

Considering Complementary and Alternative Medicine Alternatives in Cases of Life-Threatening Illness: Applying the Best-Interests Test

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KEY WORDS

complementary therapies, jurisprudence, critical illness, pediatric, decision-making

ABBREVIATIONS

GSD IV—glycogen storage disease type IV

TCM—traditional Chinese medicine

CAM—complementary and alternative medicine

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abstract

In this article we explore decision-making about treatment when a child faces a life-threatening illness but conventional treatment presents substantial risk and uncertain benefit. When is it acceptable for parents to decide to use complementary and alternative medicine as an alternative, rather than a complement, to conventional care? We use the example of a young child suffering from progressive glycogen storage disease, for whom liver transplant offers the only prospect of a cure. Without a liver transplant, the disease usually results in death within a few years. However, experience using transplant to treat this illness has been limited, success is far from ensured, and the risks (including death and continued progression of the disease) are substantial. The child's parents, who are first-generation immigrants, consider the risks of the transplant unjustified because it still does not offer good prospects for a healthy future. They believe that traditional Chinese medicine could help remediate their daughter's disease. In the article we (1) review parents' obligation to make treatment decisions in the best interests of their child, (2) explain limits on parents' decision-making authority, (3) explore how "best interests" are determined, focusing on cases of serious illness for which conventional treatment is risky and benefit is possible but uncertain, (4) explain the standard of care that physicians must meet in advising about treatment, and (5) outline factors that clinicians and parents should take into account when making decisions. *Pediatrics* 2011;128:S175–S180

Angela is a 3-year-old Asian child who was diagnosed at 15 months of age with glycogen storage disease type IV (GSD IV), a rare genetic metabolic disorder. Since her diagnosis, her parents have watched her health slowly deteriorate. Angela's gastrointestinal specialist tells her parents that although her condition is not imminently life-threatening, without intervention the condition usually results in death before 5 years of age. Given her disease progression, only a liver transplant offers any prospect for a cure. However, success is far from ensured, and the risks are substantial. Her specialist suggests that Angela be placed on the transplant waiting list.

Three weeks later, Angela's parents return to the primary care physician and state that they do not want her on the transplant waiting list. They oppose the invasive nature of a treatment that poses so many risks and yet still does not seem to offer good prospects for a healthy future. Instead, they have spoken with a traditional Chinese medicine (TCM) practitioner, who recommended specific dietary treatment, mind-body imagery, and acupuncture. Angela's parents are first-generation immigrants from China and strongly believe that TCM could help remediate her disease. Respecting their sincere concern, the physician explores the use of TCM for GSD but cannot find any published literature on TCM and GSD. However, the physician also realizes that experience with liver transplantation for treating GSD IV has been limited and begins to consider whether the risks and burdens of the procedure and posttransplant outcome are worthwhile, given the success rate. The physician is uncertain what to advise, but Angela's parents would appreciate her input.

Because conventional treatment presents substantial risks and only uncertain benefits, Angela's parents pro-

pose using TCM as an alternative, rather than a complement, to conventional care. As with many first-generation immigrants, they may well consider TCM or other types of complementary and alternative medicine (CAM) to be "mainstream" and allopathic medicine to be "alternative" or "complementary." In this article we (1) review parents' obligation to make treatment decisions in the best interests of their child, (2) explain limits on parental decision-making authority when illness poses serious risks to a child's life or health, (3) explore how "best interests" are determined, focusing on cases of serious illness for which conventional treatment is risky and benefit is possible but uncertain, and (4) outline factors that clinicians and parents should take into account when assessing alternatives.

ETHICS

Parents

Parents have an ethical duty to make decisions for their children. A primary consideration is to do what is possible to preserve the child's life, consistent with the principle of sanctity of life. This is not the only consideration, however. Parents should think broadly about what they believe to be in their child's best interests while considering also the potential harms and benefits of treatment options, consistent with duties of beneficence and non-maleficence. Included in this harm/benefit assessment should be consideration of how best to minimize the child's suffering and maximize quality of life. Parents should assess these factors according to their beliefs and values, what they know about their child, and in light of their goals and expectations of what a good life would be like for their child. These factors may be shaped by their cultural and religious backgrounds, their personal

experience, and their own ethical framework.

Physicians

Parents are accorded considerable latitude in making health care decisions for their children, especially in circumstances of medical uncertainty. Physicians may experience a tension between their obligation to respect this parental role (ie, the parents' moral and legal authority to make decisions for their children) and their own obligation to advocate for and protect their patients. In some situations, a physician together with other members of the health care team may feel strongly that there is only 1 ethically justifiable course of action, given the child's condition and what is predictable regarding the treatment's effectiveness and the consequences of not having treatment. Should that be the case, the physician should provide parents with as much information as is available about treatment options, make a medical recommendation, and offer assistance with making decisions. The physician should explore the parents' rationale and explain why he or she believes the particular treatment is necessary. Whenever possible, information should be provided in the parents' language of choice, and interpreters should be available to assist with communication to ensure understanding. If parents continue to resist despite serious risk to the child's life or health and the physician concludes that the reasons that support treatment outweigh the parents' rationale, he or she is likely obliged to consult with child welfare authorities.

In this scenario, however, the primary care physician is uncertain that liver transplant is the only justifiable course of action. Consultation with professional colleagues and/or specialists about the advisability of transplant can help the physician ensure

that she adheres to the standard of practice when advising Angela's parents. Consultation with a bioethicist or ethics committee, if available, may also help everyone concerned and may allow Angela's physician to share the burden of moral distress associated with this challenging situation.

LAW

Best Interests and Parental Obligations

Parents and guardians have a legal duty to ensure that minor children are provided with needed health care. Their decisions to consent to or refuse treatment should be made in the child's best interests.¹⁻⁵ In some jurisdictions, health care consent legislation specifies factors to consider, including relative burdens and benefits of treatment and alternatives, whether treatment would improve the person's condition or slow deterioration, congruence with the patient's values and beliefs, and whether less intrusive treatment would be as beneficial.⁶ Even without specific legislation, courts undertake a similar assessment when determining best interests.^{5,7-9} People may disagree about how to weigh these factors. Apart from religious and cultural considerations, when the benefits of treatment are far from certain and the associated risks and burdens are significant, views about a child's best interests may differ radically.¹⁰

Constraints on Parents' Decision-Making Authority

Although the law allows parents considerable discretion in deciding about their children's health care, they are subject to significant limits. If a child is deemed in need of protection in child-protection proceedings (which can be triggered when parents fail to obtain or permit needed medical care), the state can intervene to authorize medi-

cal treatment to protect his or her life, health, or well-being.^{1-5,7,11} Parents' religious beliefs and cultural values alone cannot justify treatment decisions that seriously endanger a child's life or health. There must be reasonable therapeutic justification for subjecting children to medical procedures that have potentially damaging effects.^{5,9,12,13} Parents' authority to refuse needed treatment is also restricted.¹¹ *In Re B(R.) v Children's Aid Society of Metropolitan Toronto*, a case in which child welfare authorities were authorized to consent to blood transfusions needed to prevent serious risk to a child's health, the Supreme Court of Canada summarized limits on parental decision-making authority: their decisions must not "exceed the threshold dictated by public policy, in its broad conception."^{1,*} Although it is not a precise test, it emphasizes the primacy of parents' responsibility to protect and nurture their children.

Intervention Principles

When illness seriously threatens a child's health and the parents will not consent to available effective treatment, the child's health care providers must notify child welfare authorities.^{5,11,14,15} Legislation in all American and Canadian jurisdictions authorizes measures to ensure that needed medical care is provided to a child found in need of protection.^{11,14-17}

When risks of foregoing treatment are less serious or less immediate, parental refusal of treatment is more likely to be allowed to stand by health care providers, child-protection authorities, and courts.^{11,18-22}

*See *In Re Nikolas E* ([1998], WL 80328 [MD Sup J Ct]), a case in which a mother was permitted to reject recommended antiretroviral therapy for her 4-year-old HIV-positive son when other medical evidence confirmed lack of information on use in children and long-term effects.

Applying the Best-Interests Test

How do courts determine best interests? First, the "best interests" must be the child's, not other people's.⁹ Second, decided cases emphasize expert evidence about medical practice and assessment of benefits and burdens of treatment and alternatives, including nontreatment.^{1,13,20} Third, courts recognize the importance of other dimensions in decision-making beyond clinical factors and take psychological, social, and emotional considerations into account when appropriate.²⁰⁻²²

When the threat to a child's life or health is serious and imminent and there is a reasonable prospect that treatment can help, courts will authorize child welfare authorities to consent to treatment when the parents will not.^{1,7,11,23,24} For instance, a Quebec court temporarily transferred custody to a child welfare authority to make treatment decisions for 2 HIV-positive children whose mother refused medically recommended antiretroviral therapy and treated them with natural remedies.^{25,*} In another case, a Saskatchewan court concluded that it was in the best interests of a 13-year-old boy with bone cancer who lacked the capacity to decide about treatment to undergo medically recommended chemotherapy and amputation of the affected leg despite objections by the boy and his parents, who wanted to rely on alternative therapies and prayer (ultimately, the cancer was too advanced to proceed).²⁶ In the United States, child welfare authorities were awarded custody of a child when his parents, who preferred dietary supplements and prayer, refused renewed chemotherapy for his leukemia.¹² In *Renfro v Renfro*,¹³ the court noted that when unconventional treatment (various CAM modalities) hindered generally accepted medical treatment for a child's malignant brain tumor, alternative treatment was not in the child's

best interests. These decisions and others like them make courts' strong orientation toward preserving children's life and health clear.

However, other courts have upheld parents' refusal of aggressive treatment for a child with life-threatening illness, generally when the burdens of treatment are great and chances of benefit are low^{7,20,22} or when the parents' decision was supported by medical experts.¹⁵ In Saskatchewan, parents' refusal of a potentially life-saving liver transplant for their infant son was sustained.^{20,27} Expert medical testimony was divided, but a majority of the experts viewed the parents' decision as reasonable. The court concluded that the parents' decision was within the bounds of current medical practice and in keeping with the values society expects from thoughtful, caring parents of a terminally ill child.

Advances in transplant technology and posttransplant care can alter medical and judicial assessments. In our scenario, the nature of Angela's illness introduces another consideration: a transplant may not stop progression of the disease,^{28–31} which in turn affects the assessment of risk and benefit.

Because the jurisprudence is limited, the range of factual circumstances and their interplay with medical and other considerations are so varied, and the associated calculus of risks and benefits is often contentious, it can be difficult to predict when courts will intervene beyond the guidance offered by these general principles and examples. In cases of disagreement that cannot be resolved, an assessment of best interests by specialized tribunals (when available) and, ultimately, courts prevails, even when there may reasonably be scope for differing views.^{5,7,32} Judges are the final arbiters of whether a parent's decisions justify intervention.

CLINICAL RESPONSE

When making clinical decisions, physicians rely on the available evidence base to develop and assess a management plan. If the patient has a rare disorder about which there has been limited research, the task becomes much more difficult. The situation is complicated further when a patient/parents also want to consider an alternative option and a truly challenging scenario emerges. Consultation with colleagues can clarify the standard of practice when treating patients with this condition, but the question still remains: what is the best course of action given limited data about the conventional medicine option and non-existent data about the CAM option?

The classical form of GSD IV presents as hepatosplenomegaly and failure to thrive in the first year of life and is characterized by progressive liver cirrhosis with portal hypertension, ascites, and esophageal varices. Transplantation is only indicated for GSD IV when there is clear evidence of progression, as in our scenario.^{28,29,31} At that point, the disease is considered curable only by means of liver transplant. Without a transplant, the condition usually results in death from liver failure before 5 years of age.³³

The largest review of this treatment modality was based on only 17 cases. Death was reported for 5 of 17 patients (3 from sepsis, 1 from hepatic artery thrombosis, 1 from cardiomyopathy). Of the 12 survivors, 1 patient was reported to have mild hypotonia and arthrogyrosis, and another was reported to have portal vein thrombosis. Two of the patients required a second liver transplant.²⁹

The situation is complicated further by conflicting evidence about disease progression after transplantation. Although some researchers have suggested that the disease may progress in other organs even after transplant,

necessitating multiorgan transplantation,^{34,35} others have found reabsorption of extrahepatic deposits of amylopectin after transplant.³⁰

If, after assessing all the evidence, the physician concludes that the best decision for Angela is transplantation, she should ensure that the parents understand her recommendation and the risks and benefits of the various alternatives and have access to a second opinion. She should try to dissuade them from relying solely on TCM. Depending on the urgency of Angela's situation (ie, whether a transplant can be delayed safely), a reasonable approach may be a compromise: seek the parents' permission to place Angela on the transplant waiting list while allowing a trial of TCM in the interim. The parents should be encouraged to bring Angela for regular visits so that her condition can be monitored. Treatment plans can be revisited should the urgency of Angela's condition change. The primary care physician may also assist the family by mediating discussions with the gastrointestinal specialist. Consultation with a bioethicist or ethics committee, if available, may be helpful.

If the physician concludes that a transplant is the only reasonable choice and the parents continue to reject conventional treatment, child welfare authorities will have to be involved, and if necessary, resolution will have to be sought from a court or specialized tribunal.^{7,11,14–17}

In our scenario, however, the primary care physician is uncertain that liver transplant is the only justifiable course of action. It is the only option conventional medicine offers, but it is risky and burdensome. Angela may suffer severe or fatal complications from the transplant, and although reported only rarely, her disease may continue to progress even if this highly invasive procedure is performed. An-

gela's parents are not neglecting their child's medical needs, and their assessment of the potential harms and benefits of liver transplant and the uncertainties involved is realistic; however, their expectations of TCM do not seem to be as realistic.

TCM is based on an entirely different paradigm of health and healing than conventional Western medicine.³⁶ Some US states license practitioners of various TCM treatment modalities,³⁷ whereas in Canada it is formally recognized in 2 provinces: British Columbia and (when transitional arrangements are complete) Ontario.^{38,39} Although the numbers of systematic reviews of TCM have been increasing, there are no specific data for Angela's condition to help guide her physician.

The physician wishes to continue to play an active part in Angela's care and, therefore, should avoid alienating her parents by disparaging their wish to pursue TCM, which seems to be consistent with their cultural background and deeply held beliefs.^{40,41} Nonetheless, she must comply with the professional standard of care expected of her. She owes Angela's family a duty of candor in advising them about treatment and should tell the parents what she has learned about the lack of evidence supporting the use of TCM for this condition, the evidence regarding transplantation, and their daughter's expected life span without it. When conventional treatment offers poor prospects with great risks and burdens, such that its advisability is contestable, clinicians can justifiably accord greater consideration to parents' unconventional choices and belief systems. If the physician concludes after assessing all factors and appropriate consultation that both decisions (transplant and no transplant) are justifiable, then the final

decision is the parents' to make with the physician's advice and support. A treatment plan should be developed in accordance with their decision.

RECOMMENDATIONS

Clinicians

Overall, clinicians should aim to facilitate and enhance parents' decision-making capacity by providing the best information available about their child's condition, prognosis, recommended treatment, and alternatives and support them in discharging their responsibilities. When advising about CAM alternatives, clinicians should consider:

- whether parents propose abandoning effective conventional care and/or monitoring¹¹;
- whether providing the CAM therapy will delay imminently necessary conventional treatment¹¹;
- medical evidence about safety (risks of conventional and CAM therapies, such as invasiveness, toxicities, adverse effects, complications) and efficacy (prospects for successful treatment associated with conventional care and, if known, with CAM therapy)⁴²;
- the extent of medical support for a conventional or CAM treatment regimen (consultation with colleagues and specialists can clarify the standard of care);
- the need for bioethics consultation, which can provide important support to decision-makers; and
- compliance with applicable legislation^{15,39,43} or policies about CAM use (eg, professional governing bodies^{44–46} or health facilities⁴⁷).

Parents

- Parents of gravely ill children facing risky conventional treatment with limited or uncertain prospects

of benefit must make tremendously difficult decisions about their child's best interests. They bear a heavy responsibility, and clinicians should be attentive to how best to maintain supportive relationships with parents and patients. Health facilities and clinicians should facilitate families' access to supports and resources (clinical, bioethical, and spiritual) to aid and comfort them in the decision-making process.

- Parents must comply with legal requirements that govern substitute decision-makers and should familiarize themselves with these obligations, consulting as needed. They may also be constrained by hospital policy.
- Even when using a CAM alternative, parents should ensure continued conventional monitoring and treatment, as appropriate.

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