Hospitals and Complementary and Alternative Medicine: Managing Responsibilities, Risk, and Potential Liability

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KEY WORDS

complementary therapies, hospitals, policy-making, organization policy

ABBREVIATION

CAM—complementary and alternative medicine

www.pediatrics.org/cgi/doi/10.1542/peds.2010-2720I

doi:10.1542/peds.2010-2720I

Accepted for publication Mar 30, 2011

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PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: *The authors have indicated they have no financial relationships relevant to this article to disclose.*

abstract

Patients and families increasingly press hospitals to facilitate provision of complementary and alternative medicine (CAM) therapies and products. At the same time, a growing number of hospitals and health care facilities have taken steps to integrate CAM and conventional care. In this article we consider institutional responsibilities when patients/parents use or are considering CAM. We (1) review hospitals' responsibilities to patients and parents, (2) explain how these principles apply in the case of CAM practitioners and products, (3) address institutional responsibilities for different models of service delivery, and (4) highlight issues that should be addressed when developing institutional policies to govern CAM use and propose ways to do so. *Pediatrics* 2011;128:S193–S199

We continue with the example of 6-year-old Jake's success with acupuncture for chemotherapy-induced nausea and vomiting, described in the preceding article in this supplemental issue of Pediatrics.[1] *His parents had originally requested that he receive acupuncture at the local children's hospital where he was an inpatient. The hospital concluded that its policies did not allow for a community-based acupuncturist to deliver inpatient care. When Jake's parents took him out of the hospital on intermittent passes for acupuncture treatments, the frequency and severity of his adverse effects decreased, and he began eating better and regaining weight. His parents are delighted but remain distressed that they were unable to obtain inpatient acupuncture therapy or coordinate care between his oncologist and acupuncturist. They wonder whether arrangements could be made to better integrate conventional treatment and complementary and alternative medicine (CAM) therapies.*

In this article we consider institutional responsibilities when patients use CAM. Patients and families increasingly press hospitals to facilitate provision of CAM therapies and products. At the same time, a growing number of hospitals and other health care facilities have taken steps to integrate conventional and CAM care[2–5]; some of them have adopted formal policies, whereas others proceed on a more informal, ad hoc basis.[6–9]

Here, we (1) review hospitals' responsibilities to patients/parents, (2) explain how these principles apply in the case of CAM practitioners and products, (3) explore the implications of different models of service delivery for hospitals, and (4) highlight issues that should be addressed when developing institutional policies to govern CAM.

ETHICS: ORGANIZATIONAL RESPONSIBILITY AND FAMILY-CENTERED CARE

Organizational ethics in health care comprises issues with which a health care organization must grapple to ensure that care is provided in a safe, efficient, and respectful way, consistent with its mission.[10,11]

Health care organizations that care for children often profess to offer family-centered care.[12] Beyond the recognition that children are a part of families and families are deeply involved and invested in their child's treatment, family-centered care suggests that a family's values and beliefs shape not only their decisions and perceptions of what is in their child's best interests but also their understanding of and the meaning they assign to health and illness. Folk remedies, traditional medicines, and healers are important and meaningful to many cultures and, indeed, are used by most of the world's population as first-line therapy. Because many families incorporate CAM into their health strategies, hospitals should recognize this fact and, when possible, accommodate reasonable requests from families who wish to receive natural health products or CAM services within the hospital setting. Of course, hospitals have a duty to create a safe environment for patients, which should include going to reasonable lengths to provide or allow provision of safe and effective CAM treatments that current evidence indicates could improve patients' health or help them manage their symptoms.

Although hospital administrators have obligations that extend beyond those to particular patients and families, they should enable the provision of care that is consistent with patient and family preferences and values when it is also consistent with providing a safe environment and meeting their fiscal responsibilities.

LAW

Even in different jurisdictions, hospitals share broad areas of legal responsibility. Hospitals owe a legal duty to provide reasonable care for patients.[13] A hospital may be directly liable to a patient for its own negligence or breach of contract when it fails to meet its obligations.[13,14] It may also be vicariously liable for the negligence of those for whom it is legally responsible, such as employees and those with apparent authority to act on its behalf.[13,14] If a hospital decides to allow CAM practitioners to provide care onsite or to coordinate care with CAM practitioners off-site, it must be cognizant of both its duty of care to patients and that owed by service providers. General legal principles governing hospital liability provide the starting point for analysis.

Direct Liability

In the United States and Canada, the most common duties hospitals owe patients are "(1) to use reasonable care in the maintenance of safe and adequate facilities and equipment; (2) . . . to select and retain only competent physicians; (3) . . . to oversee all persons who practice medicine within its walls as to patient care; and (4) . . . to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients."[14(p474),15,*] Legal scholars in Canada and the United States identify the most basic duty of the hospital as ensuring that those who treat patients are qualified and competent.[13,14] This obligation is not limited to hospital employees; it extends to physicians and other health professionals such as midwives and dentists who are

*These duties are phrased similarly in Canada: "1. to select competent staff and monitor their continued competence; 2. to provide proper instruction and supervision; 3. to provide proper facilities and equipment; and 4. to establish systems necessary for the safe operation of the hospital."[13(p460)]

granted privileges to work in the hospital but are not employed by it. The hospital has to ensure that personnel are working within their competence and receive appropriate training and supervision. Hospitals must also establish "safe systems" for the protection of patients[16,17] and ensure proper coordination among the various elements of patients' treatment programs.[13,17–19]

Vicarious Liability

In addition to direct liability for their own failure to take reasonable care, hospitals can be held vicariously liable for the negligence of those for whom they are legally responsible, such as employees and volunteers, provided they are acting within the scope of their employment or duties.[16,20–22] In Canada, hospitals are generally not liable for the negligence of nonemployees, which is the position of most physicians and others, such as dentists, who have been granted privileges to work at the hospital and may be affiliated as independent practitioners.[16] However, recent developments in the law may make this limit on hospitals' liability vulnerable to challenge.[13,20,23] Courts in the United States have been more willing to hold hospitals liable for nonemployed physicians' negligence and have most often used theories of ostensible agency, apparent authority, or nondelegable duty.[24–26]

Managing Risk Associated With CAM Therapies for Acupuncture

Lawsuits alleging that CAM use caused harm are rare,[27,28] and allegations of institutional responsibility are more rare still. In 1 Canadian case, a negligence claim against an acupuncturist and a physician-owner of the clinic at which treatment was received was settled before trial.[29] Whether a hospital would be liable if a CAM practitioner negligently injured a patient would depend on the relationships between the hospital, the patient/parents, and the CAM practitioner and the circumstances and terms under which treatment was provided. Different arrangements may prevail. The most common arrangements are listed in Table 1.

Because adequate supervision and control offer the best opportunity to prevent or limit substandard care and patient injury, the wisest course for hospitals that allow on-site provision

TABLE 1 Potential Hospital Liability for Negligence of CAM Providers

Location of Care	Practitioner Relation With Hospital	Type of CAM Practitioner	Considerations That Affect Potential Hospital Liability
Off-site	None	Any	No relation between hospital and provider, so no hospital liability for practitioner negligence
Off-site	Selected or recommended by hospital	Any	Possibility that hospital owes duty of care if it selected or recommended the practitioner[13,24]
In hospital	Retained and paid by patient/family	Any	Hospital has duty to take reasonable care for patients' safety[24,57]; if analogous to privately hired special-duty nurse, then generally there is no hospital liability[13] unless the hospital recommended the practitioner or knew or ought to have known of problems; CAM therapies may differ from conventional care, less is known about treatments and practitioners, and there are different goals of therapy, which suggests the need for an approval process or other "vetting" of what occurs on-site[26]; prohibit practices with unacceptable risk to patient safety; the hospital is obliged to comply with child-protection laws (reporting obligations to child welfare authorities)
In hospital	Credentialed by hospital; nonemployee	Practitioners regulated by government	Could develop from existing credentialing process for conventional practitioners (eg, physiotherapists)[31,42]; status of regulated health profession is meant to provide some assurance that providers meet specified qualifications and are in good standing[31,42,59]; the hospital may restrict a provider's institutional scope of practice if lacking desired level of evidence of safety and/or efficacy[39,42]; the hospital may limit type of practitioner[39]
In hospital	Credentialed by hospital; nonemployee	Unregulated practitioner	Hospital specifies training and qualifications and conditions for providing therapy; if regulated in other jurisdictions, may provide guidance to establish required qualifications
In hospital	Employed by hospital	CAM practitioner or conventional practitioner who also provides CAM therapy (eg, registered nurse who performs therapeutic touch)	Hospital is vicariously liable for negligence of employees within the scope of employment[16,24]; "scope of employment" is often interpreted broadly by courts; the patient may consent to care because the practitioner is part of hospital organization; CAM care will likely be considered within scope of employment of an employed health practitioner caring for that patient

of CAM is to take reasonable steps to control and supervise practitioners to maintain safety and quality of care.[26]

Managing Risk Associated With CAM Products

CAM products can present different challenges, especially because patients often use natural health products or dietary supplements without consulting health care providers. If the prospect of toxicity or adverse interactions between conventional treatments and pharmaceuticals and CAM therapies or products is known or ought to be known and is not effectively managed, resulting in harm to patients, both clinicians and their hospital could face the prospect of liability.[30,31]

CLINICAL RESPONSE

Despite success in extending survival rates for pediatric cancer (in 2000, >70% of children who developed cancer were expected to survive[32]), chemotherapy-induced nausea and vomiting remain significant and debilitating adverse effects. CAM use is prevalent in pediatric oncology[33–35]; utilization rates are estimated in the range of 36% to 46%. Of 17 academic pediatric integrative medicine programs in North America, 8 offer integrative cancer care or access to acupuncture.[9]

Parents rarely believe that CAM will cure their child's cancer. Instead, they use CAM in conjunction with conventional therapy to provide relaxation and comfort and improve overall health.[36,37] In pediatric oncology, "lack of confidence" or "disappointment" in conventional treatment is rarely cited as a factor when seeking CAM therapies. Instead, parents' decision to turn to CAM is based on their desire to do "everything possible."[34,38] Accustomed to being their child's substitute decision-makers, parents want to work closely and collaboratively with health care providers.[34] Integrating CAM therapies that offer a reasonable prospect of therapeutic benefit is a way to assure parents that hospitals and clinics will aid them in doing everything possible to make their child as comfortable as possible. Nevertheless, integration is not simple; it depends, in part, on the level of staff expertise and comfort with CAM and whether there are institutional barriers, including perceptions of CAM and concerns about potential liability.[39]

Medical leadership should initiate the development of guidelines and policies to respond to requests for CAM and perhaps establish a multidisciplinary working group with family representation. Less may be known about particular types of CAM than conventional health care, but decision-making under conditions of uncertainty occurs frequently in conventional health care as well. An important starting point would be to assess anticipated benefits and risks of the treatment on the basis of available evidence of safety and efficacy. Adams et al[40] proposed a decision-making framework to assist clinicians' assessment of CAM therapies and suggested that (1) if evidence supports both safety and efficacy, the physician should recommend the therapy but continue to monitor conventionally, (2) if evidence supports safety but is inconclusive about efficacy, then the treatment should be cautiously tolerated and monitored for efficacy, and (3) if evidence supports efficacy but is inconclusive about safety, the therapy could be tolerated and monitored closely for safety. However, (4) if evidence indicates either serious risk or inefficacy, the treatments should be avoided and patients actively discouraged from use.[40,41] This framework could be adapted to hospital decision-making but with the caveats we noted earlier in this series[42]: evidence for many types of CAM therapies is lacking,[40] CAM therapies must still be assessed in light of conventional therapies and what they offer patients, and there is a special duty to act in the best interests of those pediatric patients who are not yet capable of making their own treatment decisions.

It would be prudent for hospitals and other health facilities to consider adopting a formal protocol and/or some formal process to establish (1) what CAM therapies to allow or make available on-site, (2) which kinds of CAM practitioners can provide them, (3) under what conditions would they provide them, and (4) how the practitioners will function and interact with patients, other health care providers, and the institution.[27,43,44]

RECOMMENDATIONS FOR INSTITUTIONAL POLICY DEVELOPMENT

The following are issues that should be considered when formulating policy.

Credentialing

Credentialing is "the process of obtaining, verifying, and assessing the qualifications of a health care practitioner to provide patient care services in or for a health care organization."[45] Hospitals could adapt credentialing processes used for other health care providers to CAM practitioners,[43,46] which would include proof of licensure or membership in a regulated health profession (when applicable); satisfactory completion of required courses, examinations, and continuing education; satisfactory history in relation to disciplinary action and malpractice liability; and, for nonemployees, appropriate malpractice insurance. If the practitioner is not a member of a health profession regulated by statute, then consideration should be given to specifying required training and com-

pletion of examinations or certification by an authoritative body.[47]

Even if CAM practitioners are not credentialed by the hospital and their provision of services at the patients' or families' request is merely accepted, the hospital should still ascertain the practitioner's identity and training and what care will be provided on-site so that it can fulfill its obligation to provide a safe environment for its patients.

As with conventional health care, additional controls are needed to ensure practitioner competence and that treatments meet hospital requirements for safety and efficacy, as outlined in the following section.

Governing CAM Practice

Informed Consent

It is essential to obtain informed consent for treatment regardless of whether it is conventional care or CAM.[1] Given the nature of the treatment, the hospital may wish to specify what information must be reviewed with patients/parents (eg, the nature and strength of evidence supporting the therapy and the potential for interactions between CAM and conventional therapies such as adverse herb–drug interactions).

Standard of Care

CAM is an emerging area for practice, regulation, and research; as such, the evidence base is generally less developed than for much conventional health care.[26,48] This lack of evidence can make the task of developing institutional standards of practice difficult, particularly for unregulated practitioners. However, research is ongoing, and information about safety and efficacy is increasing and should enable more informed judgments to be made. Hospitals will have to determine how they will weigh risks and benefits and what level or kind of evidence of safety and efficacy will be sufficient to allow therapeutic recommendations.[49] The decision-making framework described previously could provide a useful starting point for this process.

If a CAM therapy is recommended or undertaken, provision should be made for how, by whom, and where the rationale for this therapeutic choice, patient/parent consent, and the care provided will be documented.[50]

Scope of Practice

Hospitals should be aware of the scope of CAM providers' practice authorized by legislation and ensure that therapies provided on-site comply with regulatory requirements. Uncertainty about safety or efficacy may affect decisions about the scope of practice permitted on-site. Institutions may narrow CAM providers' scope of practice in the hospital from that authorized by their governing statute. If there is not convincing evidence of efficacy for some part of CAM providers' practices, some American health care institutions limit them to what is supported in the literature.[43] Alternatively, institutions may limit provision of some treatments to specified types of practitioners such as members of regulated professions.[39]

Collaborative Practice

Hospitals should develop protocols to guide collaborative practice among different types of practitioners (conventional or CAM) and clarify their respective roles and responsibilities.[26,51]

Supervision

Liability implications for supervisors and the institution should be assessed, particularly if the supervisor is an independent practitioner and not a hospital employee.

Duty to Refer

Consideration should be given to outlining circumstances in which CAM providers should refer for conventional care. Conversely, there may be instances when conventional providers should consider referral to CAM providers, depending on the strength of evidence for a particular application. Policies should be consistent with regulatory requirements, such as a duty to refer to a physician if there has been no improvement within a specified time.[52–54]

Monitoring

Patients should be monitored by conventional means and conventional care should be provided as appropriate, with consent. In hospitals, CAM is generally meant to be a complement to conventional care, not a replacement or substitute. Health care providers need to be alert to the possibility that CAM may affect the therapeutic benefits that conventional care can provide, whether synergistically or antagonistically.[30,55]

Products

The prevalence of patient-initiated use of CAM products without consultation suggests the need to (1) ascertain and document patient use, (2) consider what products can be used while the patient is in the hospital and which must be discontinued, (3) clearly explain these policies to patients, and (4) monitor compliance to avoid risk to patients' health.[56]

Quality Assurance

Hospitals have important responsibilities to ensure the quality of care. Obligations to report adverse events internally and externally and to disclose harm to patients are expanding.[23,57,58] Quality-assurance programs can and should be adapted and applied to CAM.

Liability Insurance

When employees provide CAM, hospitals need to ensure that existing liability insurance covers this type of care.

For CAM providers who are independent practitioners, consideration should be given to whether the practitioner must establish proof of adequate insurance coverage. Practices applicable to other nonemployees who are credentialed and have hands-on responsibilities for patient care could provide useful guidance about both insurance and indemnification.

Cost

Hospitals, patients/parents, and practitioners need a clear understanding of who is responsible for payment. Private third-party insurance may not cover CAM services or may limit reimbursement. Coverage under public health insurance plans for CAM treatments in Canada is limited or nonexistent.[59,60]

ACKNOWLEDGMENTS

Funding for this project was partially provided by the SickKids Foundation (Toronto, Ontario, Canada). Dr Vohra received salary support from the Alberta Heritage Foundation for Medical Research and the Canadian Institutes of Health Research.

We gratefully acknowledge the contributions of Soleil Surette and Alison Henry for help in literature searching and manuscript preparation, Maya Goldenberg and Andrew Milroy for bioethics research assistance, and Osgoode Hall Law School students (now graduates) Nicola Simmons, David Vitale, Kristine Bitterman, and Janet Chong for assistance with legal research.

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Pediatrics 2011;128;S193
DOI: 10.1542/peds.2010-2720I

PEDIATRICS®
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