# CLINICAL REPORT

# The Use of Complementary and Alternative Medicine in Pediatrics

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# ABSTRACT

The American Academy of Pediatrics is dedicated to optimizing the well-being of children and advancing family-centered health care. Related to these goals, the American Academy of Pediatrics recognizes the increasing use of complementary and alternative medicine in children and, as a result, the need to provide information and support for pediatricians. From 2000 to 2002, the American Academy of Pediatrics convened and charged the Task Force on Complementary and Alternative Medicine to address issues related to the use of complementary and alternative medicine in children and to develop resources to educate physicians, patients, and families. One of these resources is this report describing complementary and alternative medicine services, current levels of utilization and financial expenditures, and associated legal and ethical considerations. The subject of complementary and alternative medicine is large and diverse, and consequently, an in-depth discussion of each method of complementary and alternative medicine is beyond the scope of this report. Instead, this report will define terms; describe epidemiology; outline common types of complementary and alternative medicine therapies; review medicolegal, ethical, and research implications; review education and training for complementary and alternative medicine providers; provide resources for learning more about complementary and alternative medicine; and suggest communication strategies to use when discussing complementary and alternative medicine with patients and families. Pediatrics 2008;122:1374-1386

# INTRODUCTION

The National Center for Complementary and Alternative Medicine (NCCAM) of the National Institutes of Health (NIH) defines complementary and alternative medicine (CAM) as a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional Western medicine.<sup>1</sup> Complementary medicine is used in conjunction with conventional medicine; for example, massage, guided imagery, and acupuncture may be used in

addition to analgesic medications to help decrease pain. Alternative medicine is used in place of conventional Western medicine; for example, some adolescents use herbs rather than antidepressant medications to treat depression.

The distinction between CAM and mainstream medicine has lessened as many practices have undergone rigorous research and have been integrated increasingly into mainstream care. For example, guided imagery and massage have been proven to be effective in the treatment of pain and are now included in many tertiary care settings.<sup>2–5</sup> Since the American Academy of Pediatrics (AAP) convened the Task Force on Complementary and Alternative Medicine in 2000 and since the creation of the NCCAM, these complexities inherent in the definition of CAM have become more problematic. Given the wide usage and general understanding of the term "CAM," it will be used throughout this report. However, the term "CAM" has been replaced increasingly with "holistic" or "integrative" medicine. Holistic medicine refers to patient-centered care that includes consideration of biological, psychological, spiritual, social, and environmental aspects of health. Integrative medicine is relationship-based care that combines mainstream and complementary therapies for which there is some high-quality scientific evidence of safety and effectiveness to promote health for the whole person in the context of his or her family and community.<sup>1</sup> Integrative medicine also reaffirms the importance of the relationship between the practitioner and the patient, emphasizes wellness and the inherent drive toward healing, and focuses on the whole person, using all appropriate therapies to achieve the patient's goals for health and healing.<sup>6</sup>

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#### Key Words

complementary, alternative, patientcentered, communication, ethics, epidemiology, health services, integrative

#### Abbreviations

NCCAM—National Center for Complementary and Alternative Medicine NIH—National Institutes of Health CAM—complementary and alternative medicine

AAP—American Academy of Pediatrics TCM—traditional Chinese medicine FDA—Food and Drug Administration DSHEA—Dietary Supplements Health and Education Act

RCT—randomized, controlled trial

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American Academy of Pediatrics The AAP Provisional Section on Complementary, Holistic, and Integrative Medicine, established in 2005, also contributed extensively to this report.

# Epidemiology

The use of CAM in Western medicine has grown dramatically in recent decades. Many CAM therapies, such as herbal remedies, are mainstream or traditional in many parts of the world. The World Health Organization estimates that most of the world's population regularly uses "traditional medicine" such as traditional Chinese medicine (TCM), Ayurvedic medicine, and Native American healing practices.

In the United States, more than one third of adults have used CAM.<sup>7</sup> The total number of visits to CAM providers increased by 47.3%, from 420 million visits in 1990 to 629 million visits in 1997.<sup>8</sup> The number of visits to CAM providers in 1997 exceeded the total number of visits to primary care physicians in the same year.<sup>8</sup> Estimated expenditures for CAM services for adults increased by 45.2% between 1990 and 1997, with a conservative estimate of \$21.2 billion spent in 1997. Of that total, out-of-pocket expenses were estimated to be \$12.2 billion. This figure exceeded the 1997 out-of-pocket expenditures for all US hospitalizations.<sup>8</sup> More recent studies have described CAM use among adults as high as 62%,<sup>9</sup> with 41% of adults using 2 or more CAM therapies in a 12-month period.<sup>10</sup>

Children and adolescents also are using CAM therapies increasingly. Weighted estimates of the amount paid for pediatric expenditures on CAM visits and remedies were \$127 million and \$22 million, respectively.11 An analysis of the 1996 US Medical Expenditure Panel Survey indicated that only 2% of the pediatric population uses CAM.<sup>12</sup> However, an early study of Canadian children reported 11% use of professionally provided CAM therapies, with chiropractic, homeopathy, naturopathy, and acupuncture accounting for 84% of CAM use.13 Approximately 20% to 40% of healthy children seen in outpatient pediatric clinics14-17 and more than 50% of children with chronic, recurrent, and incurable conditions use CAM, almost always in conjunction with mainstream care.<sup>18–20</sup> The use of CAM is considerably higher in certain groups of children, including children with special health care needs<sup>21</sup> and homeless adolescents, who have a reported use as high as 70%.<sup>22</sup> Use tends to be most common among patients with asthma,<sup>23-25</sup> attention-deficit/hyperactivity disorder,26-28 autism,29-31 cancer,<sup>32-36</sup> cerebral palsy,<sup>37</sup> cystic fibrosis,<sup>38</sup> inflammatory bowel disease,<sup>39,40</sup> and juvenile rheumatoid arthritis.<sup>41</sup> Presently, there is little research on the effectiveness of most CAM therapies for many of these conditions.<sup>42</sup> The NCCAM funds various studies, but to date, they have not addressed the pediatric population as a priority focus area for research.

Most pediatric patients who receive complementary therapies also receive conventional care.<sup>13</sup> This fact underscores the importance of pediatricians being aware of the necessity to have an open, respectful relationship and clear communication with families. A 2001 policy

statement from the AAP Committee on Children With Disabilities, "Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness or Disability,"<sup>43</sup> recognized that the use of CAM is increasing and provides information and guidance for pediatricians when counseling families about CAM.

# Patients' Characteristics and Reasons for Using CAM

Children who use CAM are more likely to be seeing their pediatrician for an illness, take medication on a regular basis, and have ongoing medical problems.<sup>14</sup> Approximately half of parents/caregivers of children who used CAM saw a CAM provider for themselves. The majority (66%) of parents/caregivers of CAM users had not informed their child's doctor of the use of CAM for their child.<sup>14</sup> There has been no consistent connection between CAM use and parent income, children's gender, or usual source of care,<sup>13,14,16–19,44</sup> and there have been mixed findings connecting CAM use and parent education level, family ethnicity, insurance coverage, and child's age.<sup>13,16–19,44,45</sup>

There are various reasons for the growing use of CAM. Many users of CAM reported use "not so much as a result of being dissatisfied with conventional medicine, but largely because they found these health care alternatives to be more congruent with their own values, beliefs, and philosophical orientations toward health and life."<sup>46</sup> Parents' reasons for seeking care for their children from CAM providers included, in decreasing order of frequency, word of mouth, particular treatment was considered effective, fear of drug adverse effects, dissatisfaction with conventional medicine, and the need for more personal attention.<sup>13</sup> In addition, many cultural groups may use CAM because of cultural values and beliefs.

# Insurance Coverage

Many insurers offer coverage for CAM services. A 1996 survey of managed care organizations reported that 70% of surveyed plans have experienced an increased demand from members for CAM services and that 58% intended to offer some services within the next 2 years.<sup>47</sup> A 2004 Kaiser Family Foundation employer survey revealed that 87% of covered employees had chiropractic coverage, and 47% had acupuncture coverage.48 The Landmark Report II on Health Maintenance Organizations and Alternative Care reported that 67% of health maintenance organizations offer some type of alternative care.49 In addition, many Medicaid programs pay for the use of some CAM services. Of 46 reporting states, 36 (78.3%) Medicaid programs provide coverage for at least 1 alternative therapy,<sup>50</sup> most commonly chiropractic care (reimbursed by 33 programs), biofeedback (reimbursed by 10 programs), acupuncture (reimbursed by 7 programs), and hypnotherapy and naturopathy (reimbursed by 5 programs each).<sup>50</sup> Because state Medicaid benefits packages change frequently, pediatricians are encouraged to become familiar with their state's list of covered services.

Some states require coverage for CAM services. In 1996, Blue Cross of Washington launched a plan called AlternaPath in response to the passing of a Washington state law in the same year mandating that all commercial health insurance companies cover the services provided by every category of licensed provider.<sup>51</sup> Currently, most states require coverage of chiropractic care, and more than 50% of all health maintenance organizations cover these services.<sup>47</sup> Although very few states mandate coverage of acupuncture or massage therapy, these services are quickly becoming part of many insurers' benefit plans. The scope of services covered by insurers varies considerably; most coverage is disease-treatment oriented, with limited (either by scope or by number) visits allowed per diagnosis. Many plans offer a separate rider for purchase by either the employer or employee at an additional cost, and other plans offer CAM coverage as an embedded benefit to everyone in the program. Another type of program is an affinity discount network, in which certain CAM providers are designated as members of the network. Members of the program pay providers directly at a discounted fee.52

In a 1998 survey, the most common treatment modality covered by insurance plans was chiropractic care, with coverage ranging from 41% to 65%. By contrast, homeopathic treatments were covered by only 4% to 11% of all plans; acupuncture was covered by 9% to 19%; biofeedback was covered by 4% to 10%; and massage therapy was covered by 6% to 10%.<sup>52</sup>

Despite the public's increasing use of CAM therapies and willingness to pay out-of-pocket for these services, health insurers have had difficulty including them in their plans because of variation in credentialing, difficulties with accounting, and because there are so few *Current Procedural Terminology* (CPT) codes that cover these services.<sup>52</sup> Although there are CPT codes that cover some CAM techniques, CAM providers may find them difficult to implement because of philosophical differences with a system that singles out disease states or organs from the whole person. Some CAM providers use a separate coding system of more than 4000 codes for CAM procedures and supplies, known as the alternative billing concept or "ABC" codes.<sup>53</sup>

#### **Government Response**

The Office of Alternative Medicine was established as part of the NIH by congressional mandate in 1992. In 1998, the Office of Alternative Medicine became the NCCAM. The NCCAM has increased its fiscal-year appropriations from \$50 million in 1998 to an estimated \$123 million in 2006.<sup>1</sup> Total funding by all institutes and centers of the NIH for research and training on CAM and the training of investigators to study CAM exceeded \$225 million in 2006, with additional funding being provided by other agencies and philanthropic foundations.1 Of the approximately 360 NCCAM-funded research projects in 2006, fewer than 5% were related to pediatrics, including research on the effects of massage for preterm infants, probiotics, omega-3 fatty acids, and food allergies.<sup>1</sup> In 2007 and 2008, the AAP Provisional Section on Complementary, Holistic, and Integrative Medicine urged the NCCAM to consider increasing their priorities and funding for pediatric research, education, and information dissemination (Harry Gewanter, MD, verbal communication).

In 2000, the US President and Congress assembled and mandated the White House Commission on Complementary and Alternative Medicine Policy to make administrative and legislative recommendations to maximize the benefits of CAM for Americans. Comprising 20 physicians and other clinicians, CAM providers, and other experts, the commission was charged with developing a report to address the following:

- education and training of clinicians;
- research to increase knowledge regarding CAM;
- provision of reliable information to clinicians and the public; and
- guidelines for appropriate access to and delivery of CAM.

In March 2002, the commission issued its report, which addressed these charges and examined the relevance of CAM to national efforts to promote health, and created a central coordinating office. The report included 29 recommendations and more than 100 action items for federal agencies, Congress, state government, and other groups.<sup>54</sup>

In 2005, at the request of the NIH and the Agency for Healthcare Research and Quality, the Institute of Medicine released the report *Complementary and Alternative Medicine in the United States*. The report assessed what is known about Americans' reliance on CAM therapies and assisted the NIH in developing research methods and setting priorities for evaluating such products and therapies.<sup>55</sup>

The US Food and Drug Administration (FDA) also has weighed in on CAM-related issues. The Dietary Supplements Health and Education Act of 1994 (DSHEA) amended previous FDA statutes to encompass dietary supplement–specific provisions, including the definition of a "dietary supplement," product safety, nutritional statements and claims, ingredient and nutritional labeling, good manufacturing procedures, and the classification of "new" dietary ingredients.<sup>56</sup>

Under the DSHEA, a dietary supplement is:

- a product (other than tobacco) intended to supplement the diet that bears or contains 1 or more of the following ingredients: a vitamin, a mineral, an herb or other botanical, or an amino acid;
- intended for ingestion in pill, capsule, tablet, or liquid form;
- not used as a conventional food or as the sole item of a meal or diet; and
- labeled as a dietary supplement.

This classification of dietary supplements is specifically separate from food or drug categories and, as such, lies outside the jurisdiction of many of the safety and regulatory rules that cover food and drugs.<sup>56</sup> According to the DSHEA, manufacturers bear the burden of proof of ingredient safety of dietary supplements. However, unlike pharmaceutical preparations, dietary supplements can be marketed without proven safety or efficacy. A manufacturer does not have to provide the FDA with the evidence on which it relies to substantiate safety or effectiveness before or after it markets its products. For new ingredients, the manufacturer is only required to provide evidence to the FDA that the product is "reasonably expected to be safe."<sup>56</sup>

Manufacturers of supplements are not required to report any data on adverse events to the FDA. The FDA can demonstrate that a supplement is unsafe only after it reaches the market. The FDA must prove that the product is unsafe before it can restrict a product's use or take other legal action. The FDA largely relies on the Med-Watch voluntary reporting system to collect safety data on dietary supplements.<sup>57</sup>

The DSHEA also regulates third-party literature regarding dietary supplements. Informational materials (ie, articles, fact sheets, etc) may be displayed in commercial retail sites provided they are displayed separately from the product, do not contain false or misleading information, and do not promote a specific brand of supplement. Most important, the DSHEA regulates the labeling of dietary supplements. Under this provision, any claims to prevent, treat, or cure a specific disease are expressly prohibited (unless approved by the FDA). Labels can include statements describing the supplement's effects on the "structure and function" or general "wellbeing" of the body as long as they are truthful and bear the statement, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."56

Finally, like food products, dietary supplements are allowed to have suggested dosages on the label and must bear nutritional labeling. The label must include the name and quantity of each dietary ingredient, and if the ingredient is botanical in origin, the label must state the part of the plant from which the ingredient is derived.<sup>56</sup>

#### Physician Awareness, Attitude, and Perception

In 1995, the American Medical Association passed a resolution suggesting that its 300 000 members become better informed regarding the practices and techniques of CAM.<sup>57</sup> Many primary care physicians, including pediatricians, recommend and refer patients for complementary therapies.58,59 In the 2001 AAP Periodic Survey 49, "Complementary and Alternative Therapies in Pediatric Practice," pediatricians reported that they recognize patients' frequent use of CAM therapies and expressed a strong desire for additional education on CAM topics.<sup>60</sup> Topics of greatest immediate interest included herbs, dietary supplements, special diets, and exercise. More than one third of the pediatricians reported that they or their families used some type of CAM therapy. Of those reporting CAM use, 70% used massage therapy, 21% received chiropractic care, 13.5% consulted a spiritual or religious healer, and 13% had used acupuncture.60

TABLE I THE REINPEL MODEL OF HOUSCIC Care	TABLE 1	The Kemper Model of Holistic Care
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Component	Example
Biochemical	Medications, dietary supplements, vitamins, minerals, herbal remedies
Lifestyle	Nutrition; exercise/rest; environmental therapies such as heat, ice, music, vibration, and light; mind-body therapies (behavior management, meditation, hypnosis, biofeedback, counseling)
Biomechanical	Massage and bodywork, chiropractic and osteopathic adjustments, surgery
Bioenergetic	Acupuncture, radiation therapy, magnets, Reiki, healing touch, qi gong, therapeutic touch, prayer, homeopathy

A growing number of pediatric generalists and subspecialists have begun to offer complementary therapies and advice as part of their practice. In addition, there is a growing number of academic pediatric integrative medicine programs and new initiatives to promote systematic sharing, support, and dissemination of information to improve collaborative and comprehensive care. These initiatives include the AAP Provisional Section on Complementary, Holistic, and Integrative Medicine<sup>61</sup>; the International Pediatric Integrative Medicine Network; and the Pediatric Complementary and Alternative Medicine Research and Education Network.<sup>62</sup> However, these initiatives may be insufficient to ensure consistent, quality education across the spectrum of medical education. Standardized curricula or content specifications for physician education on CAM therapies should be considered for medical school, residency, and continuing medical education activities.

#### **COMMON CAM THERAPIES**

As a means of understanding and integrating different modalities encompassing complementary and mainstream therapies, the Kemper model of holistic care (Table 1) has been widely accepted.<sup>63</sup> This paradigm integrates complementary and mainstream therapies into a coherent construct of treatment options.<sup>63</sup> Another model for understanding CAM therapies has been developed by the NCCAM. This framework focuses on CAM rather than integration of therapies. The most common CAM therapies used by infants, children, and adolescents within the NCCAM framework follow. A complete description of all therapies and scientific evidence regarding each of them is beyond the scope of this report.

# Biologically Based Practices (Use of Vitamins, Herbs, Other Dietary Supplements, Diets, and Foods)

According to the NCCAM, biologically based practices include the use of botanicals, animal-derived extracts, vitamins, minerals, fatty acids, amino acids, proteins, prebiotics and probiotics, whole diets, and functional foods.<sup>1</sup> Of these, multivitamins are the most frequently used CAM products by children, with up to 41% reported usage.<sup>14,15</sup> Among teenagers who use CAM, nearly 75% use herbs and other dietary supplements.<sup>64</sup> Controlled studies have investigated the use of dietary

supplements for various conditions including asthma, upper respiratory infections, diarrhea, depression, anxiety, and attention-deficit/hyperactivity disorder.<sup>65–67</sup> Several studies are in progress, and the research literature is expanding rapidly. For example, the use of probiotics was considered complementary in the mid-1990s but has become mainstream practice in the 21st century as many gastroenterologists recommend and use them in daily practice for patients with inflammatory bowel disease.

There are a number of excellent review articles on the use of herbal products in pediatric populations<sup>64–66,68,69</sup> as well as data on potentially toxic herbal products and herb-drug interactions.<sup>70–79</sup> Because of regulations differing from those governing the use of pharmaceuticals, there are concerns about the purity and potency of herbal products and other dietary supplements sold in the United States. Product quality is influenced by many factors, including which portion of the plant is used (ie, root, stem, leaves, flowers), the time of harvest (ie, young versus old plants), the handling of the product, and proper identification of the plant. Furthermore, labeling is often inaccurate.<sup>80–82</sup> To conduct research, the quality of product must be guaranteed, and to compare clinical trials, the similarity of product must be ensured.

Dietary therapies such as the ketogenic diet in the treatment of seizure disorders<sup>83</sup> have become an accepted practice for some health conditions. However, the popularity of other diets has risen to a new level as the prevalence of obesity and metabolic syndrome has increased and traditional exercise and diet "prescriptions" have failed. The macronutrient content of these popular diets varies widely.<sup>1</sup>

# **Manipulative and Body-Based Practices**

As defined by the NCCAM, manipulative and bodybased practices include chiropractic and osteopathic manipulation, massage therapy, reflexology, Rolfing, Bowen technique, and Trager approach.<sup>1</sup>

Chiropractic care is one of the most common professionally provided CAM practices. It focuses on the relationship between body structure (primarily that of the spine) and bodily function and how that relationship affects health. With more than 50 000 chiropractors licensed in the United States, the number of children visiting chiropractors is substantial and increasing.<sup>84</sup> Recent studies have confirmed that up to 14% of all chiropractic visits were for pediatric patients<sup>14,15</sup> and that chiropractors were the most common CAM providers visited by children and adolescents.<sup>14</sup> Few randomized, controlled trials (RCTs) have demonstrated significant clinical benefits of chiropractic practices among pediatric patients<sup>85</sup>; additional studies are needed, and parents need to be cautioned not to rely on chiropractic care as the primary treatment for serious conditions such as cancer. Although anecdotal data suggest that severe complications are possible with chiropractic treatment of infants and children, such adverse effects seem to be rare.86 Further systematic studies are needed to determine the costs, benefits, and safety of this widely used practice.

Massage is another common manipulative practice that is frequently provided at home by parents and by licensed massage therapists and nurses in clinical settings. Massage is now routine practice in many NICUs to promote growth and development in preterm infants.<sup>2–4</sup> Massage also has been demonstrated to be beneficial in alleviating symptoms from asthma, insomnia, colic, cystic fibrosis, and juvenile rheumatoid arthritis.<sup>87–92</sup>

#### **Mind-Body Medicine**

As defined by the NCCAM, mind-body medicine includes diverse practices such as relaxation, visual imagery, tai chi, qi gong, yoga, meditation, prayer, hypnosis, biofeedback, diaphragmatic breathing, progressive muscle relaxation, and cognitive-behavioral therapies. Many of these practices, particularly prayer, are commonly used among adults.<sup>11</sup> In children, popular techniques include prayer, progressive relaxation exercises, meditation, biofeedback, and hypnosis.<sup>14,15</sup> Hypnotherapy encourages the child to use his or her imagination to improve health and health behaviors.

Guided imagery, hypnosis, and biofeedback have been shown to be effective adjuncts to medical therapy for such common conditions as chronic, acute, and recurrent pain; anxiety and stress disorders; enuresis; encopresis; sleep disorders; autonomic nervous system dysregulation; habitual disorders; attention and learning disorders; asthma; cancer; and diabetes.<sup>5</sup> These therapies generally have few or no adverse effects.<sup>5</sup>

Spiritual healing includes prayer and is the most prevalent complementary therapy in the United States.<sup>9</sup> Spiritual healing is sometimes included under the rubric of mind-body therapies and sometimes under the rubric of biofield or bioenergetic therapies.<sup>1</sup> Eighty-two percent of Americans believe in the healing power of personal prayer, 73% believe that praying for someone else can help cure their illness, and 77% believe that God sometimes intervenes to cure people who have a serious illness.<sup>93</sup> Prayer is used by up to two thirds of parents for their children.<sup>14,15</sup>

Studies have suggested that spiritual/religious beliefs and practices may contribute to decreased stress and increased sense of well-being and enhanced immune system functioning.<sup>93</sup> RCTs of the clinical therapeutic effects of prayers in pediatrics are lacking. Some states have pursued legal measures against parents seeking to use prayer or spiritual healing as an alternative to conventional medical therapy for children with serious medical problems such as cancer. However, most families view spiritual healing as a personal practice that is complementary to medical care rather than a replacement for it.

#### **Biofield Therapies**

According to the NCCAM, biofield therapies are "intended to affect energy fields that purportedly surround and penetrate the human body." These therapies "manipulate biofields by applying pressure and/or manipulating the body by placing the hands in, or through, these fields."<sup>1</sup> Biofield techniques include acupuncture, homeopathy, polarity therapy, magnet therapy, Japanese Reiki and Johrei, Chinese qi gong, therapeutic touch, healing touch, and spiritual healing.

Perhaps the best known of the noninvasive biofield therapies is therapeutic touch, which is taught in more than 80 nursing schools and provided in numerous hospitals in the United States. Therapeutic touch is a form of energy medicine that has been developed by nurses on the basis of the premise that healing is promoted when the body's energies are in balance. Nurse-healers are trained to identify and treat energy imbalances to improve the patient's well-being.<sup>94</sup>

Studies on the effectiveness of biofield therapies in pediatric populations have been limited, but the therapies are generally safe.<sup>95,96</sup>

# Acupuncture

Acupuncture has been one component of TCM, which also includes herbal remedies, diet, massage, and lifestyle. Today, acupuncture describes a family of procedures involving stimulation of anatomic points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea, and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by hand or by electrical stimulation.<sup>1</sup> Variants of needle therapy include stimulation of acupuncture points by vigorous massage (shiatsu), heat (moxibustion), lasers, magnets, gentle massage or pressure (acupressure), or electrical currents.

Acupuncture is used by an increasing number of pediatric patients. A meta-analysis of the use of acupuncture in the treatment of recurrent headaches suggested potential benefit.<sup>97</sup> Additional applications for acupuncture may include nausea, pain, and allergy.<sup>98-101</sup>

#### Whole or Traditional Medical Systems

Whole medical systems involve complete systems of theory and practice that have evolved independently from or parallel to conventional Western medicine.<sup>1</sup> They include homeopathy, naturopathic medicine, TCM, Ayurvedic medicine (India's traditional system of medicine), and healing systems of American Indian/Alaska Native, African, Middle Eastern, Tibetan, and other indigenous populations.

# Homeopathy

Developed by Samuel Hahnemann in 1790, homeopathy is based on the theory that "like cures like," meaning that small, highly diluted quantities of medicinal substances are given to cure symptoms, when the same substances given at higher or more concentrated doses would actually cause those symptoms.<sup>1</sup> Unlike classic pharmacology, homeopathy follows the theory that the greater the dilution, the greater the potency of the product. In the United States, an estimated 3000 clinicians, including physicians, nurses, chiropractors, naturopaths, and dentists, use homeopathy in their practices.<sup>101</sup> A range of 2% to 10% of children use homeopathic remedies, most often for respiratory problems, teething, otitis media, and other conditions related to the ears, neck, and throat.<sup>14,15</sup>

# **SPECIAL POPULATIONS**

#### Adolescents

Numerous reports have described the frequent use of CAM by adolescents.<sup>44,102–106</sup> In Seattle, Washington, 70% of homeless adolescents reported using some form of CAM,<sup>22</sup> and among 9th- and 12th-grade students in Massachusetts, herbal remedies were used by up to 20% of respondents.<sup>107</sup> In a survey of New York teenagers, the most frequently used therapies were massage, prayer or faith healing, herbs, vitamins, performance-enhancing supplements, and special exercises.<sup>105</sup> Many adolescents use supplements to improve their body image or athletic performance. As many as 4.5% of boys and 0.8% of girls in secondary school used creatine<sup>108</sup>; of those, 73% were student athletes.

In general, adolescents seem to be more open than adults are to using CAM therapies, and adolescents are more inclined to use CAM if their parents also use these therapies.<sup>103</sup> Adolescence is characterized by increasing cognition, independence, increased desire for privacy and autonomy, and higher incidence of risky behavior. In addition, as they begin to take responsibility for their own health needs, adolescents also may use CAM therapies as self-treatment. The Internet is also becoming a larger influence on the lives of teenagers. Many dietary supplements are promoted on the Internet and promise relief of adolescent concerns such as acne and obesity, or they promise enhanced energy and sports performance. Some pediatricians refer patients to CAM providers or provide complementary therapies themselves, integrating them into conventional medical practice.

# Children With Chronic Illness or Disability

Children with special health care needs are frequent users of CAM. The rate of CAM use for this population is estimated to be 30% to 70%.<sup>21,29–41</sup> In a recent survey of families of children with developmental disabilities, families wanted their clinicians to be able to counsel them about CAM options.<sup>109</sup> An overview of these issues and recommendations for counseling children with special health care needs and their families is outlined in a 2001 AAP Committee on Children With Disabilities statement, "Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness or Disability."<sup>43</sup>

# **Ethnic and Cultural Groups**

Use of CAM therapies varies among different ethnic and cultural groups. Excluding prayer, CAM is used less commonly by Hispanic and black individuals than by white individuals, and its use by Hispanic and black people is less likely to be disclosed to clinicians.<sup>110</sup> Families of different cultural backgrounds use different herbs, over-the-counter remedies, and other items traditionally used for cooking as home remedies.<sup>111,112</sup> Many ethnic and cultural groups also use traditional

healing practices such as TCM, Ayurvedic medicine, and American Indian/Alaska Native healing practices, which can include a variety of diverse therapies and native healers within a coherent cultural belief system.<sup>113,114</sup> Use of these remedies is often integrated with conventional medicine but may not be reported unless the clinician specifically inquires about them.<sup>110</sup>

# **RESEARCH ISSUES**

Although many CAM therapies have not yet been evaluated formally in children, a 2002 review identified more than 1400 RCTs and 47 systematic reviews of pediatric CAM.<sup>115</sup> Formal evaluation has suggested that the quality of RCTs of CAM is as good as that of RCTs of conventional medicine,<sup>116</sup> and the quality of systematic reviews of CAM exceeds that of systematic reviews of conventional medicine.117 It should be noted that publication bias in CAM research is opposite that of conventional medicine; that is, negative studies are more likely to be published in well-known journals, and positive studies are more likely to be published in foreign-language journals.<sup>118</sup> Those interested in promoting an evidence-based approach to the use of CAM therapies must be cognizant of the bias created by applying language restrictions in their search strategy. Other approaches to evidence-based CAM include *n*-of-1 evaluation, whereby methodologic rigor (eg, blinding, randomization) is combined with an individualized approach fundamental to many CAM therapies.<sup>119</sup>

There are some unique considerations when examining the efficacy of CAM, including heterogeneity of both products and practices. Lack of regulation of many commonly used practices exacerbates heterogeneity, making treatment effect difficult to measure. The relative lack of CAM expertise in conventional institutions results in inadequate peer review and undue difficulties when attempting to obtain institutional review board approval to study CAM in children.

Although CAM use is common in children, there have been few reports of serious adverse effects. Most current safety data come from case reports. Some population-based surveillance studies to monitor adverse events have been conducted in adults receiving acupuncture, and the resulting data are reassuring.<sup>120</sup> The need for rigorous safety evaluation is questioned by some who perceive "natural" to be equivalent to "safe." More complete data about safety in children would require prospectively gathered, population-based studies, which are expensive to conduct.

There are numerous challenges inherent in all clinical research, and these difficulties are compounded when performing research in children and on therapies based on different cultural concepts of what causes or constitutes disease and health. The NCCAM has identified women and minority populations as priority groups for federally funded research on CAM, but it has not yet added pediatrics to this priority listing.

# **EDUCATION AND TRAINING**

The number of CAM providers is increasing. The number of CAM providers in the United States is projected to

increase 88% between 1994 and 2010, compared with a 16% increase in the number of physicians. However, few CAM providers undergo extensive education or training specific to pediatric populations. For example, although chiropractic training typically lasts 4 years, pediatric certification in chiropractic requires only a 10-module, 120-hour certification program.<sup>121</sup> Naturopathic training at the 4 US colleges also typically requires 2000 hours of training over 4 years, which includes clerkships in dermatology, family medicine, psychiatry, medicine, radiology, pediatrics, obstetrics and gynecology, neurology, surgery, and ophthalmology.<sup>122</sup> Some CAM training programs do not offer any specific training for diagnosing or treating pediatric patients.

Many CAM providers seek additional training in pediatrics.123 Likewise, many physicians seek additional training in CAM. As of 1998, 64% of US medical schools reported having CAM curricula,124 and 18 of the 19 colleges of osteopathic medicine offered CAM instruction.<sup>125</sup> These programs have a wide range of content and quality. Although many medical schools and residency programs offer survey courses on CAM, 126, 127 the extent to which pediatric residencies and postgraduate courses address educational needs about CAM are unknown.<sup>128–131</sup> However, there have been significant gains in the growth of academic integrative medicine since the establishment of the Consortium for Academic Health Centers for Integrative Medicine in 2000. There are also well-established training programs for physicians in specific modalities such as hypnosis and acupuncture.

# LICENSING

Licensure of CAM providers varies significantly from state to state. Licensing does not mean that CAM providers can practice medicine. In some states, CAM providers must have clients sign a form acknowledging that they understand the provider is not a physician and not practicing medicine. As of the writing of this report, chiropractic medicine is licensed in all states, acupuncture and massage therapy are licensed in more than half of the states, and naturopathy and homeopathy are licensed in less than one third of the states. Lobbying efforts by CAM providers to win licensure and expanded scopes of practice are ongoing in many states. It is essential for physicians to understand local and state statutes and regulations governing specific therapeutic modalities. If a CAM provider is unlicensed, then he or she may be engaged in the unauthorized practice of medicine, and if a physician refers a patient to an unlicensed provider, the referring physician may be liable for negligent referral. If a CAM provider is licensed, then he or she must be practicing within his or her "scope of practice" as defined by local and state statutes and regulatory boards.<sup>132</sup> Similar to physician licensing, licensing information about other health care professionals is maintained by state licensing boards.

# MEDICOLEGAL AND ETHICAL CONSIDERATIONS

#### Medicolegal

CAM poses a challenging risk-management issue with the potential for either a medical malpractice lawsuit, disciplinary proceedings from state licensing boards, or fraud and abuse actions from federal or state regulators.<sup>133,134</sup> The use of some types of CAM in adults has been judicially held to be below the standard of care constituting medical negligence<sup>135</sup>; that is, use of complementary therapies in and of themselves does not constitute negligence. In terms of practicing within the standard of care, more clinicians are willing to offer CAM, and more insurers are willing to pay for it.<sup>136</sup>

Clinicians need to be aware of individual state laws relating to CAM, because medicine is regulated by state rather than federal laws.<sup>137</sup> In its database of closed pediatric malpractice claims from 1985–2005, the Physicians Insurers Association of America reported that the average indemnity payment for all CAM claims was \$358 333, which was 37.1% higher than the average for all pediatric claims (\$261 321).<sup>138</sup> A proposed risk-management model limits liability for the use of CAM if the physician is recommending, accepting, or avoiding CAM depending on availability of evidence relating to safety and/or efficacy.<sup>139</sup>

Some CAM modalities may need to be included in discussions about informed consent for treatment. The informed-consent process may potentially require a discussion about possible risks of CAM, notwithstanding the ability of a patient to acquire CAM without the involvement of the pediatrician (eg, dietary supplements and their interaction with prescribed medication). Case law has placed a burden on clinicians to at least discuss viable options of treatment even though he or she may be unwilling to offer the therapy.<sup>140</sup>

Pediatricians need to be aware of the use of alternative therapies as a substitute for conventional medical care for children with life-threatening conditions and whether they believe such treatment is reportable under state abuse and neglect laws. Another legal duty of pediatricians relates to the assurance that seeking reimbursement for CAM therapy does not trigger a potential violation of fraud and abuse laws for therapy deemed "medically unnecessary." It is prudent to be cautious about any representations or guarantees.

#### Ethics

There are several ethical challenges to integrating CAM into mainstream pediatric practice. There is a lack of systematic pediatric education about the safety and effectiveness of CAM therapies; uncertainty about the scope of practice, licensing requirements, and credentialing of nonphysician CAM providers; concerns about patient safety and legal liability when recommending CAM therapies or therapists; and uncertainty about how to translate principles of medical ethics into CAM.<sup>141</sup>

The first guideline of ethical practice is to seek reliable, evidence-based information about the safety and effectiveness of specific therapies and therapists. Indeed, the 2001 AAP policy statement "Counseling Families Who Choose Complementary and Alternative Medicine for Their Child With Chronic Illness or Disability" recommended that pediatricians seek information, evaluate the scientific merits of specific therapeutic approaches, and identify risks or potential harmful effects.<sup>43</sup>

It is also prudent to apply common sense to balancing risks and benefits when making therapeutic decisions (see Fig 1).<sup>142</sup> The specific ethical questions in clinical practice vary in different clinical situations. If a therapy is both safe and effective, the pediatrician is ethically obligated to recommend and encourage its use as he or she would for any other such therapy in conventional care.

Factors to be included in a risk/benefit analysis when considering CAM therapies include the severity and acuteness of illness; curability with conventional care; degree of invasiveness; toxicities and adverse effects of conventional treatment; quality of evidence for efficacy and safety of the complementary therapy; and the familv's understanding of the risks and benefits of CAM treatment, voluntary acceptance of those risks, and persistence of the family's intention to use CAM therapy.139 Thus, the level of evidence required for evaluating efficacy can be small when there is little to no risk of harm from a therapy, especially when other therapies are likely to be futile. Likewise, the level of evidence for efficacy required to endorse a particular complementary therapy would be quite high when that therapy is risky and safer, more effective therapies are available.

Situation-specific variables can also affect ethical decisionmaking. Situation-specific variables include the patient's and parents' personal beliefs, cultural values and practices, and therapeutic goals; the type and severity of illness; and the lack of efficacy and safety data in a specific patient. Even when such data are known for other populations, application of population data to individual pediatric patients requires inference and implies some degree of uncertainty. The tolerance of the patient, family, and clinician for uncertainty varies from one situation to another.<sup>139</sup>

Finally, clinicians should be aware of the 4 basic principles of biomedical ethics: (1) respect for patients' autonomy; (2) nonmaleficence (avoiding harm); (3) beneficence (putting the patient's interest and well-being first); and (4) justice (fairness in providing access to essential care).<sup>139</sup>

A common-sense guide to CAM



#### FIGURE 1

Guide to CAM treatment recommendations. (Reproduced with permission from Kemper K, Cohen M. Ethics meet complementary and alternative medicine: new light on old principles. *Contemp Pediatr.* 2004;21:65.)

# CONCLUSIONS

Pediatricians and other clinicians who care for children have the responsibility to advise and counsel patients and families about relevant, safe, effective, and age-appropriate health services and therapies regardless of whether they are considered mainstream or CAM. In the 2001 AAP Periodic Survey of Fellows, 73% of pediatricians agreed that it is the role of pediatricians to provide patients/families with information about all potential treatment options for the patient's condition, and 54% agreed that pediatricians should consider the use of all potential therapies, not just those of mainstream medicine, when treating patients.<sup>60</sup> Because most families use CAM services without spontaneously reporting this use to their clinician, pediatricians can best provide appropriate advice and counseling if they regularly inquire about all the therapies the family is using to help the child.<sup>143,144</sup>

Pediatricians should seek continued and updated knowledge about therapeutic options available to their patients, whether they are mainstream or CAM, and about the specific services used by individual patients to ensure that issues of safety, appropriateness, and advisability of CAM can be addressed. Only then can pediatricians appreciate the concerns of their patients and families and offer them the thoughtful and knowledgeable guidance they may require.

Finally, if the pediatrician confirms that the patient is seeing a CAM provider, the pediatrician can (with the permission of the patient and family) include the CAM provider in overall care-coordination activities.

# **TIPS ON TALKING WITH PATIENTS**

- Ask about the different therapies received by your patients. Patients and parents often do not tell their clinicians about CAM use, because many of them believe that it is not relevant or not within the clinician's interest or expertise.<sup>143,144</sup> By asking routinely, pediatricians can learn whether a child is receiving complementary therapies. This knowledge is essential for the pediatrician to evaluate and counsel about potential adverse effects and to enhance the probability of correctly attributing improvements or adverse effects to the specific intervention. Questions that include examples are often helpful in jogging memories and enhancing disclosure. Thus, rather than asking whether a patient is using any "alternative" therapies, the pediatrician might ask whether the patient is using any "vitamins, herbs, supplements, teas, home remedies, back rubs, chiropractic, acupuncture, or other services to enhance health." It is also often useful to ask how the patient manages stress; examples here may include exercise, prayer, music, or talking with friends or trusted adults.
- Respect the family's perspectives, values, and cultural beliefs in open, ongoing communication centered on the patient's well-being. Recognize cultural or educational differences. Demonstrate respect for families and their values. Work together with the parents as a team to consider and evaluate all appropriate treatments. This may require discussing an array of treatment options. By actively listening to families and patients, pediatricians can become important allies in examining all potential treatment options for children. Maintaining a dialogue

to promote the best interests of the child is critical to the integrity of the medical home.

- Monitor the patient's response to treatment and establish measurable outcomes for evaluation. Measurable outcomes such as specific goals for symptom relief can be established. The *primum non noceri* ("first do no harm") concept is central to all clinical practice. If there is a lack of response or untoward response, the therapy needs to be reevaluated.
- Maintain current knowledge of popular complementary therapies and evidence-based resources about them. Become familiar with the definitions, terms, and uses of CAM and learn about specific CAM therapies patients are using. Pediatricians are encouraged to educate themselves about the modalities and professionals that are available in their practice area. Provide evidence-based information about relevant therapies, available from the NCCAM, the Consortium of Academic Health Centers for Integrative Medicine member institutions, and an increasing number of publications in peer-reviewed publications and professional review articles.

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