

# Holistic Pediatrics: A Research Agenda

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**Abstract.** Increasing numbers of American families seek complementary and alternative medical care (CAM) for their children; at the same time health care organization and financing are undergoing radical changes. The combination of these factors provides a powerful incentive for research on the effectiveness and safety of CAM therapies and their role in treating children. This article describes a rationale, spectrum, priorities, and methodologies for a research agenda in holistic pediatrics. The top priorities are clinical research projects addressing the safety and effectiveness of alternative therapies used for vulnerable children suffering from serious illnesses. Additionally, major research questions involve the impact of the various definitions such as “alternative,” “complementary,” “folk,” “integrative,” and “holistic” medicine on perceptions of health care, professional education, and funding of products and services. Research efforts in alternative therapies need to address explicitly the tremendous heterogeneity between and among the practices, beliefs, and providers of professional and lay services. Qualitative ethnographic research is needed to understand the consequences of diverse explanatory models and meanings of health and illness for patient-provider communication, adherence with professional recommendations, and satisfaction with care. Health services researchers need to address questions related to the epidemiology of CAM practices, health manpower issues, practice characteristics and the process and content of health care and how discoveries about CAM care may enhance the quality of mainstream health services. A rationale is provided for prioritizing certain conditions and therapies within these efforts. *Pediatrics* 1999; 103:902–909; *holistic pediatrics, research.*

ABBREVIATION. CAM, complementary and alternative medicine.

Over the last 30 years, the general public has increasingly sought complementary and alternative medical (CAM) care. Currently 33% to 50% of adults in the United States, Canada,

and Australia use CAM therapies and spend substantial sums of money out of pocket for these services.<sup>1–3</sup> Certain cultural groups, such as African-Americans, Chinese-Americans, Mexican-Americans, and Puerto Rican-Americans, may have even greater use of folk medicines.<sup>4–6</sup> Most adults prefer self-care and home remedies when given a choice between such remedies and medications.<sup>7</sup> Health conscious American adults who want to know about and exercise their options, not simply discard mainstream care, use a wide spectrum of health practices.<sup>8</sup>

Those who use CAM care most tend to be well-educated, employed persons who represent an attractive market to the entire medical industry. Promoters frequently market CAM products and services on the basis that these therapies are safer and have fewer side effects and lower costs, and that CAM is more humanistic and more empowering to patients than mainstream health care. These powerful arguments appeal to consumer values and also offer hope to families searching for relief for their children’s chronic and incurable conditions.

As public interest in these therapies grows, many families turn to their primary care physicians for advice about using CAM alone or in combination with conventional care. Despite physicians’ limited formal training in CAM and the public perception that physicians oppose CAM, survey results indicate that the majority of primary care doctors personally use, make referrals to, and have positive attitudes toward alternative providers.<sup>9–14</sup> The only study addressing pediatricians’ attitudes toward CAM found that more than half of the responding pediatricians talk with their patients about CAM and personally use and refer patients for CAM therapies.<sup>15</sup>

Governments and insurers wrestle with policy questions about which therapies and therapists to pay for and in what circumstances.<sup>16</sup> The overriding clinical question behind these policy issues is the effectiveness and safety of such therapies, particularly for children. Until recently, no federally funded projects addressed these issues in pediatrics. In 1997, the Office of Alternative Medicine at the National Institutes of Health funded a pediatric Center for Alternative Medicine at the University of Arizona.<sup>17</sup>

This article describes a research agenda for holistic or CAM pediatrics. The most obvious immediate need is for sound scientific data on the safety and effectiveness of CAM therapies. Research methods to address these questions encompass

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qualitative and quantitative methods in fields ranging from clinical and health services research, to basic science, to methodologic studies, to research addressing educational, behavioral, cultural, ethical, and medicolegal issues.

#### DEFINITIONS OF ALTERNATIVE MEDICINE

Earlier definitions of CAM included therapies 1) generally not taught at US medical schools, 2) generally not provided at US hospitals, 3) lacking evidence of effectiveness, and 4) generally not reimbursable by 3rd party payers.<sup>18</sup> Shifting practices make this definition problematic. Most medical schools now offer courses on CAM. Therapies not provided previously, such as hypnosis, biofeedback, and acupuncture, are now widely available in American hospitals, and >50% of conventional physicians refer patients for some CAM treatment.<sup>19</sup> Increasingly, mainstream medical journals publish studies evaluating the effectiveness of treatments previously considered alternative—vitamin B6 to prevent certain types of seizures; Saint John's wort to treat depression; hypnosis and guided imagery to prevent migraine headaches and to treat common behavioral problems; massage to enhance growth in premature infants; and acupuncture to treat pain and nausea. Increasing numbers of insurers reimburse for services by licensed alternative and complementary care providers at least for certain patients suffering from certain conditions.<sup>16,20</sup> Faced with these shifting practices, “alternative” has come to mean any health care remedy or system not generally accepted in modern biomedicine or therapies that are offered in place of or as substitutes for conventional therapies.<sup>21</sup> “Alternative” also has been used interchangeably with “unproven,” a term that may simply mean that a therapy has not yet undergone scientific scrutiny, but that frequently carries the connotation that the therapy has been disproved and should not be considered.<sup>22</sup>

“Folk remedies” refer to self-administered therapies that typically are provided within an identified cultural group. These include dietary therapies such as chicken soup for respiratory infections, “cold” foods to treat “hot” diseases, chamomile tea to treat colic, “coining,” and religious or ritual healing practices such as the Navajo sand paintings and “sings.”<sup>23</sup>

“Complementary medicine” typically refers to care provided in conjunction with conventional medical care, such as patient support groups for those suffering with cancer. Support groups do not replace chemotherapy, radiation, or surgery, but help patients cope with their disease and treatment. Similarly “integrative medicine” refers to the combined use of conventional and (previously considered) unconventional therapies for which there is now reasonable scientific evidence, such as combining hypnosis or guided imagery with counseling and behavioral therapy for children with enuresis.

“Holistic medicine” typically refers to the care of the whole patient (body, mind, relationships, emotions, and spirit) in the context of the patient's

values, culture, and community. Also called “contextual medicine,” this notion has strong references to the World Health Organization's definition of health as “a state of complete physical, mental, and social well-being” rather than simply the absence of disease. “Allopathic” medicine is a term technically referring to mainstream medical practice, but often is used in a pejorative context.<sup>24</sup> Those leaning toward more positive views of CAM practices tend to use the terms complementary, holistic, or integrative care, seeking to find common ground among healers rather than fostering divisiveness.<sup>25</sup>

Research is needed to assess how the use of different terms affects perceptions of health care's safety, effectiveness, costliness, and satisfaction with care. The use of different terms also may impact providers' self-assessment of the care they provide and role satisfaction. Variability in the use of different terms may have cultural and even political (eg, research-funding decision) ramifications.<sup>26</sup>

#### EXPLANATORY MODELS AND MEANING

Explanations for disease and injury and the meaning of illness, suffering, recovery, and death are central to the process and success of health care.<sup>27</sup> Part of the appeal of holistic health practices may be their alternative explanatory models for disease. Optimal care involves an understanding and cooperative agreement among the therapist, patient, and family about explanatory models. Physicians whose explanations are based on statistical, biomechanical, biochemical, or genetic factors are unlikely to fully engage patients with limited experience with technical science and whose explanatory models encompass cosmic, karmic, astrologic, or spiritual forces.<sup>28</sup> Despite the dominance of the biomedical model in American culture, these spiritual, ethnic, and folk beliefs contribute significantly to explanatory models of illness for many Americans. How many physicians have been frustrated in trying to explain to their own family members that respiratory illnesses are caused by viral infections rather than by exposure to cold, damp weather? How much more difficult is it for a mainstream physician to communicate effectively with a family who believes that their child's symptoms are attributable to the “evil eye,” sins from a past life, a vertebral subluxation, a lack of Chi (vital energy), or a planetary malalignment?

Research regarding explanatory models and meaning requires multidisciplinary efforts involving healers, anthropologists, sociologists, philosophers, psychologists, sociologists, and religious experts. Ethnographic and sociologic research will help understanding of the diversity of explanatory models, the practices built on these beliefs, and how alternative explanatory models may inform and enhance mainstream biomedicine.<sup>29</sup> Observational studies should assess how different healers communicate their beliefs, explanations, and caring attitudes.

## SCOPE AND HETEROGENEITY OF RESEARCH

Although the highest priority for pediatric CAM research is on the safety and effectiveness of these therapies for vulnerable children and families, the growing numbers of families without apparent illness seeking these services demand an even wider scope of research efforts. Research should describe the number and types of children seeking CAM therapies; the values and rationale underlying the use of CAM in pediatrics; characteristics of the workforce and practice characteristics of pediatric CAM providers; access to CAM care; the process and content of CAM care (including communication styles and effectiveness); methodologic issues related to the scientific standards by which such evaluations should be made; and issues related to medical ethics, politics, and legal aspects of health care.<sup>30</sup> Before explicitly prioritizing research related to effectiveness, side effects, toxicity, satisfaction, and costs, we will consider a number of important, related research questions that bear ultimately on clinical outcomes.

One largely untapped area of sociologic and methodologic research concerns the heterogeneity of practices, beliefs, and providers included in CAM. Some alternative practices may be limited to the incorporation of a single nutritional supplement or exercise to prevent or treat a specific disease (eg, the use of magnesium supplements or yoga to treat pediatric asthma). This kind of research is relatively straightforward and may be considered routine, cutting-edge, mainstream biomedical research. Other CAM practices such as Traditional Chinese Medicine (TCM) and homeopathy may encompass comprehensive changes in diet, the use of herbs, exercise, and spiritual practices. These different beliefs may result in different diagnostic classification systems, eg, a single diagnosis in mainstream medicine may yield multiple TCM diagnoses requiring different TCM treatments. In evaluating TCM treatment for a mainstream condition, should treatment be standardized based on the biomedical diagnosis (using the same points and treatment regimen in every patient to meet mainstream scientific standards for reproducibility) or individualized based on the TCM diagnoses (which may mean different, nonreproducible treatment regimens)? This thorny theoretic issue has important implications for conducting and evaluating CAM research.

Heterogeneity exists even within specific groups of licensed providers. For example, if one wishes to study the effectiveness of acupuncture in treating a specific condition, should the intervention use Chinese, Japanese, Korean, French, Russian, or American providers—all of whom have different styles of treatment? Furthermore, what type of stimulation should be used—manual needle therapy, electrical stimulation, heat (moxa), massage (shiatsu), laser, or magnets? Providers also may vary in terms of the intensity, frequency, duration, and number of recommended treatments, even if they agree on

the biomedical or TCM diagnosis, selection of points, and method of point stimulation.

## HEALTH SERVICES RESEARCH

National surveys have addressed the epidemiology of CAM use among adults. Many adults who use CAM do not discuss the use of these therapies with their conventional doctors.<sup>31</sup> Different demographic groups have marked differences in utilization, eg, higher percentages of men seek care from chiropractors, whereas more women seek care from naturopaths and Reiki practitioners.<sup>32</sup> No national studies have evaluated the population and characteristics of children who use CAM.

In the limited studies that have been conducted, the use of CAM seems to be less common in children than in adults (10% to 15% vs 30% to 45%)<sup>33</sup>; however, rates of use in certain subgroups (eg, children with arthritis, cancer, and cystic fibrosis) are much higher (50% to 70%), particularly among those who have suffered relapses or other setbacks.<sup>34–39</sup> Rates also are extremely high (70%) among homeless youth, many of whom suffer from chronic physical and mental health problems and who are disaffected by mainstream institutions.<sup>40</sup> Population-based national data on pediatric CAM care are lacking. Some families may forsake effective mainstream treatments to pursue CAM care.<sup>41</sup> Studies are needed to understand how and why families combine or substitute CAM for mainstream care, family–physician communication about CAM care, how the use of CAM affects adherence with mainstream medical recommendations and vice versa, the effect of using CAM on patient satisfaction with conventional care, and the cost of CAM services. These studies form the basis for an agenda in pediatric health services research on CAM for children.

Almost no studies address workforce issues in CAM care for children or how the availability of increasing numbers of CAM providers affects utilization and cost of conventional health services. Research also is needed to understand how growth in the numbers of CAM providers impacts access to, use, cost, and overall quality of health care for children. Patients with increased access to nonprescription drugs (through price subsidies) used more of these products, but did not reduce their use of prescription drugs; new therapies added to rather than replaced existing medications, thereby increasing overall health care costs.<sup>42</sup> Does the availability of CAM reduce costs by replacing more expensive services or add to costs? As the numbers of pediatric CAM providers increase, pediatricians may face increasing competition.<sup>43</sup>

Health services research in CAM has a special opportunity to evaluate the process and content of delivering such care to children. Mainstream physicians laud high-quality, patient-centered, comprehensive, multidisciplinary health care. Patients desire accessible, high-quality, personalized care, and to be listened to and taken seriously.<sup>44</sup> Conventional wisdom says that CAM care is more holistic and humanistic, more empowering and patient-

centered, less technical and time-pressured than mainstream medical practices. Scientific evidence is needed to evaluate the truth of these claims.

Are alternative medical practitioners really better at the process of delivering the care valued by families? Despite perceptions that visits are getting shorter, recent data suggest the opposite; in fact, pediatricians may be taking more time and doing a better job now than previously in addressing families' psychosocial concerns and promoting healthy lifestyles.<sup>45,46</sup> The vast majority of families are very satisfied with their pediatric care, and substantial numbers talk with their pediatrician about "non-medical" concerns.<sup>47</sup> Few data describe the process of care provided by CAM practitioners. For example, what is the average pediatric visit length to a chiropractor? How much time is spent in the waiting room, in actual contact with the provider, getting diagnostic x-rays, and so forth?

As in mainstream medicine, there also are likely to be vast differences in the content of care and provider-patient communication among different kinds of CAM professionals. What are the key elements of the taking of a history by different CAM providers (eg, homeopaths vs acupuncturists, massage therapists or spiritual healers)? How comprehensive are the physical examinations performed by different types of providers? In what percentage of pediatric CAM visits are x-rays, hair analyses, or other diagnostic tests performed? What percentage of time is spent in giving specific health advice? What is the range of topics covered, the time spent on reassurance and providing hopeful messages, and the time spent performing therapeutic maneuvers? How do verbal and nonverbal communication styles differ between different kinds of providers? Are CAM practitioners less paternalistic and more empowering in their communication styles than mainstream doctors? Are CAM providers more effective in helping patients effect behavior changes than mainstream physicians and, if so, how do they achieve these results?<sup>48</sup>

Health services research also is concerned with evaluating variations in quality of care. The Institute of Medicine has defined the quality of care as

the "degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." This definition has been operationalized for mainstream medicine through large national efforts such as the Health Plan Employer Data and Information Set indicators and the Joint Commission on Accreditation of Health care Organizations National Library of Health Care Indicators.<sup>49</sup> Similar instruments need to be developed to assess the quality of care for the various CAM specialties, particularly for pediatric care. Current information about CAM quality is based on periodic case reports of serious adverse effects, but denominator data even for these crude outcomes are lacking.<sup>50</sup> Quality evaluations should include patient and family views, including care of the patient's "problem" as well as the medical "diagnosis."<sup>51</sup> Surveys of patient satisfaction among children visiting CAM practitioners are lacking. There are important differences in patient satisfaction with care depending on practice characteristics; for example, patients of solo practitioners who billed on a fee-for-service basis report higher levels of satisfaction than those patients in multispecialty groups or health maintenance organizations.<sup>52</sup> CAM practitioners typically provide care in solo practice settings and bill patients directly on a fee-for-service basis, which might be expected to enhance patient satisfaction. However, in one survey of adults, patient satisfaction levels were as high for visits with general practitioners as for visits with CAM providers.<sup>53</sup> No studies have specifically evaluated satisfaction with care provided to children by CAM practitioners.

#### CLINICAL OUTCOMES RESEARCH: DISEASES, THERAPIES, METHODS

Priority should be given to conditions and diseases that satisfy the criteria in Table 1: those that impose a heavy burden of suffering for which mainstream therapies are insufficient and for which CAM therapies offer a reasonable likelihood of being helpful and are already used by families. Examples include anxiety, asthma, attention deficit

**TABLE 1.** Criteria for Conditions, Diseases, and Risky Health Behaviors Suitable for CAM Research

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<p>Those that</p> <ul style="list-style-type: none"> <li>● impose a heavy burden of suffering on individuals, families or the community either because of their <ul style="list-style-type: none"> <li>● severity</li> <li>● chronicity</li> <li>● prevalence</li> </ul> </li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>● for which current mainstream therapies are unacceptable or insufficient because of <ul style="list-style-type: none"> <li>● lack of proven efficacy</li> <li>● substantial side effects</li> <li>● cost</li> <li>● lack of availability</li> </ul> </li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>● for which alternative or complementary therapies offer a reasonable likelihood of being helpful based on <ul style="list-style-type: none"> <li>● proven effectiveness and safety in adults</li> <li>● proven safety in animal models</li> <li>● lengthy historical use or compelling results from case reports, case series, epidemiologic studies, case-control trials or cohort studies, or clear scientific rationale</li> </ul> </li> </ul> <p>And</p> <ul style="list-style-type: none"> <li>● for which families and physicians are already using complementary and alternative therapies</li> </ul>
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disorder, cancer, chronic and severe pain syndromes, depression, developmental disorders, recurrent respiratory infections and otitis media, rheumatic and autoimmune disorders, and addictive disorders.

Priorities related to types of CAM therapies and therapists should focus on those:

1. already widely used by children and families;
2. already researched to some extent in animal models and adults; and
3. having a potentially significant risk of substantial costs or side effects.

These therapies include research on nutritional supplements such as vitamins, minerals, and herbal remedies (Table 2). Such therapies are widely used; numerous European and Asian studies have addressed the effectiveness of such therapies for a variety of adult conditions. Yet important questions remain about safety and toxicity in pediatric populations.<sup>54,55</sup> Similarly, therapies emphasizing dietary restrictions may impose a large burden on the family and lead to nutritional deficiencies in the child.<sup>56</sup>

Therapies requiring professional intervention also are worthy of research because of the substantial costs associated with professional care. Thus, research on the effectiveness, safety, and costs of chiropractic, acupuncture, electroencephalographic biofeedback, hypnosis, or other mind-body techniques requiring professional therapists should be high priorities.<sup>57,58</sup> CAM practitioners (including spiritual healers) who advocate abandoning conventional medical care (eg, transfusions or immunizations) also require investigation into the scope of their effect on individual health practices and overall public health.

Research on placebo effects is particularly important in CAM research.<sup>59</sup> The placebo effect operates even in surgical trials; at least one third of patients usually respond to placebo preparations, implying wide-ranging and powerful therapeutic benefits.<sup>60,61</sup> Although often maligned, placebo effects often are invoked in clinical practice. The clinical question is how best to activate this response? For example, what is the least toxic, least expensive,

most culturally acceptable placebo for pediatric upper respiratory infections? If mainstream medications have unacceptable costs or side effects for diseases that are largely self-limited (eg, antibiotics for the treatment of otitis media), is it worth offering an untested but inexpensive, nontoxic placebo instead (eg, homeopathy)? Answering these questions requires sophisticated, critical, and creative cost-benefit analyses.

The same research techniques and the same levels of scientific evidence should be used to address questions about CAM as are used to evaluate similar types of mainstream therapies.<sup>62</sup> It may be useful to group similar mainstream and CAM practices together to address the effectiveness and safety of similar types of therapy.<sup>63</sup> For example, herbs, vitamins, minerals, and other supplements, like medications, are all examples of biochemical therapies. Although medications may be more synthetic and standardized and herbs may be considered more natural, there is no inherent reason they cannot all be judged using the same gold standard—the randomized, double-blind, placebo-controlled clinical trial.<sup>64,65</sup> Both mainstream and CAM lifestyle therapies (diet, exercise, environmental changes) and mind-body therapies are very difficult to perform in a randomized, blinded manner. One cannot randomize children to breastfeeding or macrobiotic diets and then compare their general health and disease rates with those randomized to formula or a fast-food diet. Rather, researchers rely on case-control, cohort, and epidemiologic studies, and on statistical techniques to control for potential confounders whenever possible. Similarly, in studies of massage, acupuncture, and spinal adjustment, as in studies of new surgical techniques, it is impossible to blind the therapist as to whether the true therapy was provided. Furthermore, we would not expect psychotherapy to work if the patient population was skeptical about its value or asleep during sessions. We should not expect more from other types of mind-body therapies. Outcomes (discussed below) should include costs, adverse events, and patient preferences.<sup>66</sup>

Given the frequently conflicting data from mainstream medical research studies, overviews and

**TABLE 2.** Research Questions on Dietary or Nutritional Supplements for Children

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What is the <i>purity</i> of the products available to the public (does brand X really contain the herb promised with standardized amounts of the putative active chemical constituents, and to what extent is it contaminated by other herbs, herbicides, pesticides, animal products, heavy metals, and/or pharmaceuticals)?
What is the <i>reliability</i> of nutritional products available (lot to lot variability in active ingredients in products from a single manufacturer and variability between manufacturers)?
How <i>effective</i> are the putative active compound(s) in supplements for children?
What are the <i>safety and toxicity</i> of the product for <i>short-term use</i> in infants and young children whose metabolism and risks may differ substantially from those of adults, eg, tetracycline widely used in adults and presumed safe until adverse effects on dentition noted
What are the <i>safety and toxicity</i> of <i>long-term</i> administration of products in developing humans (fat-soluble vitamins, etc.)?
What are the <i>potential interactions</i> between supplements and pharmaceuticals?
What are the <i>safety and toxicity</i> of products used in children with <i>specific organ impairments</i> , eg, decreased renal or hepatic metabolism?
What are the basic <i>pharmacokinetics</i> in children at different ages and with different underlying diseases on other medications; appropriate dosing and frequency in children?
How much do <i>costs</i> vary between different products and how do price fluctuations affect consumer choices about the use of supplements, nonprescription medications, and prescription medications?
How do <i>legislative changes</i> regarding nutritional supplements affect access to, quality of, and use of supplements by children?

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data synthesizing analyses are critically important for translating research into practice.<sup>67,68</sup> Practice guidelines are an emerging area in mainstream pediatric research on quality of care.<sup>69,70</sup> No practice guidelines have been published for pediatric CAM care.<sup>71</sup> Mainstream researchers will be involved in outcomes research for CAM care and also may need to help take the next steps in synthesizing that information into evidence-based practice guidelines.

Scientific standards should be higher and studies more rigorous for the most vulnerable patients (eg, premature infants), the most serious diseases (eg, cancer), and the riskiest or costliest therapies. For minor diseases and low-cost, low-risk interventions, standards of proof may not need to be so rigorous and research may be a lower priority. Are there any therapies or therapists that are not high priorities for research? We believe that therapies such as prayer (when performed at no cost by family and friends) are lower research priorities, not because they are likely to be ineffective, but because their risk of side effects and their costs are so low for society. Similarly, whether or not chicken soup is effective in treating the common cold, it is an important part of some cultural traditions, is low risk (except for the chicken!), is low cost, and may help build an important bond among family members.

Although the idea of accepting lower standards of proof for certain therapies and certain conditions may seem radical, most of mainstream medicine for most minor illnesses is still based on tradition rather than gold-standard scientific data.<sup>72</sup> For example, pediatricians routinely recommend the BRAT diet for diarrhea and vaporizers for colds, not because randomized controlled trials support these interventions, but because of tradition and

because the costs and risks of such interventions are low. Textbooks and standard practices also are based to a large extent on expert consensus opinion rather than to irrefutable data evaluating the long-term risks and benefits. In fact, many mainstream practitioners continue to recommend therapies that have been disproved in randomized trials (eg, commonly used pediatric cold medicines). Mainstream medicine as it is actually practiced relies on a variety of levels of evidence and should not expect substantially higher levels of proof from CAM practices. Nor should CAM practices slide by with the assertion of greater safety at lower cost than mainstream medicine.

### SAFETY AND EFFECTIVENESS

Perhaps the most important pediatric CAM research is in clinical outcomes research, addressing three primary questions: Does it work? What are the adverse effects? How much does it cost?<sup>73</sup> One benefit of studying holistic health care is its invitation to consider health outcomes very broadly. Outcomes include not only traditional measures of morbidity, mortality, cost of care, and patient satisfaction (ie, what works),<sup>74</sup> but also the impact of care on family cohesiveness, cultural identity, spiritual beliefs, resilience, coping, and self-efficacy. The impact on the environment such as the extinction of certain plant and animal species caused by overharvesting also should be considered (Table 3). Additional outcome measures may need to be developed to address the quality of life and the concept of health as optimal functioning rather than as the absence of disease.<sup>75</sup>

For example, an evaluation of the effectiveness of mindfulness meditation in helping pediatric oncology patients cope with their illness and intensive mainstream treatment regimens should examine

**TABLE 3.** Outcomes of Interest in Pediatric CAM Research

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<b>Patient outcomes</b>
<ul style="list-style-type: none"> <li>● Mortality rates, years of life saved</li> <li>● Morbidity—physical, psychological, emotional and social symptoms; severity of illness</li> <li>● Health behaviors—dietary, exercise patterns; smoking, drinking, drug use; unprotected sexual relations</li> <li>● Health care utilization, including self-care, CAM care, and conventional care</li> <li>● Satisfaction with care</li> <li>● Developmental milestones and behavior</li> <li>● Activities of daily living</li> <li>● Quality of life</li> <li>● Costs associated with care <ul style="list-style-type: none"> <li>Direct and indirect financial costs; opportunity costs of missed treatments; side effects—symptomatic and asymptomatic organ dysfunction, injuries, infection; adverse interactions with other therapies; x-ray and other toxic exposures</li> </ul> </li> <li>● Social outcomes <ul style="list-style-type: none"> <li>Days of work/school missed; delinquency, incarceration</li> </ul> </li> </ul>
<b>Family outcomes</b>
<ul style="list-style-type: none"> <li>● Days of work missed for parents; out-of-pocket costs; impact on insurability</li> <li>● Psychosocial impact on parents, siblings; emotional impact on sense of empowerment</li> <li>● Spiritual outcomes: coping, peace, serenity, harmony in relationships, a sense of meaning or purpose in life, self-efficacy, self-esteem.</li> <li>● Social outcomes: divorce</li> </ul>
<b>Community outcomes</b>
<ul style="list-style-type: none"> <li>● Sense of cohesiveness, cultural identity</li> <li>● Cost to society, rate of malpractice suits</li> <li>● Environmental impact: cost of remedy to society, environment, (overharvesting of herbs leading to extinction?)</li> </ul>
<b>Provider outcomes</b>
<ul style="list-style-type: none"> <li>● Provider satisfaction with role</li> <li>● Burnout; other? sense of effectiveness and part of healing community?</li> </ul>

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outcomes ranging from adherence with recommended practice and therapy, impact on quality of life, sleep, school attendance, family interactions, parental stress levels, sense of self-efficacy, and hope. If the intervention were simply acupuncture stimulation to reduce nausea, outcomes might include patient and family acceptance of this novel therapy, need for antiemetic medications, and impact on health beliefs. When looking at an adjunctive herb to treat oncology patients, questions might focus instead on safety and toxicity in animal models, drug interactions, pharmacokinetics, side effects, effectiveness in enhancing immune function and/or reducing tumor burden, overall morbidity, quality of life, and impact on the total cost of care, including the cost of other supportive measures.

Outcomes focusing on adverse effects, safety, and impact on developing systems are of paramount importance in pediatrics.<sup>76</sup> Alternative therapies generally are believed to be less expensive and less toxic than mainstream therapies, but specific and overall cost comparisons have not yet been conducted.<sup>77</sup> Many mainstream pediatric medications contain alcohol, artificial colors, flavors, and a variety of other ingredients with potential effects on the child.<sup>78</sup> Medications with excellent safety profiles in adults (eg, tetracycline and chloramphenicol) may have major consequences for children. The widespread use of herbal and nutritional supplements with the potential for acute and chronic toxicity makes this a high priority for pediatric research.

### SUMMARY

The research agenda for holistic or CAM care in pediatrics encompasses every aspect of child health and includes all types of health-related research methodologies. Priority should be given to evaluating therapies for conditions that impose a heavy burden of suffering and for which current mainstream therapies are unacceptable or insufficient and for which CAM therapies offer a reasonable likelihood of being helpful based on existing data (eg, cancer, asthma, attention deficit disorder, recurrent otitis media, and chronic pain syndromes). Priority also should be given to evaluating widely used CAM therapies with high potential for toxicity (eg, herbs, nutritional supplements, and restrictive diets) or substantial health care costs (eg, chiropractic, acupuncture, massage, and other therapies provided on a frequent, ongoing basis by professional providers). Health services research is needed to address the CAM workforce and the process and content of care to determine how CAM services affect overall access, quality, and cost of health care. Anthropologic research can assist clinicians in identifying and understanding alternative explanatory models and the meaning of health and illness in different groups and how these variations affect health-seeking behavior, adherence with mainstream recommendations, physician-patient relationships, and satisfaction with care. This

broad research agenda implies a comprehensive multidisciplinary approach spanning the range from molecules to mountains—precisely the niche for generalist pediatrics.

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