Informed Consent: Advising Patients and Parents About Complementary and Alternative Medicine Therapies

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KEY WORDS
complementary therapies, evidence-based practice, acupuncture, nausea, neoplasms

ABBREVIATIONS
CINV—chemotherapy-induced nausea and vomiting
NIH—National Institutes of Health
CAM—complementary and alternative medicine

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abstract

Although research on complementary and alternative medicine (CAM) therapies is still limited, systematic reviews have revealed sufficient evidence to conclude that CAM can be effective for certain conditions. In this article we discuss clinicians' responsibilities to inform parents/patients about CAM alternatives and use the example of acupuncture for chemotherapy-induced nausea and vomiting. Chemotherapy-induced nausea and vomiting remain significant adverse effects of cancer therapy, and some patients cannot find relief with standard therapies. When making decisions for a child with a life-threatening illness, parents must consider all reasonable options and decide what is in the child's best interests. A physician's failure to provide parents with relevant information regarding therapies with the prospect of therapeutic benefit impedes their ability to make an informed decision. Physicians have the ethical duty of beneficence; they must be aware of current research in pain and symptom management and other aspects of care. A physician's duty of care does not necessarily include the obligation to provide information about therapies outside the range of conventional treatment or those not yet supported in the medical literature. However, as CAM therapies such as acupuncture become better studied and their safety and efficacy are established, the scope of disclosure required may expand to include them. The legal and ethical obligation to obtain informed consent to treatment requires disclosure and discussion of therapies when there is reliable evidence of potential therapeutic benefit. At the same time, the more limited state of knowledge regarding effects of a particular therapy in the pediatric population must be factored into decision-making when treating a child. *Pediatrics* 2011;128:S187–S192

The parents of 6-year-old Jake, a young boy with medulloblastoma, are distressed by the nausea and vomiting he is suffering as a result of chemotherapy. His chemotherapy-induced nausea and vomiting (CINV) occur spontaneously and are also being triggered by sights, sounds, and smells for up to 2 weeks after a course of chemotherapy. His parents believe that this is preventing him from eating properly and that the psychological toll of the adverse effects of treatment are limiting his ability to combat the cancer. They ask Jake's oncologist about other options to alleviate his nausea. He has tried dimenhydrinate and dexamethasone in addition to ondansetron, but like metoclopromide, they have not provided Jake with sufficient relief. Jake's oncologist recommended that he continue with nabilone, a synthetic cannabinoid; however, Jake refuses to continue this drug, because it makes him feel dizzy and anxious. Disappointed, his parents resign themselves to the possibility that Jake might not find relief from his CINV.

While communicating online with other families of patients with cancer, Jake's parents discover that a consensus panel through the US National Institutes of Health (NIH) has recognized the effectiveness of acupuncture for alleviating CINV.[1,2] *They ask their oncologist about it, but his response is noncommittal. Jake's parents take him out on intermittent passes from the hospital to an acupuncturist in the community. They are delighted to see that his nausea and vomiting are much improved after each acupuncture session. Jake begins to regain his appetite, gains weight, and generally has a better sense of well-being.*

Jake's parents are upset that their physician, whom they believe also had access to information outlining the potential benefits of acupuncture, did not tell them that it was potentially a safe and effective treatment option for CINV. When they describe their son's improvements after acupuncture, their physician dismisses them as a "placebo effect." Jake's parents are concerned that the physician instead offered antiemetic medications that, from their point of view, only created more problems and unnecessary adverse effects.

Although research continues to develop, there is now evidence that some complementary and alternative medicine (CAM) therapies can be effective in treating certain conditions.[1,3,4] CAM use is especially prevalent among people with certain types of illness: "chronic, recurrent and incurable conditions such as asthma, allergies, cancer, cystic fibrosis, HIV infection, inflammatory bowel disease and specific health needs."[5] Children with these conditions commonly use CAM therapies concurrently with conventional medical care.[6,7]

In our scenario, the parents learned through online social networks, not their son's physician, that a CAM therapy (acupuncture) might ease their son's suffering. What responsibilities does a clinician have to bring CAM alternatives to the attention of patients/parents? In this article we (1) explain clinicians' obligations when obtaining informed consent to treatment and (2) discuss clinicians' responsibility to tell parents/patients about a potentially beneficial CAM therapy.

ETHICS

One way of thinking about the ethical issues in this case is in terms of the nature of the relationships that exist between Jake as a child and patient and those who are caring for him and what responsibilities are owed by the physicians and parents to him as a child patient.[8]

Informed Choice

Because he is a young child, Jake has minimal control over the decisions that are made about his treatment. The primary responsibility for such decisions rests with his parents. As those closest to him, they have the best knowledge of him as a person and, therefore, how he will be affected by his illness and treatment; they also have the greatest interest in his well-being and achieving a good outcome.[9,10] Making decisions for a child with a life-threatening illness involves a huge burden of responsibility for parents. They must attempt to consider all reasonable options that are available and decide according to what they believe will be best for their child. To do this they must have all relevant information. The physician, as gatekeeper of this information, must ensure that the parents have the information they need and are able to understand it. Providing this information is part of the informed-consent obligation, which applies to pediatric as well as adult care.

When parents are informed about the whole plan of care, they should receive not just information about the primary treatment (in Jake's case, chemotherapy) but also about other conventional alternatives, including nontreatment, and what is likely to happen with each of them (ie, benefits and risks such as adverse effects and how they will be managed). Parents also need to know about reasonable CAM options. Physicians who are not convinced that CAM treatments are beneficial may be reluctant to discuss them with patients or their substitute decision-makers, which is reasonable when research data are unavailable or inconclusive. When there is reliable evidence from research indicating that symptoms may be relieved by a particular intervention, even if that intervention might be considered outside conventional

health care, physicians should inform patients and/or substitute decision-makers about it, especially when conventional therapies have been unsuccessful. When physicians are not capable of providing the treatment themselves, they can offer to arrange a referral.[11] In any event, the physician should disclose and discuss the relevant therapy. Otherwise, he is impeding Jake's parents from fulfilling their responsibility to make the best possible decisions for their son and doing whatever they can to relieve his suffering.

The Goals of Medicine

To better understand the responsibilities that physicians have to their patients, it is important to be mindful of the principal goals of medicine in relation to patients: to promote patients' good, as defined by the patients themselves or, in the case of young children, by their parents working collaboratively with physicians and other health care providers; to preserve life (in keeping with the principles of sanctity of life and beneficence); and to alleviate suffering (in keeping with the principle of nonmalfeasance, which requires us to prevent or refrain from causing harm).[12,13]

The treatments necessary for patients with life-threatening illnesses will often cause them suffering, so the diligent physician will pay special attention to pain and symptom management. He or she should be aware of current research in the area, be available to assist families with their research and decision-making, and be as creative and aggressive as possible (consistent with safety and efficacy) in the alleviation of suffering, especially for young children, who are less able to describe their symptoms and communicate their distress.[14,15]

LAW

Informed Consent

In the United States and Canada, clinicians have a legal duty to obtain informed consent for treatment from patients or, if they are incapable of deciding for themselves, from substitute decision-makers, usually their parents. Patients/parents must be given material information about the treatment proposed, its risks and benefits, and alternative courses of action (including nontreatment), that is, the information that a reasonable person in similar circumstances would want to help them decide.[16–18] Clinicians must also answer specific questions or requests for additional information. Special needs or particular concerns, such as managing adverse effects of treatment, can necessitate even broader disclosure.[19]

The duty to obtain informed consent for treatment is based on and reinforces patients' rights to autonomy and bodily integrity. It is recognized in common law and, in some jurisdictions, has been codified in legislation.[18,20–24] The standard for disclosure is high and has become increasingly demanding over time.[25] In Canada and some American states, the test is patient-centered (what the reasonable patient/parents would want to know to decide whether to consent). Some US states[26] and some other countries use a profession-centered standard of disclosure (what reasonable health professionals would consider appropriate to disclose).

The obligation to discuss alternative treatment choices in addition to those proposed by the treating physician is not unlimited. Although the boundaries of the obligation have not been well developed in case law, the alternative should offer at least the prospect of some therapeutic benefit; that is, it must be reasonable to consider it to be an alternative.[27–29] US Federation of State Medical Boards guidelines for using CAM require "a favorable risk/benefit ratio compared with other treatments for the same condition. . . based on a reasonable expectation that it will result in a favorable patient outcome. . . ."[30] The extent of disclosure is driven by the reason it is required: to equip patients/parents with the information needed to make an informed choice. However, even in the realm of conventional care, physicians may disagree about what treatments are appropriate. In that context, it has been suggested that when there is a genuine difference of opinion within the medical community and the treating physician does not support the alternative, there is still a duty to tell the patient about it and why the doctor considers it inappropriate.[25,28] Some cases have shown a narrower view, holding that the treating physician is only obligated to disclose options that in his or her reasonable medical judgment are appropriate for the patient.[31,32] This distinction may make little difference in practice because, as 1 court noted, when there is more than 1 medically reasonable treatment and the risk/benefit analysis engaged by the alternatives involves different considerations, then "a reasonable person would want to know about the alternatives and would want the assistance of the doctor's risk/benefit analysis of the various possible treatments. . . ."[33] The physician's assessment and recommendations can help place the treatment options in perspective and assist the patient/parents in making an informed decision.[34,35]

Discussing CAM Therapies

There is little American or Canadian law on whether the duty to inform patients/parents about alternatives extends to CAM.[20] Existing case law focuses on the scope of the duty to

review conventional treatment options, not CAM. However, indications are that any requirement to alert a patient to alternative therapies not accepted by conventional biomedicine would be sharply limited.[5,20,28,29,36–38,*]

Neither Canadian nor US legal scholars have reported locating a case in which conventional health care providers were found liable for not advising a patient of an unconventional or alternative form of treatment.[5,36,39] However, disclosure obligations evolve over time. As the evidence for a particular therapy (whether conventional or CAM) grows and it becomes more accepted in the medical literature, clinicians' duty to disclose information about them can be expected to expand accordingly as well. When advising patients about alternative treatments, clinicians should comply with applicable professional and institutional policies.[40]

CLINICAL RESPONSE

Childhood cancer survival rates have climbed steadily over the past decade.[41] Nonetheless, CINV still remain significant and debilitating adverse effects. The current standard of prevention and treatment of CINV—the use of serotonin[3] antagonists with or without corticosteroids and adjunctive antiemetic medications—has provided many patients with a substantial degree of control over their symptoms.[41] However, there still remains a minority of patients who do not find relief from standard therapies and for whom other methods of treatments should be considered. In addition, many patients object to taking what they consider excessive or debilitating medication.

More than a decade ago, an NIH consensus conference on acupuncture concluded that there was clear evidence supporting the efficacy of needle acupuncture in treating adult CINV.[1] Although the mechanisms of action are not yet fully understood, the NIH considered there to be considerable evidence that stimulation of acupuncture points is associated with the release of opioid peptides, changes in immune function, and systemic effects from the activation of the pituitary and hypothalamus.[1] A meta-analysis published in 2006 of 11 randomized controlled trials for acupuncture-point stimulation to reduce CINV has corroborated the NIH findings.[42] The authors concluded that acupuncture-point stimulation is safe and that all methods except noninvasive electrostimulation are effective adjunct therapies for reducing acute vomiting and possibly effective for reducing the severity of acute nausea.[42] In addition, of 4 recent randomized controlled trials not included in this meta-analysis, the results of 3 of them favored acupuncture-point stimulation,[43,44] and 1 of them found it ineffective.[45]

The adverse events reported in randomized controlled trials of acupuncture have been mild and short-lived,[42] and the occurrence of adverse events from properly performed acupuncture is considered rare[46–49]; the risk of a "serious side effects from acupuncture therapy when performed by a licensed acupuncturist are 1:10 000 to 1:100 000—about the same risk as a serious adverse event from taking penicillin."[50] Weiger et al[51] have suggested that patients who seek acupuncture for CINV be advised that the option is acceptable and that doctors consider recommending acupuncture as an option from the outset. It is significant, however, that although acupuncture on children has been shown to be feasible and acceptable,[50,52–54] and children have shown little discomfort or fear, only 5 recent studies on the effectiveness of acupuncture-point stimulation for CINV have included pediatric subjects.[45,55–57]

Cohen[58] has suggested that, to provide the best possible care, the physician balance 7 important factors when deciding whether to recommend a CAM treatment: (1) severity and acuteness of the illness; (2) curability with conventional treatment; (3) invasiveness, toxicities, and adverse effects of conventional treatment; (4) quality and evidence of safety and efficacy of the CAM treatment; (5) degree of understanding of the risks and benefits of conventional and CAM treatments; (6) knowledge and voluntary acceptance of those risks by the patient; and (7) persistence of the patient's intention to use CAM.

Applying the decision-making framework described in the introduction to this supplemental issue of *Pediatrics*,[59] there is evidence that acupuncture for CINV is both safe and effective, at least for adults. Conventional treatment with antiemetic medications has failed for Jake. In these circumstances, the physician could discuss the options and recommend acupuncture or, mindful of the lack of research specific to children, inform the parents about this alternative and the state of knowledge regarding children and consider a trial of this CAM therapy as an option. In any event, monitoring of the patient's CINV should continue.

RECOMMENDATIONS

Advising About CAM Therapies: Disclosure Standards

Medical knowledge is continually evolving, as is the scope of physicians' duty of disclosure. As the results of re-

*See *Moore v Baker* ([1991], US Dist LEXIS 14712 [SD Ga, 1991]) (a physician is not obliged to disclose the possibility of chelation therapy as an alternative to carotid endarterectomy to treat coronary blockage because it is not generally recognized and accepted in the medical community), and *Plumber v State Department of Health* ([1994], 634 So 2d 1347, 1352 [La Ct App]) (disclosure of alternatives to chemotherapy for cancer treatment were not required under the circumstances; the alternative recognized by conventional medicine is to not undergo chemotherapy).

search concerning different forms of CAM become more widely known and are reported in the medical literature, physicians' duty of disclosure could well expand to include informing patients and parents about potentially beneficial CAM options, especially if they involve less risk or fewer adverse effects than conventional therapy. Whether a CAM therapy has attained sufficient medical acceptance for a given condition to trigger an obligation to disclose as part of the informed-consent process would depend on prevailing medical evidence about safety and efficacy. In the example of acupuncture to treat chemotherapy-related nausea, current evidence (including support by the NIH consensus panel) is likely sufficient to make its disclosure material to patients'/parents' decision about treating the nausea. Consequently, parents should be informed of this option.

Pain and Symptom Management

Physicians should be aware of relevant current research in this area, whether it involves a conventional or CAM therapy, be available to assist families with their research and decision-making regarding all potentially beneficial therapies, and be as creative and aggressive as possible (consistent with safety and efficacy) in the alleviation of suffering, especially for young children, who are less able to describe their symptoms and communicate their distress.[10,12]

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