

Concluding Comments: Maximizing Good Patient Care and Minimizing Potential Liability When Considering Complementary and Alternative Medicine

abstract

Our goal for this supplemental issue of *Pediatrics* was to consider what practitioners, parents, patients, institutions, and policy-makers need to take into account to make good decisions about using complementary and alternative medicine (CAM) to treat children and to develop guidelines for appropriate use. We began by explaining underlying concepts and principles in ethical, legal, and clinical reasoning and then used case scenarios to explore how they apply and identify gaps that remain in practice and policy. In this concluding article, we review our major findings, summarize our recommendations, and suggest further research. We focus on several key areas: practitioner and patient/parent relationships; decision-making; dispute resolution; standards of practice; hospital/health facility policies; patient safety; education; and research. Ethical principles, standards, and rules applicable when making decisions about conventional care for children apply to decision-making about CAM as well. The same is true of legal reasoning. Although CAM use has seldom led to litigation, general legal principles relied on in cases involving conventional medical care provide the starting point for analysis. Similarly, with respect to clinical decision-making, clinicians are guided by clinical judgment and the best interests of their patient. Whether a therapy is CAM or conventional, clinicians must weigh the relative risks and benefits of therapeutic options and take into account their patient's values, beliefs, and preferences. Consequently, many of our observations apply to conventional and CAM care and to both adult and pediatric patients. *Pediatrics* 2011;128:S206–S212

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KEY WORDS

complementary therapies, clinical ethics, evidence-based practice, legal liability, pediatrics

ABBREVIATION

CAM—complementary and alternative medicine

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Our goal for this supplemental issue of *Pediatrics* was to consider what practitioners, parents, patients, institutions, and policy-makers need to take into account to make good decisions about using complementary and alternative medicine (CAM) to treat children and to develop guidelines for appropriate use. We began by explaining underlying concepts and principles in ethical, legal, and clinical reasoning¹ and then used case scenarios to explore how they apply and identify gaps that remain in practice and policy. In this concluding article, we review our major findings, summarize our recommendations, and suggest further research. We focus on several key areas: practitioner and patient/parent relationships; decision-making; dispute resolution; standards of practice; hospital/health facility policies; patient safety; education; and research.

Ethical principles, standards, and rules applicable when making decisions about conventional care for children apply to decision-making about CAM as well. The same is true of legal reasoning. Although CAM use has seldom led to litigation, general legal principles relied on in cases that involve conventional medical care provide the starting point for analysis. Similarly, with respect to clinical decision-making, clinicians are guided by clinical judgment and the best interests of their patient. Whether a therapy is CAM or conventional, clinicians must weigh the relative risks and benefits of therapeutic options and take into account their patient's values, beliefs, and preferences. Consequently, many of our observations apply to conventional and CAM care and to both adult and pediatric patients.

FOSTERING RESPECTFUL RELATIONSHIPS

Parents and the health practitioners who treat their child share a common

goal: the child's best interests. Making decisions about treatment should be a shared process. Health care providers should strive to build and maintain good relationships with patients/parents, because it will increase levels of trust, encourage discussion and openness about CAM use, allow ongoing monitoring of the child, and avoid causing the child distress when he or she perceives conflict between parents and clinicians.¹

COMMUNICATION AMONG EVERYONE INVOLVED IS KEY

Clear communication improves care, enhances patient safety, and strengthens relationships between practitioners and their patients/parents. Practitioners should use language that is straightforward and understandable, provide clear advice and conclusions when possible, and acknowledge areas in which information is lacking.² We have suggested several concrete strategies for encouraging and optimizing open communication in other articles of this supplemental issue of *Pediatrics*.⁵⁻⁷

CLARIFYING CHILDREN'S BEST INTERESTS AND PARENTS' DECISION-MAKING AUTHORITY

Parents have an ethical and legal duty to make health care decisions in their child's best interests. Because views on what constitutes those best interests differ, affected by value systems, religious, and other beliefs, cultural background, perceptions of risk and benefit of treatment alternatives, and other considerations, the law allows parents considerable latitude in these decisions. Collaboration among parents and health care providers is ideal, but when conflict exists, parents' wishes should prevail unless serious, unreasonable harm to the child is likely.^{3,8}

However, there are limits on parental authority. If treating health care pro-

viders conclude that there is only 1 justifiable course of action, given the child's condition and what is predictable about the treatment's effectiveness and the consequences of non-treatment, they should provide the family with the available information about treatment options, make a recommendation about treatment, and explain their reasons. Should parents be reluctant to consent, their reasons should be explored.

Parents' decisions to forgo needed medical care for their child can trigger health care providers' obligation to report them to child protection services if a child is exposed to serious, unreasonable risk to life or health as a result. Different clinicians or teams may judge this threshold differently. Child welfare authorities and courts or specialized tribunals can intervene to ensure that needed treatment is provided and harm is avoided.^{8,9}

DECISION-MAKING IN CONDITIONS OF UNCERTAINTY

Sometimes, the appropriate course of action when treating a seriously ill child is not clear. Data about treatments may be limited, patients often have complex conditions or comorbidities that complicate the decision-making process, and available conventional treatments may carry considerable risk or impose substantial burdens, whereas benefit may be unlikely or uncertain. Consultation with specialist colleagues may assist in clarifying standards of practice expected of clinicians.

When a child's best interests are uncertain, the physician's obligation is to share with the parents a clear understanding of the various treatment options and, if possible, make a recommendation consistent with what he or she and the treatment team believe is in the child's best interests. If the physician and treatment team believe

that there is more than 1 justifiable course of action, confirmed by consultation with specialist colleagues to ensure adherence to standards of practice, parents may decide among options that are reasonable under the circumstances.⁸

DECISION-MAKING ABOUT CAM

The decision-making framework described in earlier articles in this supplement can assist in evaluating CAM therapies or products. Briefly, it recommends that clinicians “[d]etermine the clinical risk by assessing the medical evidence and thereby decide whether to recommend; allow, caution and monitor; or avoid and discourage.”¹⁰ However, evidence about CAM therapies may be limited or lacking.^{10,11} In addition, treatment planning often requires both complex comparative assessments and consideration of additional factors. As we noted at the outset, debates about determining adequacy of evidence are beyond the scope of these articles. Nonetheless, clinicians must weigh alternatives and balance potential benefit and harm.

A final consideration when deciding about children’s health care is the particular vulnerability of the pediatric population and the duty of health care providers and parents to make treatment decisions in the child’s best interests. Additional research is required to clarify what evidence bases are appropriate for clinical decision-making in different circumstances.^{12,13}

DISPUTE RESOLUTION

The adversarial nature of legal proceedings and the limited range of remedies that courts can order make law a blunt tool. When time permits, encouraging those involved to work out a solution that everyone concerned can accept is likely to result in greater cooperation and less emotional harm to a child caught between medical and

familial authority. Consultation with a bioethicist or ethics committee, when available, may assist in dispute resolution. However, agreement is not always possible. When there is serious risk to a child’s life or health that results from parents’ refusal of needed care, clinicians’ legal obligation to report the parents to child welfare authorities will be triggered, and resolution by a court or specialized tribunal may be required.^{8,14}

INFORMED CONSENT

Clinicians must obtain informed consent for treatment from patients or from substitute decision-makers (usually parents, in the case of children) when patients are unable to decide for themselves.^{3,6} Parents bear a heavy responsibility when deciding about their child’s health care, especially in cases of serious illness. Clinicians should ensure that parents have the best information and advice they can give and are able to understand it. They should remain available to assist and support families in their decision-making.

The scope of clinicians’ duty to disclose and explain treatment alternatives as part of the process of obtaining informed consent continues to grow. Whether a CAM therapy for a given condition has attained sufficient medical acceptance to trigger an obligation to disclose as part of the informed-consent process will depend on prevailing medical evidence about its safety and efficacy.⁶

DECISION-MAKING BY ADOLESCENTS

Young people who are able to (1) understand and appreciate the nature and consequences of the proposed treatment and alternatives and (2) make a voluntary decision can make their own decisions about health care, absent statutory restrictions.¹⁵ The health care provider who proposes

treatment usually decides in the first instance whether a patient is decisionally capable, but that determination can be challenged. Especially in cases of conflict between parents and children or with the health care provider, it is essential to carefully determine who can consent to treatment.

Clinicians should consult as needed to ensure compliance with legal requirements about decision-making by minors in their jurisdiction, especially in the context of child-protection proceedings; in some instances, courts or tribunals can authorize treatments without patient or parental consent.¹⁵

When a patient is not capable of making treatment decisions, it is still important and respectful to include the child in discussions and decisions to the greatest extent possible. In these situations, the child’s assent or appropriately informed agreement should be sought, although it is not controlling. Nonetheless, a child’s sustained dissent, or resistance to treatment, should be taken seriously, and discussions with the parents and team should be held in an attempt to reach a conclusion that everyone involved can live with.⁴

TAKING CAM INTO ACCOUNT

Health care providers cannot afford to ignore CAM use, given its prevalence. Regardless of clinicians’ personal views regarding CAM, routine history-taking should include explicit questions about CAM, using specific terms such as “alternative,” “natural,” and “herbal” to fully convey the meaning of the question. Patient information should be updated regularly.⁵

Patients/parents should discuss their use of CAM therapies and products with treating clinicians and be encouraged to do so.^{3,5}

For hospitals and health facilities, guidelines should clarify for all medical staff (including allied health pro-

professionals, when appropriate) that the patient intake and informed-consent processes must include questioning to ascertain use of CAM therapies and products and discussion of potential adverse herb-drug interactions.^{5,16}

Health care providers and institutions should guard against overly broad prohibitions and warnings. Some CAM therapies and products may improve a patient's condition or well-being, and the autonomous choices of that patient and his or her parents should not be unduly skewed by unfounded concerns.

STANDARD OF CARE AND SCOPE OF PRACTICE

Medical knowledge constantly evolves. Consequently, what constitutes reasonable practice for different types of practitioners (and, hence, the standard of care expected) will change over time and become more expansive in response to new realities. Clinicians must modify their practices to reflect these changes. Clinicians should ensure that they have the necessary knowledge, skills, and training to treat patients' presenting conditions, and they must comply with restrictions on unauthorized practice. Those who treat children should have ample formal pediatric training. All health care providers, whether conventional or CAM, must be able to recognize limits to their own abilities and those of their profession and to refer appropriately.^{7,17}

REFERRALS

The referring clinician should have a reasonable expectation that the therapy or expertise could benefit the patient, ensure that the practitioner to whom the referral is made has the requisite qualifications, and continue to monitor and treat the patient as appropriate. He or she should also comply with applicable legislation and pro-

fessional and institutional policy when referring. Communication among those treating the patient is important to improve patient safety and quality of care. Referral must be timely to ensure that needed care is not delayed.¹⁷

Ideally, physicians will become comfortable referring to CAM practitioners when the risks and benefits of therapy are favorable for their patient's condition. However, if a physician feels unable to appropriately advise patients about CAM, he or she should explain that to the patient, refer the patient to another practitioner who may be more comfortable advising about the referral or to a regulatory authority or professional association, and assure the patient that their relationship will not be affected by the patient's decision.¹⁷

SHARED OR COLLABORATIVE CARE

With shared or collaborative care, responsibility for managing the patient's care or an aspect of it is assumed by 2 or more health care providers. Simply continuing to provide conventional care and monitoring a patient's health status while he or she receives CAM therapy from another practitioner should not, without more, involve the conventional practitioner so closely with the alternative treatment that he or she would be considered to have entered into a joint undertaking with the CAM provider and lead to joint liability if one or the other harms the patient.^{10,14,17,18}

When undertaking shared or collaborative care, clear communication among everyone involved is especially important. Patients, parents, and health care providers should understand (1) health care providers' individual roles and responsibilities, (2) decision-making processes, (3) policies about care provision, and (4) the care to be provided, all documented by appropriate record-keeping.^{7,17,19}

ENDING THE CLINICIAN-PATIENT/PARENT RELATIONSHIP

Parents can reject clinicians' advice and still make good decisions about their child's health care. Respectfully disagreeing with parents while continuing to treat their child provides an opportunity for clinicians to continue to build trust and perhaps ultimately change the parents' views. However, subject to any express legal requirements, a clinician who believes that he or she cannot continue to provide care for a patient may generally end the relationship, but not until another clinician has assumed responsibility for the patient or the patient/parents have been given reasonable notice that the clinician intends to terminate the relationship.⁵

CAM IN HOSPITAL SETTINGS

Hospitals and health facilities that decide to allow some CAM therapies to be provided on-site should structure policies to achieve that end and, at the same time, ensure informed decision-making, quality care, and patient safety. Accommodating reasonable requests from families who wish to receive CAM therapies or products within the hospital setting, provided it can be done in a way that is consistent with institutional obligations to provide a safe environment and quality care, can further an organization's commitment to patient-centered (or, in pediatric hospitals, family-centered) care. Medical leadership should initiate development of guidelines and policies and perhaps establish a multidisciplinary working group with family representation.¹⁶

It would be prudent for hospitals and health facilities to consider adopting a formal protocol and/or formal processes to establish what CAM therapies and products to allow or make available on-site, which kinds of CAM

practitioners can provide them, under what conditions they may be provided, and how they will function and interact with patients, other health care providers, and the institution.¹⁶

IMPROVING PATIENT SAFETY

Improving patient safety and reducing errors are priorities in health care. Therefore,

- education about how errors occur and how to avoid or minimize the risk of patient harm would enhance all health practitioners' ability to provide safe, high-quality patient care¹⁸;
- adverse events should be reported by everyone involved in patient care regardless of whether they result from conventional treatment, CAM therapy, or the interaction of the two of them^{5,17};
- when adverse events occur, it is essential that health facilities and practitioners analyze what happened and take effective steps to prevent recurrence^{7,16}; and
- regulatory authorities and professional associations should develop programs to improve safety and quality of care and alert members about preventable adverse events.

ENHANCING EDUCATION

Clinicians have a fundamental responsibility to maintain and improve their professional knowledge and skills. Conventional practitioners need not become homeopaths or herbalists; they simply need to be familiar with the CAM therapies and products they most often encounter or anticipate encountering, both in general and with specific patient populations.^{5,6,17} Continuing education (eg, through educational programs, journal clubs, self-study) is important for ensuring that conventional and CAM practitioners learn

about new developments and reported adverse events.^{5,7} Educational programs tailored to the needs of different types of CAM and conventional practitioners should be developed through relevant educational institutions, regulatory bodies, or professional associations (eg, about routine childhood immunization).^{3,17}

Hospitals and health facilities should develop resources and policies that provide accurate and timely information to physicians and other health care providers about CAM therapies and products, as well as potential interactions with conventional treatment.¹⁶

Patient/parent, practitioner, and public education campaigns are needed to inform all sectors, and CAM users in particular, about potential risks and adverse effects such as adverse herb-drug interactions.^{3,5,16}

Patients and parents need to become aware of potential risks, as well as benefits, of products and therapies they use regardless of whether they are CAM or conventional, and clinicians have an important role to play. Educating patients and their parents about the potential harm and benefits of all treatments, whether conventional or CAM, should be a priority for clinicians.^{1,3}

Parents, patients, and the public may have too much information rather than too little, particularly from Internet sources. Assessing credibility and reliability can be difficult. Open communication with and support from health care providers are important. In addition, tools are available to help explain how to evaluate the credibility of Internet sites and information about health, illnesses, and treatments.^{20–30} These tools can enhance patients', parents', and the public's ability to critically assess the vast array of resources available.

EXPANDING RESEARCH

Decision-making about CAM is particularly challenging, because evidence is often lacking or less adequate than desired. 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 and to improve the quality of care.²⁰ Widespread and growing use of CAM makes the need for research even more pressing.

Research, both interdisciplinary and discipline-specific, should examine:

- efficacy and safety of CAM therapies and products generally and when used to treat children and youth;
- interactions between CAM and conventional therapies and products;
- appropriate evidence bases for decision-making about CAM and conventional treatments in clinical practice;^{31–33}
- regulatory models appropriate for different types of CAM providers³⁴;
- why public health initiatives strongly supported by evidence and that pose minimal risk, such as routine childhood immunization, are accepted, rejected, or ignored by different groups among patients, parents, practitioners, and the public;
- effective communication strategies;
- how disparate types of practitioners with different approaches to healing can best cooperate in practice and policy development; and
- the role that no-fault compensation for patient injury could play in encouraging greater participation in public health programs such as routine childhood immunization.

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