

Complementary and Alternative Medicine Practitioners' Standard of Care: Responsibilities to Patients and Parents

abstract

In this article we explain (1) the standard of care that health care providers must meet and (2) how these principles apply to complementary and alternative medicine practitioners. The scenario describes a 14-year-old boy who is experiencing back pain and whose chiropractor performed spinal manipulation but did not recognize or take steps to rule out serious underlying disease—in this case, testicular cancer—either initially or when the patient's condition continued to deteriorate despite treatment. We use chiropractic care for a patient with a sore back as an example, because back pain is such a common problem and chiropractic is a common treatment chosen by both adult and pediatric patients. The scenario illustrates the responsibilities that complementary and alternative medicine practitioners owe patients/parents, the potential for liability when deficient care harms patients, and the importance of ample formal pediatric training for practitioners who treat pediatric patients. *Pediatrics* 2011;128:S200–S205

AUTHORS: Joan Gilmour, LLB, JSD,^a Christine Harrison, MA, PHD,^b Leyla Asadi, MD,^c Michael H. Cohen, JDA, MBA,^d and Sunita Vohra, MD, MSc^{e,f}

^a*Osgoode Hall Law School, York University, Toronto, Ontario, Canada;* ^b*Department of Bioethics, SickKids Hospital, Toronto, Ontario, Canada;* ^c*Departments of Medicine and ^dPediatrics, Faculty of Medicine, University of Alberta, Edmonton, Alberta, Canada;* ^e*Fenton Nelson LLP, Los Angeles, California;* and ^f*CARE Program for Integrative Health & Healing, Stollery Children's Hospital, Edmonton, Alberta, Canada*

KEY WORDS

complementary therapies, legal liability, evidence-based practice, clinical competence

ABBREVIATION

CAM—complementary and alternative medicine

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Address correspondence to Sunita Vohra, MD, MSc, Edmonton General Hospital, 8B19-11111 Jasper Ave, Edmonton, Alberta, Canada T5K 0L4. E-mail: svohra@ualberta.ca

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Michael is a 14-year-old boy who complains of new-onset back pain with no known precipitating cause that limits his activities and wakes him from sleep. He visits his mother's chiropractor, who takes a history, completes a physical examination, and concludes that Michael has a misaligned spine. He performs spinal manipulation on Michael during 12 visits over a 6-week period. When Michael begins to complain of increasing pain and fatigue, the chiropractor suggests that they are likely to be adverse responses to the spinal manipulation and recommends nutritional supplements and relaxation techniques for improvements to his overall health. Michael's mother takes her son to his pediatrician for a second opinion. On examination, the pediatrician discovers that Michael has lost 5 kg in the past month and has a mass lesion in his left scrotum. Additional testing confirms the suspicion of testicular cancer and also reveals lung and retroperitoneal nodal metastases. A unilateral inguinal orchiectomy is performed, and it is determined that Michael has a nonseminomatous testicular tumor. Combination chemotherapy is quickly initiated.

Testicular cancer is not a common cancer, but it is the most common malignancy in males between the ages of 15 and 35 years. Of patients with disseminated disease, ~25% initially present with symptoms that arise from the metastasis and not the primary tumor.¹ Back pain is the most common symptom of metastatic disease.²

Many people suffer from back pain, although relatively few of them have cancer. They may consult conventional, complementary and alternative medicine (CAM), or a combination of health care providers to find relief. In a large 2007 survey, the most common reason for which American adults used CAM

was for back pain; back or neck pain was also the second-most common reason that young people did so.³ Chiropractic is one of the most established CAM therapies. It is a regulated health profession in all jurisdictions in Canada and is licensed in every US state.^{4,5} Because back pain is such a common problem and chiropractic is a common response, we use it here to illustrate the responsibilities that CAM practitioners have to patients/parents and the potential for liability when deficient care harms patients. In this article we (1) explain the standard of care health care that providers must meet and (2) examine how these principles apply to CAM providers.

ETHICS

Canadian chiropractors are required by their code of ethics to “recognize the limitations of [their] expertise, and when indicated, will recommend to a patient that additional options and services be obtained.”⁶ Smith⁷ has suggested that chiropractors have an ethical duty to understand the limits of their own competence and those of the profession. Pearle⁸ cautioned that chiropractors should be knowledgeable about the current literature and research, in part so they may recognize the limits to their own abilities. This ethical obligation is common to all health care providers.

LAW

In the introductory article of this supplemental issue of *Pediatrics*⁹ we explain the legal duty of care that health practitioners owe their patients and outline what a plaintiff must prove to succeed in a negligence action. In this article we focus on one aspect of clinicians' obligations: the legal standard of care owed to patients and how it is determined.

CAM Practitioners' Standard of Care

Regulated/Recognized CAM Practitioners

When considering the more widely recognized CAM therapies such as chiropractic, US and Canadian courts judge practitioners by the standard appropriate to their discipline,^{10–13} that is, standards that “conform to [their] education, training, and peer expectations.”¹⁴ (pp235–236) Courts have articulated the standard of care to which chiropractors are held in the same terms that apply to physicians: “that degree of care, diligence, judgment and skill which is exercised by a reasonable chiropractor under like or similar circumstances.”^{15–19}

Principles generally applicable when determining medical liability apply to these CAM practitioners as well.^{18,20} Departure from approved practice, although not negligence per se, may underpin a finding of negligence if it is shown that what occurred was not something a reasonable practitioner would have done in similar circumstances.^{14,18} Breach of professional or clinical guidelines or policies, or failure to comply with regulatory requirements, may also provide evidence of negligence.^{21,22} When determining the professional standard of care, courts will consider expert evidence of other practitioners in that field,²³ applicable legislation, regulations, policy statements, and guidelines issued by regulatory bodies or professional associations, and judicial decisions on previous cases.^{19,21,24,25}

When a chiropractor undertakes a patient's care, he or she must investigate the cause of the patient's complaint or condition to determine if chiropractic treatment could benefit the patient and to formulate a treatment plan. Health care professionals are not expected to meet a standard of perfec-

tion; they can make errors in judgment without being found negligent unless the error is one that falls below the standard of care (ie, that a reasonable practitioner in that field would not have made in similar circumstances).^{10,12,14} When a patient's clinical condition warrants (eg, continued or unexpected deterioration or the onset of new symptoms), the practitioner should consider other possible explanations. The diagnosis or assessment may have to be reconsidered, and treatment changed or a referral made, as appropriate.^{14,26,29} Treatment determined to be ineffective should be discontinued. In both Canada and the United States, nonmedical providers (whether allied health or CAM) may have a duty to refer the patient when it becomes apparent that the patient's condition exceeds the provider's skill and training.^{14,19,27–30} Referral must be timely to avoid delaying needed care.

In some circumstances, courts do not use the previously described professional standard to judge the care provided.²⁰ When conventional, CAM, or allied health practitioners act outside the scope of practice legally permitted or generally accepted by peer practitioners, the underlying justification for judging them by standards that conform to their education, training, and peer expectations would no longer hold.^{20,31} Consequently, a professional standard of care would be inappropriate. In addition, a heightened standard of care may be imposed when clinicians' areas of knowledge or treatment overlap; expert evidence from conventional practitioners not trained in the discipline concerned may be relied on to establish standards of practice applicable to diagnosis or treatment.^{20,27} In the United States, Cohen gave an example of chiropractors being authorized by law to take radiographs, conduct urinalysis, order blood and other routine laboratory

tests, or perform physical examinations; failure to do so "may be judged against a biomedical standard of care, and constitute malpractice."^{19(p230),32} Finally, Canadian cases have not uniformly recognized the validity of differing "schools of opinion" regarding diagnosis.³³ However, courts increasingly accept that diagnoses may legitimately vary among systems of health care on the basis of different principles (provided the health system itself does not fall below the standard of care).^{20,34,35} This is consistent with growing state acceptance of different types of CAM, evidenced by their inclusion in regulatory regimes governing health professions and statutory recognition of their separate scopes of practice and distinct forms of diagnosis.

Unregulated/Less Recognized CAM Providers

Many types of CAM are neither as well recognized nor as integrated into the health care regulatory system as chiropractic. Less well-accepted types of practitioners may not be recognized as a profession or share a common practice.^{19,36} Courts will enforce statutory prohibitions on unauthorized practice,^{37,38} but beyond that, judicial guidance about the standard of care applicable to these types of CAM providers is scarce.^{19,39,40} A 2000 English case, *Shakoor v Situ*, is one of the few to have addressed this issue.³⁵ The patient died of acute liver failure, a rare reaction to an herbal remedy prescribed for his skin condition by the defendant, a practitioner of traditional Chinese herbal medicine. Articles in orthodox medical journals had suggested that the remedy carried a risk of liver damage. The defendant was unaware of these articles; he believed the remedy safe in light of Chinese medical textbooks. The court concluded that because the defendant did not hold himself out as practicing conventional

medicine and the patient had rejected the only conventional medical treatment (surgery), his treatment should not be judged by the standards of conventional medicine. However, he was held to the standard of a physician in general practice when assessing what he knew or should have known about the safety of the remedies he prescribed. He was ultimately not held liable, because the court found the medical literature too equivocal to put a reasonably competent physician on notice that the remedy was too hazardous to use. Although foreign judgments are not binding on courts in other countries, this decision reinforces the extent of clinicians' duty to take account of relevant findings from conventional biomedicine, reevaluate and modify their practices accordingly in light of reported adverse events and clinical experience, and ensure that remedies they recommend or provide are safe or, at least, that they make patients aware of the risk of harm.

If a health practitioner is sued for negligence and a common professional standard of care among practitioners cannot be identified or is not accepted, courts have judged the care provided by either (1) the standard of the reasonable person^{20,41} (who presumably should limit care to that appropriate to a layperson) or (2) accepted medical standards (because the person represented himself or herself as being skilled in healing).^{14,20,36,41–43} Practitioners must recognize the limits of their capabilities.⁴⁴

Informed Consent and CAM Practitioners

Failure to obtain informed consent to treatment is a breach of practitioners' standard of care regardless of whether the therapy is conventional or alternative. As part of obtaining informed consent to chiropractic care, clinicians must provide patients with

material information about their condition, the treatment proposed, alternatives to the treatment, and material, special, or unusual risks associated with the various options.^{19,44–48} Patients/parents should be given the information that a reasonable person in similar circumstances would want to know to make an informed decision about treatment, which should include general information about the practitioner's approach to health care and diagnosis, particularly if it departs from the mainstream, and discussion of what is known about the efficacy of the treatment proposed.

CLINICAL RESPONSE

The US Centers for Disease Control have estimated that 2.8% of American children received chiropractic treatment for various conditions in 2007, and an Australian study found rates as high as 34%.^{3,49} Although there is evidence that chiropractic treatment can be effective in treating lower back pain in adults,^{50,51} there are few data specifically pertaining to pediatric chiropractic despite its popularity for children.

Data on adverse events related to pediatric chiropractic are scarce. We identified 4 pediatric reviews. Most recently, a 2010 update of clinical research literature in the 2007 Vohra et al review, in which no serious adverse events were identified.⁵² Also, a 3-year retrospective study of pediatric case files from a teaching clinic practice did not reveal any serious complications from 781 case files.⁵³ Before that, results of a narrative review suggested that the risk of complications from chiropractic manipulation in pediatric patients is 1 in 250 million visits.⁵⁴ Vohra et al⁵⁵ suggested that this study potentially underestimated the risk, because most harms are not reported. Their systematic review identified 14 cases of direct adverse events; more

pertinent to this scenario, they also identified 20 cases of “delayed diagnosis and/or inappropriate provision of chiropractic care” that indirectly caused adverse events. They considered even this number an underestimate, as it was not the focus of their systematic review.⁵⁵ Seven of the indirect adverse events involved delayed treatment of cancer.

Some conditions clearly indicate potential serious risk to health and require immediate referral for conventional medical care. In pediatrics, persistent systematic symptoms of back pain that interferes with sleep and leads to self-imposed activity limitations are considered a “red flag” for serious disease that warrants immediate further evaluation with at least a plain radiograph.⁵⁶ Our scenario raises questions about both the reasonableness of the initial diagnosis and the failure to investigate further or consider other diagnoses given the patient's condition and response to treatment, as well as the point at which the patient should have been referred for medical care and chiropractic treatment ended. A judgment about whether this practitioner fell below the standard of care because he misdiagnosed the condition or because he failed to recognize that the patient required different expertise and referral to a physician will depend on expert and other evidence about the standard of care.

Incorporating more formal training about pediatric care into chiropractors' education could reduce the risk of adverse events caused by delays in diagnosis or referral for needed care.^{55,57,58} Treatments for testicular cancer have improved, so despite the progress of the disease to lung metastasis, there is still a >90% cure rate.⁵⁹ Nevertheless, the delay in diagnosis could very well be linked with an advance in the stage of the tumor, the

need for longer, more aggressive therapy, and greater physical and psychological adverse effects.

RECOMMENDATIONS

Scope of Practice

Clinicians should ensure that they have the necessary knowledge, skills, and training to treat the patient's condition, comply with regulatory and institutional policies, and are legally authorized to provide the treatment proposed in the jurisdiction in which they practice.^{60,61}

Standard of Care

Thorough history-taking, investigation, and record-keeping are essential, as is an appropriate physical examination when pertinent to the patient's presenting complaint.

Clinicians must exercise reasonable care, skill, and judgment in diagnosing the condition, explaining results to patients, and reconsidering diagnosis and treatment when circumstances warrant.

Clinicians must be sure to obtain informed consent for treatment and tell patients when their condition is not amenable to the type of treatment they provide.¹⁹

The patient's condition should be monitored appropriately during treatment, and treatment should be altered (with consent) as needed. Treatment determined to be ineffective should be discontinued.

Referral is indicated when the clinician cannot diagnose or assess the patient's condition, the patient's condition is not responsive to treatment, the patient needs treatment that the clinician is not competent or authorized to provide, the clinician cannot continue to treat the patient, or the clinician is insufficiently experienced to treat the patient.^{10,19,62–64} Referral must be timely

to ensure that needed care is not delayed.

Education

Clinicians who treat children should have ample formal pediatric training to provide better and safer care to their youngest patients. Best-practice recommendations for pediatric chiropractic care (based on expert opinion, because high-quality research evidence is lacking) were published in 2009.⁶⁵

Adverse Events and Patient Safety

Improving patient safety and reducing error have become priorities in health care.^{66–69} When adverse events occur, it is essential to assess what went wrong to learn how to avoid such occurrences in the future. Regulatory au-

thorities and professional associations should develop programs to improve safety and quality of care and alert members about preventable adverse events (eg, an advisory guideline that outlines the association between back pain and cancer in young men and adolescents).

Continuing education (eg, through educational programs, journal clubs, or self-study) is important to ensure that practitioners learn about new developments and reported adverse events so they can modify their practices as needed.

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