

Pediatric Use of Complementary and Alternative Medicine: Legal, Ethical, and Clinical Issues in Decision-Making

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KEY WORDS

complementary therapies, clinical ethics, evidence-based practice, jurisprudence, pediatrics

ABBREVIATION

CAM—complementary and alternative medicine

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abstract

In this article we introduce a series of 8 case scenarios and commentaries and explore the complex legal, ethical, and clinical concerns that arise when pediatric patients and their parents or health care providers use or are interested in using complementary and alternative medicine (CAM). People around the world rely on CAM, so similar issues face clinicians in many countries. In law, few cases have dealt with CAM use. The few that have apply the same general legal principles used in cases that involved conventional care while taking into account considerations unique to CAM. In ethics, as with conventional care, the issues surrounding pediatric CAM use usually involve questions about who the appropriate decision-makers are, on what ethical principles should clinical decision-making rely, and what obligations arise on the part of physicians and other health care providers. Clinical decision-making is made more complex by the relatively limited research on the efficacy and safety of CAM compared with conventional medicine, especially in children, which requires clinicians to make decisions under conditions of uncertainty. The clinical scenarios presented focus on patients who represent a range of ages, clinical conditions, and settings. They act as anchors to explore particular CAM policy issues and illustrate the application of and shortcomings in existing guidance and intervention principles. Although the focus on a pediatric population adds another layer of complexity to the analysis, many of the concepts, issues, principles, and recommendations also apply to adults. *Pediatrics* 2011;128:S149–S154

Rapid increases in the use of complementary and alternative medicine (CAM) raise important legal, ethical, clinical, and policy issues. Both adult and pediatric populations use CAM therapies for a wide variety of conditions. A large 2007 US survey revealed that ~4 in 10 adults and 1 in 9 children and youth used CAM products or therapies within the preceding year.¹ In a 2005 Canadian survey, 71% of respondents reported using 1 or more natural health products²; an earlier study found 19% had consulted a CAM practitioner.³ Rates of use are higher among people with chronic, recurrent, or incurable conditions or special health care needs.⁴⁻⁶ Worldwide, CAM use is widespread.^{7,8}

Use of CAM with children complicates the issues, because children do not usually decide about treatment for themselves and because of the vulnerability of the pediatric population. Parents, patients, health care providers (physicians, nurses, allied health providers, and CAM practitioners), and hospitals need sound information about the legal, ethical, and clinical considerations that should be taken into account in decision-making. They also need guidelines for the appropriate use of CAM. Meeting these needs is made more difficult by the relative scarcity of pediatric research in the area, challenging questions of language, definitions, and culture associated with CAM, and contention about the nature of evidence and proof that frequently marks discussions of the subject.

We examined current legal, ethical, and clinical issues that arise when considering CAM use for children and identified where gaps remain in law and policy. This article is the beginning of a more complete policy framework to guide health professionals and parents who care for children and make decisions about treatment, as well as

health facilities, regulators, educational institutions, government, and policy-makers. The researchers form a multidisciplinary team with expertise in pediatrics, epidemiology, law (Canada and United States), bioethics, and naturopathy. Although law and ethics are not always explicitly considered when decisions are made about using CAM or conventional care, both are crucial for clinical decisions and policy-making. We hope that this study will go some way toward remedying this omission. Overall, our goal is to inform and better support decision-making for children and to engage, enable, and encourage clinicians, parents, and patients in shared decision-making.

DEFINING CAM

Defining CAM is difficult, particularly because of the wide range of different therapies, products, and approaches to healing that the term encompasses. For the purposes of this study, we have adopted the definition of CAM offered by the US Office of Alternative Medicine CAM Research Methodology Group, which is also used by the Cochrane Collaboration:

“Complementary and alternative medicine is a broad domain of healing resources that encompasses all health care systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being. Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed.”⁹

Other definitions of CAM, such as that used by the National Center for Complementary and Alternative Medicine (a component of the National Institutes of Health in the United States) and the one adopted by the Institute of Medicine in its 2005 report on CAM, have considerable currency as well.^{10,11}

However, this definition, which was adopted by major reports on CAM in Canada, and in the United States and elsewhere,¹²⁻¹⁶ has a number of advantages. It is broad enough to encompass both CAM practices and products. It moves beyond early efforts to define CAM in terms of medical interventions that are neither taught in medical schools nor available in hospitals^{17,18}; the increasing use of CAM and its introduction into some medical schools' curricula^{19,20} diminish the utility of such a definition. In addition, this definition acknowledges the role played by political, social, cultural, and historical forces, which can exert a powerful influence on determinations about what is considered acceptable within a health care system. It also recognizes that boundaries between CAM and conventional medicine are fluid and that as a given CAM therapy gains research acceptance and clinical use, it may move into the medical mainstream.

METHODS

Phase 1

1. Existing data on law, ethics, and clinical considerations relevant to CAM, both generally and with children, were identified by using legal, ethics, and clinical databases. This process included searching for relevant judicial decisions, statutes, and regulations and, more generally, completing literature reviews of legal, ethical, and clinical texts, journal articles, and policies. The legal and ethics databases we used included Quicklaw, Westlaw, and Lexis/Nexis, and we also used Medline, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase, and HealthSTAR.
2. Health professionals' regulatory bodies were contacted to ascertain policies and experience about CAM use.

3. All pediatric hospitals and a random sample of 10% of all other hospitals in each Canadian province were contacted to ascertain institutional policies regarding CAM use.
4. Data collected were analyzed to identify and assess applicable legal, ethical, and clinical principles that guide decision-making and to identify shortcomings.

Phase 2

1. Case scenarios and commentaries were developed to explain how principles are applied in practice and to illustrate gaps, deficiencies, and inconsistencies that remain in law and policy.
2. Recommendations were formulated in light of the principles identified for consideration by those involved in clinical decision-making (clinicians, parents, institutions, and others).

OVERVIEW: THE CASE SCENARIOS

In this supplemental issue of *Pediatrics*, we present the results of our research as a series of 8 case scenarios and commentaries. The scenarios were developed to act as a practical anchor in the exploration of CAM policy issues and to illustrate the application of and shortcomings in existing guidance and intervention principles. These case scenarios deliberately involve a range of ages (infant to adolescent), clinical conditions (acute to chronic, health prevention and promotion to treatment of specific illnesses), settings (outpatient and inpatient), and levels of care (primary care and consultation) to more fully explore the impact of current guidelines, principles, and law.

The case scenarios address the following issues and areas of focus:

- physician/parent conflict about care (vaccination):
- clinician and patient/parental responsibilities to take CAM into ac-

count (natural health product/drug interactions);

- adolescent decision-making and parent/child conflict (CAM alternative to conventional treatment);
- informed consent when CAM could complement conventional care (chemotherapy-induced nausea);
- hospital policies about CAM;
- determining best interests of the child, limits on parental decision-making authority (life-threatening illness), and CAM as an alternative treatment;
- managing referrals to and shared or collaborative care with CAM practitioners (condition unresponsive to conventional treatment); and
- CAM practitioners' standard of care (diagnosis, monitoring, referral).

In this introductory article we briefly review the underlying ethical and legal principles and then outline general considerations in clinical decision-making.

ETHICAL PRINCIPLES

The bioethics literature frequently considers issues in health care treatment decision-making for children, but primarily in the context of conventional care. Issues may be categorized as those related to (1) who the appropriate decision-makers are (eg, parents, health care professionals, the child), (2) according to what ethical principles, standards, and rules decisions ought to be made, and (3) special obligations of physicians. Although there has not been an extensive addition to the pediatric bioethics literature addressing issues specifically related to CAM and children, there have been some attempts to identify relevant ethical issues and analyze them in light of existing models.^{21,22}

Who Makes Decisions?

In the bioethics literature there is consensus that parents are almost always the appropriate decision-makers for infants and children who have not yet achieved decision-making capacity.²³ This principle should also apply to CAM use.²⁴ The presumption is that parents know their children best, have the greatest interest in their children's well-being, and carry the greatest burden if things do not go well. Although collaboration among parents and health care providers is seen as the ideal, when conflict exists, parents' wishes should prevail unless the harm threshold at which referral to child protection services is required is met.^{25,26} Different clinicians or teams may judge this threshold differently. One of the authors (Dr Harrison) has worked with team members who disagree about whether to call child protection services regarding children who are obese and whose parents resist advice about diet and exercise, children with asthma whose parents continue against medical advice to smoke in their presence, and children for whom parental treatment decisions do not place them at risk of harm now but may result in significant harm for them as adults. Health care providers are encouraged to maintain good relationships with parents because it encourages disclosure and discussion of CAM use,²⁷ allows ongoing monitoring of the child,²⁸ increases levels of trust,²⁹ and avoids causing the child distress when he or she perceives conflict between parents and clinicians.³⁰

With regard to the involvement of the child in decision-making, it is commonly understood that children's decisions should have increasingly more weight as they mature. For children and adolescents who have the capacity to understand information and appreciate the consequences of making specific decisions, the consensus is that

they should make their own treatment decisions. It is important to increase children's control over their illnesses and have their views respected, especially for children with long-term and chronic conditions.³¹ This policy respects the child's developing autonomy and builds trust. The challenge involved with determining whether adolescents are able to make independent, sound, and reasonable treatment decisions for themselves has been as understudied in CAM-related bioethics as it has been in conventional bioethics.

How Should Decisions Be Made?

When substitute decision-makers choose treatments for infants and very young children, the best-interest-of-the-child standard applies regardless of whether the treatment decision involves therapies or products within the conventional or CAM domain.³² This determination may be more challenging when considering CAM, because evidence may be lacking or less adequate than desired.³³ As with conventional therapies, there is a moral imperative to develop good evidence through research into CAM therapies to facilitate informed decision-making and informed consent.³⁴ Disclosure standards are the same for CAM and conventional therapies,^{35,36} even when the only disclosure possibly concerns the lack of available information.

Physician Obligations

In addition to the obligations of physicians to maintain good relations and communication with families, duties commonly identified in the CAM-related bioethics literature are that physicians should keep an open mind and be nonjudgmental when patients wish to discuss CAM,³⁷ and they should be knowledgeable about CAM, the beliefs and values of various cultures, and the specific values and health-related practices of their own pa-

tients.^{15,38–41} Educating parents about the potential harms and benefits of all treatments, conventional or CAM, should be a priority.⁴²

LAW: SETTING STANDARDS AND ESTABLISHING LIABILITY

CAM use has seldom led to litigation. Legal analysis in this project was informed by the few cases of relevant judicial decisions, but most often, the issues had not yet been considered by courts in the context of CAM, and general legal principles provided the starting point for analysis. Judicial decisions not only determine liability for harm caused by deficient care but also, together with statutory and regulatory regimes, set legal standards that practitioners and health facilities must meet. Most lawsuits about health care are based on allegations of negligence (ie, claims that providers failed to meet the applicable standard of care and caused harm). Depending on factual circumstances, claims for battery, breach of contract, and breach of fiduciary duty may also be advanced.

Because they are the most common, we focused on civil lawsuits that allege negligence. To succeed in a negligence claim, a plaintiff must prove on a balance of probabilities that (1) the health care provider owed him or her a duty of care, (2) the provider breached the legal standard of care, (3) the provider's breach caused injury or loss to the plaintiff, and (4) the plaintiff's damages are not too remote to be recoverable in law. Liability can arise from substandard care and from a failure to obtain informed consent to treatment.

In addition to civil liability, regulated health professionals can be subject to disciplinary proceedings and sanctioned by their governing bodies for professional misconduct if they fail to maintain standards of practice.^{43–47} Finally, all health care providers are bound by laws of general application,

including criminal law, consumer-protection laws, and laws that prohibit unauthorized provision of health services.^{48–51}

CLINICAL CONSIDERATIONS

Relatively limited research on the efficacy and safety of CAM, especially in children, means that decisions must frequently be made in conditions of uncertainty. As with conventional therapies, even when risks and benefits are known, practitioners, parents, and patients may weigh them differently. Decisions are to be made in the child's best interests, but these interests may be contentious, especially if conventional treatment offers few or uncertain benefits or has serious adverse effects. Consequently, decision-makers (parents, providers, and institutions) are often left in a quandary. Disputes may arise about who can decide, the latitude allowed decision-makers (primarily parents in the first instance), when institutional or state intervention is appropriate, and how decisions should be made. For health care facilities, questions arise about how to respond to increasing use of and growing demand for CAM by patients and families.

When considering what advice to give about using CAM, some authors have suggested a framework to guide decision-making based on available evidence of safety and efficacy:

"If evidence supports both safety and efficacy, the physician should recommend the therapy but continue to monitor the patient conventionally. If evidence supports safety but is inconclusive about efficacy, the treatment should be cautiously tolerated and monitored for effectiveness. If evidence supports efficacy but is inconclusive about safety, the therapy still could be tolerated and monitored closely for safety. Finally, therapies for which evidence indicates either serious risk or inefficacy obviously should be avoided and patients actively discouraged from pursuing such a course of treatment."^{52(p662)}

This framework can be helpful when there is adequate reliable evidence,⁵³

but it is less helpful when evidence is lacking or limited, as is often the case with CAM.^{52(p660)} In addition, formulating a treatment plan generally entails weighing alternatives; treatment is not assessed in a vacuum. Balancing known risks and benefits of conventional therapies with unknown risks and benefits of CAM therapies poses significant challenges. Information about the safety and efficacy of CAM therapies is increasing all the time, but there are still large gaps in knowledge. Uncertainty is compounded by disagreements about the level and reliability of evidence needed. Decision-making in conditions of uncertainty is not uncommon in health care, especially in pediatrics, and it is not unique to CAM. Conventional therapies, too, may not have not been fully assessed, or at least not in similarly

complex circumstances (eg, a child on multiple therapies or with concurrent morbidities). However, the lack of evidence about many CAM therapies and products can make assessing CAM options particularly difficult. Thus, although the framework can assist decision-making, the questions that remain outstanding often require a return to first principles in decision-making.

CONCLUSIONS

Because the issues are multiple and complex, there are no easy solutions to the case scenarios presented in this supplement. Rather, in this series of articles, we illustrate the relevance and impact of identified guidelines and principles. By exploring what is known, recommending responses, and identifying issues that need further consideration, we hope these articles assist

decision-makers and act as a catalyst for policy development and for further discussion about complementary and alternative health care among everyone involved—health care providers, institutions, policy-makers, judges, and, of course, parents and patients.

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