
A Descriptive Study of 19 Integrative Health Care Centers in the United States

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**Background:** Little is known about policies governing the integration of complementary and alternative medical (CAM) therapies and providers.

**Methods:** To document emerging approaches in 19 US hospitals regarding credentialing, malpractice liability, and pharmacy policies governing integration of CAM therapies and providers into conventional medical settings, we surveyed 21 academic medical centers and 13 non–academically affiliated hospitals that are nationally visible and are integrating CAM therapies into conventional medical settings. Of the 19 respondents, 11 were tertiary care hospitals, 6 were community hospitals, 1 was a freestanding center associated with a community-based hospital, and 1 was a university-based rehabilitation hospital.

**Results:** Institutions had no consistent approach to provider mix and authority within the integrative care team, and minimum requirements for professional liability insurance, informed consent disclosure, and hiring status. Less than a third had a formal (stated) policy concerning dietary supplements; those selling supplements in their pharmacy lacked consistent, evidence-based rationales regarding which products and brands to include or exclude. Although many hospitals confiscated patient supplements on admission, institutions had inconsistent criteria regarding allowance of home supply.

**Conclusions:** Hospitals are using heterogeneous approaches to address licensure, credentialing, scope of practice, malpractice liability, and dietary supplement use in developing models of integrative care. The environment creates significant impediments to the delivery of consistent clinical care and multisite evaluations of the safety, efficacy, and cost-effectiveness (or lack thereof) of CAM therapies (or integrative models) as applied to management of common medical conditions. Consensus policies need to be developed.

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etary supplements arguably should be part of history taking, the lack of agreed-on manufacturing standards and insufficiency of information concerning safety and efficacy for dietary supplements (and individual brands of supplements) has led some health care institutions to categorically ban patient use of dietary supplements. Ideally, determining the status of current practices can help clarify whether common approaches are emerging to facilitate reproducible models of integrative health care and generalizable clinical research.

**METHODS**

**Integrative medicine** is defined as health care that “combines mainstream medical therapies and CAM therapies for which there is some high-quality scientific evidence of safety and effectiveness.” Because the universe of US hospitals offering integrative medicine cannot be accurately determined—and is rapidly changing—this pilot survey identified centers from National Institutes of Health–funded research studies concerning CAM therapies, from the Consortium of Academic Health Centers for Integrative Medicine, from among attendees at Harvard Medical School Continuing Medical Education courses on delivery of CAM therapies, and from an examination of major, operating integrative care centers. We identified a convenience sample of 21 such academically affiliated and 13 non–academically affiliated hospitals with integrative care centers. An academic medical center is defined as a health care center that includes an allopathic or osteopathic school of medicine, at least one other health professions school or program, and one or more university-owned or -affiliated teaching hospitals.

We sent invitational letters, followed up by a survey and telephone calls, to medical directors of the integrative care centers in these 34 institutions. Twelve (57%) of the 21 academically affiliated centers and 7 (54%) of the 13 non–academically affiliated centers responded with completed surveys from May 1, 2001, through June 1, 2002. Of the 19 total respondents, 11 were tertiary care hospitals, 6 were community hospitals, 1 was a freestanding center associated with a community-based hospital, and 1 was a university-based rehabilitation hospital (see acknowledgments). Institutional review board approval from Beth Israel Deaconess Medical Center and Harvard Medical School, Boston, Mass, was obtained.

**RESULTS**

**Licensure, Credentialing, and Scope of Practice**

**Practitioner Mix**

The professional mix of practitioners participating in integrative care teams reflected no discernible pattern, across institutions, geographic regions, or provider groups within a given institution (Table and Web Appendix 1 [Mind Body Experts and Other Providers]). (All Web appendixes referred to in this article can be found on the Harvard Medical School Osher Institute’s Web site: http://www.osher.hms.harvard.edu/pu_general_pub.htm).

**Practitioner Scope of Practice and Requirement for Physician Referral**

Only 40 of the 170 total providers were explicitly required to obtain physician referrals before delivering clinical services to patients (Web Appendix 2 [Practitioner Scope of Practice]). Practitioner autonomy was heterogeneous, with no apparent pattern with regard to academic vs nonacademic affiliation. Slightly more providers were approved (71) than not approved (63) to recommend dietary supplements (ie, herbs, vitamins, and nonherbal supplements). Six of 15 non-MD acupuncturists and 9 of 17 nutritionists were so approved. More than twice as many providers (99 of 170) had authority to treat inpatients than did not have such authority (43 of 170). When asked whether centers had any specific limitations on provider authority other than those indicated in Web Appendix 2, few centers added written comments (Web Appendix 3 [Limitations on Provider Authority and Other Risk Management Strategies]).
Credentialing Requirements and Policies

Our survey asked respondents to confidentially provide their credentialing policies. The policies we received required evidence of competence, such as some combination of a valid state license (where available by state to the specific provider), specified limits of malpractice liability insurance, evidence of training (eg, documentation of national certification, or of highest certification available; or a specified number of hours of theory and of clinical training), and evidence of experience (eg, letters of reference from patients and/or providers). Additional requirements included interview and skills assessment, evidence of completion of mandatory continuing education units, health clearance, ongoing peer and committee review, and background check.

PROFESSIONAL LIABILITY AND RISK MANAGEMENT

Liability Insurance Requirements

There was no consistent pattern of liability insurance, either by provider type or between academic and nonacademic centers (Web Appendix 4 [Minimum Required Professional (Malpractice) Liability; Per Claim/Cost per Aggregate]). The most frequent response was a requirement of $1 million per claim/$3 million per aggregate in liability insurance (74 of 170 providers), although there was no response for 66 providers, suggesting that this information may not be readily accessible or may be unknown at many institutions. The remainder of institutional requirements for “other” providers represented in Web Appendix 4 reflected varied responses with regard to malpractice liability insurance: $5 million/unspecified (n=10); $3 million/unspecified (n=4); $300000/$600000 (n=4); $1 million/$1 million (n=4); $4 million/$16.5 million (n=2); $600000/$600000 (n=2); $2 million/$2 million (n=1); $1 million/$2 million (n=1); $1.2 million/$1.2 million (n=1); “brings own” (n=1).

Informed Consent

While survey respondents differed in whether and how they required providers to obtain patients’ informed consent and to document consent to CAM therapies, most required risk-benefit disclosure in some form. Specifically, of 18 respondents, 8 (5 academic and 3 nonacademic institutions) indicated that their intake forms or medical records contained informed consent language specifically geared to use of CAM therapies; 8 indicated that they did not. Five of the 8 (3 academic and 2 nonacademic institutions) with CAM-specific informed consent forms also required that providers delivering CAM therapies, including dietary supplements, verbally discuss the risks and benefits of these therapies with their patients and document these discussions in the medical record. An additional 6 of 18 indicated that they required discussions only. Four of 18 institutions (2 academic and 2 nonacademic) indicated that they required neither written informed consent nor verbal discussions.

Other Risk Management and Human Resources Policies

Nine of 19 institutions indicated having no specific comprehensive risk management policies regarding their CAM providers other than the stated minimum requirements for malpractice liability insurance. Some of the institutions indicated that they addressed risk management more informally (Web Appendix 3). When asked what key issues institutions believed needed to be addressed as institutional policy, varied responses included a mix of legal, clinical, and administrative concerns (Web Appendix 5 [Key Issues of Institutional Policy]).

Institutions offered no discernible pattern (or consistently stated rationale for deciding) as to whether providers were hired as employees or independent contractors, across institutions, within institutions by provider type, or within the conventional or CAM domain (Web Appendix 6 [Employee Status]). Overall, 78 providers were hired as employees, 44 were hired as independent contractors, there were 42 nonresponses, and 6 responses were ambiguous (eg, some indicated that the same provider type was hired both ways). There was no appreciable distinction between academic and nonacademic centers.

Responses to questions regarding contractual arrangements, income tax, and billing procedures also varied and did not clarify the data regarding employee status. Survey results did not disclose whether decisions in this arena reflected liability vs administrative concerns (eg, benefits or costs, such as incentives to participate in clinical team and administrative meetings at the center). We did not collect information on reimbursement by third-party payers.

PHARMACY AND THERAPEUTICS COMMITTEE PRACTICES

As summarized in Web Appendix 7 (Policies and Practices Involving Dietary Supplements), only 6 of 19 institutions had formal policies regarding dietary supplements. For the purpose of the survey, dietary supplements were defined for the respondents to include vitamins, minerals, and herbs (such as Ginkgo biloba, saw palmetto, and coenzyme Q10) that were neither approved nor classified by the Food and Drug Administration as drugs. The category did not include liquid caloric supplements.

Outpatient Policies and Practices Involving Dietary Supplements

Formal Policy and Therapeutic Recommendations. Of the 6 of 19 centers responding affirmatively to a question about the existence of formal (stated) policy regarding the use of dietary supplements (Web Appendix 7), only 2 indicated that the policy allows staff to make recommendations involving dietary supplements (and an additional 1 indicated that staff could recommend vitamins only); several institutions indicated that they have draft policies.
Outpatient Pharmacy. Six of 19 respondents (3 academic and 3 nonacademic) reported having an outpatient pharmacy that sells dietary supplements (Web Appendix 7). Of these 6, 1 included only herbal products; 5 included herbal products and homeopathic remedies as well as vitamins, minerals, and supplements. An additional respondent indicated that such a pharmacy was in development and would include homeopathic remedies.

Inpatient Policies and Practices Involving Dietary Supplements

Confiscation; Home Supply. Seven of 19 institutions indicated that they confiscate any and all dietary supplements at the time the patient is hospitalized (Web Appendix 7). Additional written responses are included in Web Appendix 8 (Policies Regarding Confiscation of Dietary Supplements), and the criteria used to determine which dietary supplement products patients may continue using during hospitalization are included in Web Appendix 9 (Criteria Regarding Home Supply of Dietary Supplements).

Documentation of Inpatient Use. Eleven of 18 institutions responding to this question required documentation of inpatient use of dietary supplements and 7 indicated that no documentation was required. Six respondents indicated that documentation was required only in the admission note; 2 indicated that documentation was required only in the patient’s hospital chart; and 2 respondents indicated that documentation was required in the admission note, hospital chart, and medication administration record. Eleven respondents specified that the documentation must include the name of the dietary supplement; 9 of the 11 also required the dose, 5 required the indications, and 4 required product identification.

Inpatient Formulary; Influence of Third-Party Reimbursement. Nine of 16 responding institutions reported having an inpatient formulary for dietary supplements. Eight of these 9 included vitamins, minerals, and supplements; the ninth included only vitamins. One also included herbal products. The criteria used to determine which dietary supplement products and brands to include were quite varied (Web Appendix 10 [Criteria Used to Determine Which Dietary Supplement Products to Include in Formulary] and Web Appendix 11 [Criteria Used to Determine Which Dietary Supplement Brands to Include in Formulary]). Two of 13 respondents reported that the availability of third-party reimbursement would influence the decision to include dietary supplements in the formulary (Web Appendix 7). Ten reported that this factor would have no influence, and one indicated “not certain.”

Anesthesia and Surgery Recommendations Regarding Discontinuance of Herbs, Vitamins, and Supplements. Six respondents (all academic centers) indicated that they make formal recommendations regarding the continued use (or discontinuance) of dietary supplements before elective surgery (eg, to discontinue those known or thought to interact with anesthesia or clotting; see Web Appendix 12 [Anesthesia and Surgery Recommendations Regarding Discontinuance of Herbs, Vitamins, and Supplements] and Web Appendix 7). Thirteen other centers did not respond to this question.

Our pilot data suggest that hospitals are using heterogeneous approaches to address licensure, credentialing, and scope of practice of complementary care providers; malpractice liability; and dietary supplement use in efforts to develop models of integrative care. The standardization of provider education, training, and therapeutic approach facilitating consistent research across institutions and states is lacking.

Licensure, Credentialing, and Scope of Practice

We found no consistency in approaches to professional provider mix within the integrative care team. Nearly every center included a “mind-body” provider, for example, while only 4 included a naturopath; 16 included a massage therapist, while only 7 included a chiropractor; some included both MD and non-MD acupuncturists, while others included one but not the other. Even within the category of “mind-body” expert, choices ranged from psychiatrist to psychologist to “healing touch therapist” and “spiritual counselor”; and the range of “other” providers included “child life specialist,” “biofeedback technician,” “art therapist, movement therapist, and “energy practitioner,” as well as physical therapist, reflexologist, and osteopath. Such diversity may reflect the uneven map of licensure for various CAM providers across states, as well as potential liability concerns; the lack of clear definitions of integrative clinical care and of “mind-body” care; institutional reluctance to include unlicensed providers (such as naturopathic physicians in some states); the present lack of an evidence base concerning the optimal (and most cost-effective) professional provider mix in the integrative team; the effect of personal beliefs and practices (particularly involving herbal medicine) on CAM practices; and the influence of decisional norms within institutions on local credentialing decisions.
PROFESSIONAL LIABILITY AND RISK MANAGEMENT

Although the most common requirement was $1 million per claim/$3 million per aggregate, the requirements were inconsistent across institutions and across providers within institutions. Generally, legal rules governing malpractice liability involving CAM therapies are in flux and present uncertainty to clinicians. For some professions (such as acupuncture), the lack of significant published information concerning claims experience makes it difficult to determine definitively what level of insurance should be required. CAM therapies also account for only approximately 5% of the total medical malpractice insurance market; to date, both the number of claims against CAM providers and the average indemnity paid per claim have been lower than claims against primary care physicians. However, this situation may change as integrative care expands.

Concerning informed consent, respondents generally seemed aware of the need for disclosure of risks and benefits concerning CAM therapies, although there was no standardized approach, and hospitals differed as to whether such disclosure should be written or verbal and how it should be documented. Inadequate informed consent can be grounds for malpractice liability apart from any negligent care. Furthermore, new guidelines by the Federation of State Medical Boards require specified informed consent procedures, at least for physicians counseling patients regarding use of CAM therapies.

The respondents had no consistent approach to hiring status. The heterogeneity may reflect financial constraints and/or legal ambiguity concerning institutional liability: health care institutions are vicariously liable for the negligence of their “employees” but not for the negligence of affiliated “independent contractors.”

PHARMACY AND THERAPEUTICS COMMITTEE PRACTICES

Dietary supplement policies also varied. Less than a third of the sample had a formal policy concerning dietary supplements. While 6 of 10 centers indicated selling dietary supplements in their outpatient pharmacy (and 9 of 16 indicated selling in their inpatient pharmacy), there was no consistent rationale regarding which products and brands to include (or explicitly exclude); responses ranged from “no specific criteria” to “cost.” Although approximately a third had a practice of confiscating dietary supplements on the patient’s admission to the hospital, there were no consistent criteria across institutions as to which supplements to allow patients to continue using as home supply; several hospitals allowed ad hoc decisions by attending physicians. Practices also varied concerning requirements for documentation of dietary supplement use, a topic now being addressed by the Joint Commission on the Accreditation of Healthcare Organizations.

Hospitals differed as to whether the availability of third-party reimbursement would influence their policy concerning dietary supplements; only 6 of 19 respondents made formal recommendations regarding the continued use of supplements before elective surgery.

LIMITATIONS

The generalizability of this pilot study was limited by several factors, including the nonresponse rate (44%). Numerous attempts to reduce the nonresponse rate through follow-up telephone calls and e-mail were unsuccessful. However, it seems unlikely that data from the remaining sites would have significantly reduced the inconsistencies in the responses that were observed from the 19 responding sites.

The nonresponse rate across various questions may reflect the uncertainty that pervades this field, including concern about sharing data. The length and complexity of the survey, and the lack of a centralized location within each center from which to retrieve the information, may have contributed to missing data. In addition, answers to surveys suggested that some of the follow-up questions simply did not apply to particular institutions, or required information that was unknown to the respondent. Finally, hospitals define and operationalize “integrative care” differently—some create specific centers for “complementary medicine” or “integrative medicine”; others have affiliated clinics devoted to “wellness,” “mind-body,” or similar concepts; and still others have CAM providers in various hospital departments (e.g., a non-MD acupuncturist in the pain center) but no “integrative care” unit. Therefore, respondents may not have included all relevant CAM providers in their survey responses, while others may have been overinclusive.

CONCLUSIONS

Our pilot study suggests that hospitals across the United States are implementing vastly different practices and policies concerning CAM providers and therapies, as regards credentialing, malpractice liability, and use of dietary supplements. The current environment creates significant impediments to the delivery of consistent clinical care and the implementation of multisite evaluations of the safety, efficacy, and cost-effectiveness (or lack thereof) of CAM therapies (or integrative models) as applied to the management of common medical conditions. Specific obstacles include the following: (1) inconsistency of state laws regarding provider licensure of
acupuncturists, massage therapists, chiropractors, naturopaths, and “mind-body” therapists, and corresponding divergence of hospital practices concerning credentialing, limitations on practice authority, and provider mix in the integrative team; (2) divergence of approaches to liability management strategies, including minimum malpractice liability insurance, informed consent practices and documentation, and provider hiring status; and (3) variability of approaches to patient use of, and clinician recommendations involving, dietary supplements, including the presence (or absence) of relevant, formal (stated) policies, the presence (or absence) of various combinations of dietary supplements in the formulary for outpatient and inpatient pharmacies, varying criteria (or lack thereof) regarding which products and brands to include (or explicitly exclude), varying confiscation practices and criteria for allowing home supply, and varying formal recommendations (or lack thereof) regarding the continued use (or discontinuance) of dietary supplements before elective surgery.

Furthermore, institutional inconsistency and ambiguity complicate clinical decision making as well as research, and foster ethical issues.24 Such difficulties would likely benefit from national consensus approaches to credentialing, malpractice liability policies, and guidelines for dietary supplement recommendations.

In designing consensus, the regulatory landscape creates several conundrums. Since the US Constitution reserves regulation of health, safety, and welfare (and therefore licensing of health care providers) to the states, diversity of licensing and scope of practice rules across states is unlikely to change.25 Nor are hospitals likely to increase standardization of integrative care teams in the absence of data concerning what combinations of providers or therapies are most effective (and safe) for any given condition. Potential liability exposure is difficult to predict, particularly given changing case law and changing levels of evidence for specific therapies,26 and local institutional politics are likely to continue playing a significant role in the emergence of models of integrative care.10 In short, a national, standardized approach to licensure, scope of practice, credentialing, and liability management may not be feasible. In addition to regulatory issues and liability concerns,26 ethical issues complicate matters.14,22,23

While licensure, credentialing, and scope of practice and liability issues are thorny, dietary supplement policies may lend themselves more easily to research as evidence accumulates regarding safety and efficacy (or lack thereof) and mechanism of supplements, including their potential interactions with conventional medication.27 Here greater consensus might be achieved, and hospitals may be able to abandon risky and unsupported approaches that lack scientific justification.

We offer the following policy recommendations. First, while licensure and scope of practice are matters of state law, either an agency to coordinate federal policy concerning CAM research and practice,24 the Council of Governors, or another appropriate governmental body could encourage CAM professional organizations to develop model legislation and guidelines (where feasible and appropriate) to take the following steps: (1) increase the standardization in minimum required education and clinical training for licensure (and/or adopt a national certifying examination) across states; (2) create standardized, biomedical curricular components for their students; (3) facilitate reduction in scope of practice variations across states; (4) increase the proportion of educational institutions within the profession that are professionally accredited; (5) define or limit potentially misleading uses of the term primary care provider within the CAM profession; (6) enhance opportunities for licensees to participate in clinical residency in integrative care centers, with the intent of receiving supervision by senior clinicians from both the conventional and CAM communities; and (7) create performance standards and assessment of clinical skills for conventional and complementary care providers who work in integrative care settings.

Second, stakeholder groups could, individually and collectively, encourage relevant professional organizations and agencies to consider creative ways of using integrative care centers to help further consistent clinical care and research. Such centers could become key educational hubs in which biomedical and CAM clinicians and researchers receive the cross-disciplinary training necessary for safe, evidence-based integrative care and innovative investigation.

Third, regulations should encourage institutional review boards to include CAM providers and other expertise relevant to evaluation of protocols and risks for human subjects in research studies involving study of CAM therapies. Such regulations could reduce potential bias against (or for) CAM protocols, and furnish institutional review boards a broader range of expertise with which to evaluate relevant research.

Fourth, in trying to achieve sufficiently standardized approaches to developing multisite research protocols across states, investigators may find it advantageous to define the modalities specified providers are allowed to offer in clinical trials.3 Finally, the Consortium of Academic Health Centers for Integrative Medicine plans to become a national repository of information concerning preferred institutional practices.11 These steps, without intruding on states’ rights to be “laboratories for experimentation,” and while respecting the diversity of institutional approaches and pluralistic development of models of integrative care, will encourage the development of more consistent policies relating to clinical delivery and research involving integrative care.

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**Additional Information:** Copies of the survey instrument used for this study can be found on the Harvard Medical School Osher Institute’s Web site, http://www.oshers.harvard.edu.

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**REFERENCES**


