrative medicine.

THERAPEUTIC PARADIGMS

The rhetorical question—“what’s in a name?”—has had profound implications for the scientific and cultural acceptance and philosophy of care underlying the terminology. In the 1990s, the medical and scientific communities, for descriptive purposes, proposed various labels such as “non-traditional,” “unconventional,” “unorthodox,” “holistic,” and “wholistic” (the last term a revival from the 1960s) to describe what we now call integrative medicine. Amidst the calls for greater scientific objectivity, these labels shared the tendency to portray cultural values, prejudices, and judgments about the validity and appropriateness of such modalities. The more properly descriptive terminology of alternative and complementary medicine came into general acceptance at the time. “Alternative” came to imply a mutual exclusivity between these modalities and the regular practice of medicine; “complementary” more precisely described a compatibility between the use and acceptance of these modalities as an adjunct to—and not a replacement for—regular medicine. Thomas Jefferson University Hospital is one example of an institution that pioneered the use (and the practice) of “integrative medicine” at its Center for Integrative Medicine.

The term integrative medicine implies an active, conscious effort by the health professions and medical science to sort out the evidence and application of various complementary modalities for appropriate incorporation into the continuum of health care within the current parameters of the health care system. A potential irresolvable philosophical question relates to the intangible costs and benefits of integration within one system versus the continued existence of pluralism vis-à-vis healing choices for consumers. Integration is interpreted to convey improved standards of evidence, quality, appropriateness, and availability of care within the mainstream health care system. Alternative implies greater choices for consumers for those (perhaps relatively few) who are willing and able to create their own menu of heal-
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ing modalities. One view pivots on the present workforce situation, which may dictate that more appropriate care will be provided to more people through continued integration than has been the case with an uncoordinated landscape of different practices, each vying for primacy within incompletely defined, articulated, and accepted evidence-based scopes of practice.

One bellwether of change is the name of the office at the National Institutes of Health (NIH) that is charged with conducting a national research program for investigating and determining the evidence (or lack thereof) supporting the use of these modalities. Led by the U.S. Congress, particularly the efforts of Senator Tom Harkin (D-Iowa), the NIH program was established as the Office of Alternative Medicine (OAM) in the early 1990s. This was later known as the National Center for Complementary and Alternative Medicine (NCCAM), symbolizing its growth in budget as well as scope. Senator Harkin has recently indicated his interest in changing the name to the National Center for Integrative Medicine following possible hearings in the new Congress.

THERAPEUTIC MODALITIES

Many of the physical modalities that have been variously described as “alternative,” “complementary,” and “integrative” medicine can be understood to exist on a continuum with regular medicine and are now considered to have a measurable, physiological effect on the body. I have found it useful to arrange these techniques from least invasive to most invasive; this array also initiates an approach to cost-effectiveness analyses in light of the correlation between degree of invasiveness and cost—both in terms of the costs of providing care and the costs of managing the known and accepted complications of that care (Figure 1).

For example, an array would be, in increasing order of invasiveness: meditation, talk therapies, bioenergetic manipulation, massage, physical manipulation, insertion, ingestion, injection, and surgery. Alternative/complementary practices are then organized around the use of one or more of these techniques.

For example, Chinese medicine uses bioenergy (qi or chi), manipulation (tui na, qi gong), insertion (acupuncture needles), and ingestion (herbs and foods) for medicinal purposes, approximating a more “complete” system of care. Chiropractic treatment is traditionally limited to manipulative therapy. The powerful and relatively invasive techniques of injection and surgery are reserved for biomedicine.

Naturopathy was traditionally limited to the “nature cure” following a Hippocratic emphasis on “airs, waters, and places”; foods; and herbs. Contemporary naturopathic medicine consciously incorporates training and utilization in all of the recognized healing techniques in a type of formalized “neo-eclectic” medicine.

Furthermore, individual practitioners within one system of care sometimes create their own forms of eclecticism by incorporating other healing modalities from those traditionally outside that system of care (e.g., physicians or chiropractors who incorporate acupuncture).

Finally, individual techniques, when practiced in a manner that is removed from the traditional system of care (formulary approaches), have increasingly proved to be effective in certain situations. For example, in the traditional practice of Chinese medicine (in China and in the Chinatowns of urban America), clients generally seek the services of a seventh-generation Chinese practitioner who might also incorporate herbs, manipulation, and other remedies to treat a medical condition, notwithstanding historical debates among various Chinese practitioners over the use of herbs versus acupuncture (as in the discussion between the semimythical Yellow Emperor and his minister Qi Bo in the introduction to the oldest book about Chinese medicine, The Yellow Emperor’s Inner Classic of Internal Medicine, which probably first described acupuncture). In the U.S., a licensed physician may attend a six-week course in acupuncture in California and become a licensed acupuncturist. This kind of acupuncture, provided by the physician on a “formulary” basis, has been found to be effective and may even exceed cultural expectations for the average American when it is performed by a practitioner in a white coat in an antiseptic clinic rather than by, for example, practitioners in Chinatown.

Virtually all of these practice systems rely on herbal and nutritional remedies, or “dietary supplements,” in a fundamental role for therapeutic purposes, either within their traditional practices or with eclectic forms of practice (e.g., incorporating dietary supplements by therapists using manual and manipulative techniques). Many of these modalities (see Figure 1) coexisted on a more equal footing with regular medicine during the 19th and early 20th centuries and represented an eclectic practice environment until the implementation of the Flexner Report in 1910, which resulted in standardizing medical teaching and practice.

Acupuncture, for example, was introduced to American medical practice by such efforts as a translation (from the French) by Franklin Bache, a grandson of Benjamin Franklin. Acupuncture was included as a treatment for “lumbago” through the first three editions of Osler’s Textbook of Medicine. Although some alternatives were imported, others arose as varieties of popular medicine on the American frontier, where no regular physicians were readily available. Many of these modalities have persisted, providing a basis for contemporary integration.

THERAPEUTIC ACCESS AND AVAILABILITY

The availability of these physical modalities is determined by:

- the existence, numbers, and locations of practitioners trained (and licensed, where applicable) to provide these services.
- access to them through clinics, hospitals, academic medical centers, and health care systems and networks.

Individual practices have existed and often thrived, apart from the mainstream health care system. “Integration” involves a number of interrelated issues.

Given the dimensions of the movement, it is often striking how few “alternative” providers currently exist in proportion to the mainstream medical workforce. Manual and manipulative therapies are relatively well represented, with approximately 100,000 massage therapists and more than 50,000 licensed chiropractors. There are approximately 25,000 osteo-
paths, with perhaps fewer than 25% of them maintaining any practice in manipulative therapy.

Therapy that includes manipulative techniques is also relatively well regulated, with licensure available for chiropractic manipulation in all 50 states and in the District of Columbia and with accreditation programs in graduate schools, whereas osteopathy has been fully subsumed under the credentialing processes of mainstream medicine.13

In contrast to these figures, other fields of complementary medicine are sparsely represented. There are fewer than 10,000 licensed acupuncturists in the U.S., with licensure available in most states and the District of Columbia. Approximately 3,000 of these are MD-acupuncturists, and the remainder in this category include a number of traditional Chinese practitioners.

There are approximately 3,000 homeopaths, most of them licensed physicians, and nearly 3,000 naturopaths, with licensure available only in a dozen states, primarily in the northwestern U.S. and New England. There are five accredited graduate schools, primarily in the northwestern and southwestern U.S.

Naturpaths represent the practice of an eclectic style of medicine and “Western herbalism,” drawing from the herbal traditions of other cultures worldwide. Perhaps some hundreds of Ayurvedic practitioners exist; many follow highly individuated practices, and others adhere to a tightly controlled Maharishi Ayurveda school of practice.

In another tradition from India, thousands of yoga masters offer attenuated training in this discipline, primarily designed as a meditative practice intended to influence the physical body (Hatha-Yoga).

Energy healers now come from several organized schools nationwide. The practice of energy healing is widely incorporated by many nurses in the U.S., through Healing Touch, and Therapeutic Touch, and by some physical therapists who also include craniosacral therapy.13

MODELS OF THERAPEUTIC INTEGRATION

To provide integrated care, the health care system requires access to licensed health care providers and the training of existing providers in one or more modalities of complementary care. The health care system may provide credibility, appropriate practice environments, and access to new clients for practitioners. It has opportunities to make capital investments in facilities required to provide care that are not available to individual practitioners.

Often, the success of the integrated care clinic is based upon attracting the individual practitioner’s existing client base while the individual practitioner comes to the health care system looking for new referrals. An important area for the expansion of services is appropriate referrals from within the health system hosts to the practitioner’s integrated clinics and inpatient services.

When complementary medical services are added onto existing services, instead of selectively replacing them, they become a cost center rather than a cost-effective source of savings. In response to consumer demand, some managed care systems have offered access to a network of complementary care providers who have agreed to accept negotiated rates, as in other areas of health care practice. An innovative approach is available through the WellPower network of licensed “holistic” health providers, which offers an insurance rider to employers, unions, and associations for member access to services at negotiated rates.14

Academic medical centers offer an opportunity to develop not only the integration of appropriate complementary modalities into the continuum of care but also the integration of clinical research and training with the practice of integrative

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* Ayurveda also provides minor surgery.
† Some chiropractors offer dietary management, acupuncture needling, etc.
‡ Many Shamanic practitioners also provide herbs.

Figure I Various therapeutic modalities, arranged (left to right) from most invasive to least invasive. (From Micozzi MS, ed. Fundamentals of Complementary and Alternative Medicine, 2nd ed. New York: Churchill Livingstone; 2001:28. With permission of Elsevier Sciences).
medicine. In the 1990s, many academic medical centers adopted an “arm’s-length” relationship to alternative/complementary medicine with internally isolated efforts at research, teaching, or practice.

Jefferson’s Center for Integrative Medicine was an early leader in the development of a model for effective academic, research, and clinical integration.11 The Center has grown into a national model while serving increasing numbers of clients in the Jefferson health care system and in the region. A national consortium of academic medical centers has also been formed to help foster the development of integrative medical practice, research, and training.

Challenges arise when hospital policies involve the integration of approved research protocols with approved practices. For example, a hospital clinic might organize to participate in a clinical trial of an alternative infusion therapy that has been approved for research. However, the costs of special staffing, equipment, and space for the research project might not be feasible unless the clinic is also approved to offer profitable infusion therapies as a service. Thus, the clinic cannot benefit, in the short term, from offsetting operating costs of research with operating revenues, and it cannot benefit in the long term if the new therapy proves to be effective. These challenges may be addressed through adequate and realistic support for research and an “integrated” internal hospital policy process.

Integrated care has been understood to imply the provision of various medical modalities under the supervision of a physician. To the extent that such physician-supervised centers function as full-service, or even fuller-service, primary care facilities, some have expressed concern that if primary care “gatekeepers” refer patients for complementary care, they might never come back.

The national American WholeHealth Network, based upon a successful model in Chicago to provide integrated medical services under physician supervision, was unable to receive an adequate number of patient referrals from physicians and had to embark on costly direct-to-consumer marketing. It subsequently underwent a radical shift in business strategy. Individual practitioners thought that it would be necessary to receive a partial subsidy to provide the kind of care they wanted to provide, because revenues from operations under the existing health care system were inadequate to cover costs.

One response to the concern about physician referrals, created by the late William Fair, Sr., a leader in integrated care, was a facility for complementary care that was not supervised by a physician. This concept, initially developed as Synergy Health, opened in New York City under the name “Health.”

Another important implication of integrated medicine takes the concept of complementary care beyond the primary care provider and “gatekeeper” to the integration of appropriate complementary medical modalities into medical specialty practice for the management of chronic diseases. The initial primary care focus of integrated medicine is being supplemented by the availability of information on integrative medicine targeted to medical specialists; an example is the new quarterly review journal entitled Seminars in Integrative Medicine.15

**THERAPEUTIC EFFECTIVENESS AND COST-EFFECTIVENESS**

Congress’ establishment and expansion of the alternative/complementary medicine research program at the NIH have increasingly emphasized clinical trials research to help create a research database for evidence on the efficacy, or lack thereof, of available therapeutic modalities. The health care system now has access to increasingly abundant and credible data regarding the effectiveness of these modalities.

To better understand the appropriateness and cost-effectiveness of these therapeutic modalities, we must expand efforts into health care utilization research. We must also study factors such as patient motivation and satisfaction, willingness to pay for care, preference of one effective modality of care over another, and willingness to substitute methods of care. We must develop multidisciplinary guidelines for best practices in disease management and related types of analyses to better inform health care decision-makers, including policymakers, administrators, and consumers.

The Agency for Health Care Quality has worked within a limited budget to provide important analyses on the effectiveness and cost-effectiveness of various modalities for the management of low back pain when pharmaceuticals, surgery, spinal manual therapy, acupuncture, massage, and other therapies are all present at various levels of availability, cost, and effectiveness.12 If consumers, the health system, and third-party payers are to realize improved effectiveness and cost savings, it is incumbent upon integrative medicine to determine which kinds of therapeutic options can be appropriately provided to which patients, and in what order, to achieve cost-effective disease management. In this way, the development of individualizable profiles and the protocols for patients most likely to respond to various therapeutic modalities may ultimately provide a legitimate basis for increased levels of effectiveness and satisfaction at lower costs; it might also begin the process of offering individualized care.

Risk management, malpractice claims and awards, and the rising costs of malpractice insurance coverage must also be addressed. Many have claimed that integrative medical modalities produce fewer and less serious side effects, reducing the number of cases of malpractice, and that the direct relationship with practitioners (and other factors) reduces patients’ motivation to pursue malpractice actions.13 These observations also need to be studied in a rigorous manner.

Reported side effects tend to occur because of the increasingly well-known potential adverse interactions of (primarily) herbal dietary supplements with conventional pharmaceuticals, anesthetics, and medical procedures (see below). Although the medical literature tends to place responsibility for adverse drug interactions primarily at the feet of alternative modalities, it is unlikely that biomedical products and procedures will be exempted by the legal system when claims and awards for damages resulting from such interactions are considered.

**PHARMACY FOR INTEGRATIVE MEDICAL PRACTICE**

Legislative and Regulatory Environment

Under the Dietary Supplement Health and Education Act...
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(DSHEA) of 1994, as amended in 1998, the U.S. Food and Drug Administration (FDA) has the power to regulate herbal remedies and dietary supplements by:

• employing good manufacturing practices (GMPs) in terms of identity, potency, cleanliness, and stability; it should be noted, however, that the FDA has not yet promulgated GMPs even six years after the Act’s passage.
• referring perpetrators of the sale of toxic or unsanitary products for criminal action.
• obtaining injunctions against the sale of products that make false claims.
• seizing products that pose an unreasonable risk of illness and injury.
• stopping the sale of an entire class of products if it poses imminent health hazards.
• stopping products from being marketed if the FDA does not receive sufficient safety data in advance, under “generally recognized as safe” (GRAS) provisions.

The FDA’s alleged lack of regulatory authority is frequently overstated, even by the FDA Commissioner, according to the House Committee on Government Reform in July 2001. Nonetheless, the health care system must rely on vigilance by the medical profession and voluntary compliance by industry in safeguarding patients against adverse drug reactions. Following the Congressional elections of 2002, changes are not anticipated in the DSHEA, which regulates herbs as dietary supplements, not as drugs.

In his recent memoir, Senator Orrin Hatch (R-Utah), Co-Chair of the Congressional Caucus on Complementary/Alternative Medicine and Dietary Supplements, documented the unprecedented involvement of a coalition of citizens and commercial groups in the passage of the DSHEA. What might not be achieved by regulation might be helped by improved dissemination of information, by educating consumers and health professionals (see page 671).

It is also important for the health care system to work with an active and growing natural products and dietary supplements industry in the U.S. Some responsible suppliers, manufacturers, and distributors of natural products are beginning to recognize that the integration of herbal and nutritional medicine into medical practice mandates higher standards for product ingredients and information about their efficacy.

The herbs Ginkgo biloba, kava kava (Piper methysticum), and ephedra (Ephedra sinica) have come under attack in recent months. Each illustrates a different aspect of herbal remedies as information and, in some cases, misinformation come to light.

Ginkgo is well established as an effective treatment for mild dementia and has been shown to improve memory in people with memory impairment. However, it has been marketed irresponsibly as a “memory enhancer,” leading to a misguided study of the herb in standard memory tests in people without cognitive impairment. The subsequent promotion of the study’s findings has led to great confusion.

Kava kava, after being used by approximately 70 million people, was documented to be associated with liver toxicity—as has been the case with many prescription and over-the-counter drugs. As an effective treatment for anxiety, should kava kava be banned, or should a responsible approach be developed to assess the risks and benefits, as with other conventional treatments that cause side effects?

Millions of people have used ephedra for weight loss, but the herb is being misused to enhance athletic performance. Because it has been listed on autopsy reports as a contributory factor in several fatalities among otherwise healthy individuals, some have called for its abolishment. Obesity is a risk factor for many diseases, and effective weight-loss regimens elude many overweight individuals. The question is: is it possible to have safe, medically supervised, appropriate ephedra formulations for weight loss, or does ephedra have no place whatsoever in contemporary use?

The further abuses of herbal products, combined with therapeutic drugs and adulterated with contaminants (which is problematic with imports from overseas, particularly China), are a serious safety issue. Consumers, health care professionals, and responsible groups in the natural products industry all suffer when irresponsibly adulterated products are imported from abroad. The current NIH clinical trial on the Chinese herbal formulation known as PC-SPES (consisting of saw palmetto, licorice, ginseng, and other products) for prostate cancer has been undermined by the unwitting use of adulterated herbs. Some natural products from China have even been contaminated with chloramphenicol.

Improvements in manufacturing and marketing standards in the natural products industry will be required for effective integrative medical practice.

Integrative Practice

Reliance on the appropriate use of nutrients and herbs is a crucial and fundamental component of many integrative medical practices (see Figure 1). In the U.S. today, natural products are widely available. Unlike data about pharmaceuticals, information about the health effects of natural products cannot be provided on the product label or as a product insert. As a result of the increasing availability of credible third-party research on the efficacy of herbal and nutritional ingredients and the medical profession’s increasing recognition of the importance of dietary supplementation for optimal health and for the prevention and management of many medical conditions, it is incumbent upon integrative medicine practitioners to maintain medical standards for dispensing information about, and for their use of, herbal and nutritional ingredients. One approach to this requirement would be to develop and maintain the capability for a clinic-based or hospital-based formulary of effective and high-quality sources of herbs and nutrients.

In the current regulatory environment, a large part of the natural products industry is not operating according to medical and scientific standards; many irresponsible marketing claims are made; and many medical and scientific professionals are not knowledgeable about the science behind herbal and nutritional medicine. This volatile mix produces confusion and misinformation on both sides and has periodically been documented in the medical literature.
are largely on their own when it comes to trying to understand the proper indications, ingredients, and dosages for the appropriate scientific use of herbal and nutritional remedies. Consumers can only look to practitioners for guidance. New information technologies are being brought online to provide distributors, consumers, and practitioners with up-to-date information about the appropriate use of dietary supplements. The new Fair and Accurate Information Reporting (FAIR) Alliance for Dietary Supplements is designed to help remedy this shortfall by providing interactive CD-ROM technology and Internet links on a timely basis regarding dietary supplement claims, counterclaims, and current research.  

**MEDICAL EDUCATION**

The issues considered thus far point to the clear need for enhanced education in medical schools, postgraduate medical education, and continuing medical education (CME). CME programs are faced with an obstacle—generally, current practitioners have had no exposure to integrative therapies in their medical schools or in their postgraduate training.

According to surveys conducted by the Center for Research in Medical Education at Thomas Jefferson University, most of today’s medical students, in all graduating classes, want more education about integrative medicine. The proportion is increasing with each graduating class. Among medical school classes, the percentage is relatively high in the first year, when entering students embody the culture of the general population. It declines somewhat in the second and third years, as students become “professionalized” and generally witness little reinforcement for the teaching of integrative medicine. The proportion then rises again in the fourth year, after students have worked with patients.

The literature of integrative medicine is in the process of being created, and there is a need for both “basic science” and clinical texts and journals in integrative medicine. Today, traditional medical book publishers are putting forth many new titles in complementary medicine, including a series entitled *Medical Guides to Complementary and Alternative Medicine*. Much work with curriculum and faculty development remains to be done in this area, and the traditional support from state and federal governments for medical education and training might be well utilized to help provide medical schools with the needed resources and incentives. In the interim, providers of health care services have the task of stimulating appropriate CME programs and in-service training for health professionals so that practitioners can help their patients who seek guidance on the use of integrative medicine.

**PUBLIC POLICY ISSUES**

State governments have developed a traditional role in regulating medical practice and in supporting medical education. The federal government maintains a unique and critical role in stimulating and supporting medical research, regulating medical products and devices, protecting the public health, and building a health care infrastructure. It is now paying approximately one third of the costs of health care in America. Policymakers at the state and federal levels should become more familiar with the needs and opportunities in relation to integrative medicine.

The bipartisan Congressional Caucus on Complementary and Alternative Medicine and Dietary Supplements was organized for this purpose. The Senate Co-Chairs are Tom Harkin (D-Iowa) and Orrin Hatch (R-Utah). In the House of Representatives, Dan Burton (R-Indiana) has also chaired the Government Reform Committee and will now chair its Subcommittee on Health. The Policy Institute for Integrative Medicine and others are working with members of the Caucus and other elected representatives to provide broader and deeper federal support for appropriate analyses and programs in integrative medicine.

It is unlikely that the current regulatory legislation governing dietary supplements (i.e., the DSHEA of 1994, as amended in 1998) will be changed anytime soon. Although funding for the National Center for Complementary and Alternative Medicine increases each year, commensurate with the multiyear doubling of the NIH’s overall budget, it is crucial that other federal agencies charged with programs relative to health resources and services, primary care, health professions training and work force development, consumer education, health services research, and other areas participate in the important challenge and opportunity of integrative medicine.

The important role of integrative medicine requires further discussion in current Congressional actions on medical liability, insurance reform, and the national patient safety and quality assurance initiative. Public support, together with private innovation, has been the hallmark of medical advancement in the 20th century, and this should continue to be the case for integrative medicine in the 21st century.

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