



# Informed Consent in Decision-Making in Pediatric Practice

COMMITTEE ON BIOETHICS

Informed consent should be seen as an essential part of health care practice; parental permission and childhood assent is an active process that engages patients, both adults and children, in health care. Pediatric practice is unique in that developmental maturation allows, over time, for increasing inclusion of the child's and adolescent's opinion in medical decision-making in clinical practice and research.

## abstract

## INTRODUCTION

Since the publication of previous American Academy of Pediatrics (AAP) statements on informed consent in 1976<sup>1</sup> and 1995,<sup>2</sup> obtaining informed permission from parents or legal guardians before medical interventions on pediatric patients has become standard within our medical and legal culture. The 1995 statement also championed, as pediatrician William Bartholome stated, “the experience, perspective and power of children” in the collaboration between pediatricians, their patients, and parents and remains an essential guide for modern ethical pediatric practice.<sup>2</sup> As recommended in the 1995 publication, this revised statement affirms that patients should participate in decision-making commensurate with their development; they should provide assent to care whenever reasonable. Pediatric decision-making continues to evolve in response to changes in information technology, scientific discoveries, and legal rulings. Continuing limits on the widespread use of pediatric assent/refusal makes this review and restatement of AAP policy important.<sup>3</sup>

This policy statement provides a brief review of informed consent, including the ethical and legal roots, frameworks for surrogate decision-making, and information on special issues in informed consent in pediatric care. Recommendations on informed consent or refusal, parental permission, and assent in clinical practice and research are summarized at the end of this statement. A more detailed review of pediatric consent and decision-making can be found in the accompanying technical report to this policy statement.<sup>4</sup>

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## PURPOSE OF INFORMED CONSENT

The current concept of informed consent in medical practice has roots within both ethical theory and law. The support for informed consent in ethical theory is most commonly found in the concept of autonomy. The legal concept of informed consent has its roots in case law addressing issues of battery and medical malpractice. The law has evolved to require a full disclosure to the patient of the facts necessary to form the basis of a reasonable, informed consent. Informed consent incorporates 3 duties: disclosure of information to patients and their surrogates, assessment of patient and surrogate understanding of the information and their capacity for medical decision-making, and obtaining informed consent before treatments and interventions.

This background helps us understand the conceptual difficulties encountered in trying to apply the framework of informed consent in the pediatric setting, in which most patients either lack the ability to act independently or have limited or no capacity for medical decision-making. Nevertheless, the goals of the informed consent process (protecting and promoting health-related interests and incorporating the patient and/or the family in health care decision-making) are the same in the pediatric and adult population and are grounded by the same ethical principles of beneficence, justice, and respect for autonomy.

## FRAMEWORK FOR INFORMED CONSENT/PERMISSION/ASSENT

Knowledge about a medical condition is critical to making informed health care decisions. Informed consent regarding medical care must consistently incorporate several key components (see Table 1).

Pediatricians should be adept at using developmentally appropriate

**TABLE 1** Elements of Informed Consent for Medical Decision-Making

- 
- Provision of information about the following:
    - nature of the illness or condition
    - proposed diagnostic steps and/or treatments and the probability of their success
    - the potential risks, benefits, and uncertainties of the proposed treatment and alternative treatments, including the option of no treatment other than comfort measures
  - Assessment of patient and surrogate understanding and medical decision-making capacity, including assurance of time for questions by patient and surrogate
  - Ensure that there is voluntary agreement with the plan
- 

**TABLE 2** Practical Aspects of Assent by Pediatric Patients for Medical Decision-Making

- 
- Help the patient achieve a developmentally appropriate awareness of the nature of his or her condition
  - Tell the patient what he or she can expect with tests and treatments
  - Make a clinical assessment of the patient's understanding of the situation and the factors influencing how he or she is responding (including whether there is inappropriate pressure to accept testing or therapy)
  - Solicit an expression of the patient's willingness to accept the proposed care
- 

language during discussions with minors, and information must be provided in a manner that respects the cognitive abilities of the child or adolescent. Clinicians should use these opportunities to elicit information regarding their pediatric patient's value-based treatment goals and to assess whether there is adequate capacity for understanding and decision-making. Only patients who have appropriate decisional capacity and who meet legal requirements can give their informed consent to medical care. Parents or other surrogates technically provide "informed permission" for diagnosis and treatment, with the assent of the child whenever appropriate.<sup>2</sup> When defined as agreement with proposed interventions, assent from children even as young as 7 years can foster the moral growth and development of autonomy in young patients.<sup>2,5-7</sup> This consideration is based on an understanding that, starting around 7 years of age, children enter the concrete operations stage of development, allowing for limited logical thought processes and the ability to develop a reasoned decision.<sup>8-11</sup>

A stricter interpretation of assent requires that the minor meet all of the elements of an adult informed consent, a requirement

that challenges obtaining assent at younger ages. Alternatively, a developmental approach to assent anticipates different levels of understanding from children as they age.<sup>6</sup> At a minimum, assent should include the elements listed in Table 2. Note that one should not solicit a child's assent if the treatment or intervention is required to satisfy goals of care agreed on by the physician and parent or surrogate, but the patient should be told that fact and should not be deceived. Providing disclosure of appropriate diagnostic and treatment information and allowing choices about aspects of care, when possible, should be a consistent part of the care plan for children.

Completely voluntary choice in treatments may be illusory in general, but is particularly so in pediatric care. Clinicians should be aware that parental decision-making can be influenced by the quality of the clinician-patient relationship, previous medical knowledge, emotional distress, faith, and critical changes in a child's health status.<sup>12</sup> Decision-making by children and adolescents is usually influenced by their parents' point of view and may not be entirely voluntary or autonomous. Unless there is significant coercion perceived

**TABLE 3** Standards for Surrogate Decision-Making in Pediatrics

Best-interest standard	Surrogate should aim to maximize benefits and minimize harms to the patient, while using a holistic view of the patient's interests
Harm principle	Identify a harm threshold below which parental decisions will not be tolerated
Constrained parental autonomy	Parents may balance the best interest of the patient with the family's best interest if the patient's basic needs are met
Shared, family-centered decision-making	Process that builds on collaborative mechanism between families and clinicians

by clinicians, this situation is not unacceptable, because medical decision-making cannot, and should not, occur in a vacuum, isolated from all other concerns. Medical decision-making is not a discrete event but evolves over time among the health care team, family, and pediatric patient as new information becomes available.

### FRAMEWORK FOR DECISION-MAKING

Although commonly used in adult practice, substituted judgment is an uncommon standard for decision-making in the pediatric setting. An exception occurs when mature adolescents, usually those with chronic diseases, have expressed wishes about goals of care before deterioration of cognitive function. These wishes may be respected by parents and physicians in a manner similar to surrogate decision-making for adults. The opportunity to provide guidance about their future medical care should be discussed during their ongoing health care in a manner consistent with their cognitive development and maturity.

Parents generally are better situated than others to understand the unique needs of their children and to make appropriate, caring decisions regarding their children's health care. This is not an absolute legal right, however, because the state also has a societal interest in protecting the child from harm (the doctrine of *parens patriae*) and can challenge parental authority in situations in which a minor is put at significant risk of serious harm or neglect. Parental decision-making should primarily be understood as

parents' responsibility to support the interests of their child and to preserve family relationships, rather than being focused on their rights to express their own autonomous choices. By moving the conversation from parental rights toward parental responsibility, clinicians may help families minimize conflicts encountered in the course of more serious and difficult medical decision-making.

Medical decision-making in pediatrics is informed by the cultural, social, and religious diversity of physicians, patients, and families. The AAP recommends that infants, children, and adolescents, regardless of parental religious beliefs, receive effective medical treatment when such treatment is likely to prevent substantial harm, serious disability, or death.<sup>13</sup> Clinicians must balance the need to work collaboratively with all parents/families, respecting their cultures, religions, and the importance of the families' autonomy and intimacy with the need to protect children from serious and imminent harm. For some mature adolescents, it must be recognized that they may either endorse or reject the tenets of their parent's faith over time.

Several standards for pediatric decision-making have emerged in the literature (see Table 3). Historically, medical decision-making in minors has centered on the best-interest standard, which directs the surrogate to maximize benefits and minimize harms to the minor.<sup>14</sup> A broader approach for using the best-interest standard is to acknowledge the pediatric patient's emotional, social, and medical concerns along with the

interests of the child's family in the process of medical decision-making. The harm principle may be seen as a more realistic standard to apply in pediatric surrogate medical decision-making. The intent of the harm principle is not to identify a single course of action that is in the minor's best interest or is the physician's preferred approach, but to identify a harm threshold below which parental decisions will not be tolerated and outside intervention is indicated to protect the child.<sup>15</sup>

The model of constrained parental autonomy<sup>16</sup> allows parents, as surrogate decision-makers, to balance the "best interest" of the minor patient with his or her understanding of the family's best interests as long as the child's basic needs, medical and otherwise, are met. A parent's authority is not absolute but constrained by respect for the child.

Shared, family-centered decision-making, although not a standard, is an increasingly used process for pediatric medical decision-making and builds on collaborative communication between families and clinicians.<sup>17</sup>

### THE CHILD/ADOLESCENT AS MEDICAL DECISION-MAKER

Pediatric practice is unique in that developmental maturation of the child allows for increasing longitudinal inclusion of the child's opinion in the decision-making process. Encouraging pediatric patients to actively explore options and to take on a greater role in their health care may promote empowerment and compliance with

a treatment plan. With this in mind, informed consent/assent should be recognized as an essential part of health care practice.

Adolescent decision-making is dependent on several factors, including cognitive ability, maturity of judgment, and moral authority, which may not all proceed to maturation along the same timeline. Many minors reach the formal operational stage of cognitive development that allows abstract thinking and the ability to handle complex tasks by midadolescence.<sup>18,19</sup> Brain remodeling with enhanced connectivity generally proceeds through the third decade of life, with the prefrontal cortex, the site of executive functions and impulse control, among the last to mature. In contrast, the risk-taking and sensation-seeking areas (limbic and paralimbic regions) develop around puberty. This temporal imbalance or “gap” between the 2 systems can lead to the risky behavior seen in adolescence.<sup>20</sup> A detailed discussion of the neurologic maturation of the adolescent brain is beyond the scope of this policy statement, and the reader is referred to the accompanying technical report.<sup>4</sup>

The implications for decision-making by adolescents in stressful health care environments are that they may rely more on their mature limbic system (socioemotional) rather than on the impulse-controlling, less-developed prefrontal cognitive system.<sup>21</sup>

Dissent by the pediatric patient should carry considerable weight when the proposed intervention is not essential and/or can be deferred without substantial risk.

If the likely benefits of treatment in conditions with a good prognosis outweigh the burdens, parents should choose a treatment plan over the objections or dissent of the minor, as in choosing an

appendectomy for acute appendicitis. In general, adolescents should not be allowed to refuse life-saving treatment even when parents agree with the child.<sup>22–24</sup> In medical scenarios with a poor prognosis and burdensome or unproven interventions, more consideration should be given by the physician to advocating for the cognitively mature teenager who wants to refuse treatment and uphold an adolescent’s assent or refusal for further attempts at curative treatments.<sup>25</sup>

Although there is still no bright line demarcating when a minor becomes “mature” enough to independently satisfy the decision-making criteria for informed consent or refusal, the courts have weighed in on this issue with a variety of outcomes, which are detailed in the accompanying technical report.<sup>4</sup>

When conflicts about goals of treatment persist despite guidance by the physician and a collaborative approach with the patient and family, the primary health care team should enlist the involvement of consultants, including ethics consultation, psychologists, psychiatrists, chaplains, and, when appropriate, an integrated palliative care team. Seeking legal intervention should be a last resort.

### **EXCEPTIONS TO LIMITATIONS ON ADOLESCENT MEDICAL DECISION-MAKING**

There are 3 broad categories of when a minor can legally make decisions regarding his or her own health care: exceptions based on specific diagnostic/care categories, the “mature minor” exception, and legal emancipation. The legal ability of adolescents to consent for health care needs related to sexual activity, including treatment of sexually transmitted infections, contraceptive services, and prenatal care, is recognized in all states. There has been a similar expansion regarding

adolescents’ access to mental health and substance abuse prevention and treatment services. These changes reflect a public health concern that adolescents will not access these services if parental consent is required. However, state statutes that permit adolescents to consent to these services do not always protect their confidentiality. Practitioners should become familiar with their state statutes on these issues and consider promoting changes in legislation to improve adolescent confidentiality protection where appropriate.<sup>26</sup>

The mature-minor doctrine recognizes that there is a subset of adolescents who have adequate maturity and intelligence to understand and appreciate an intervention’s benefits, risks, likelihood of success, and alternatives and can reason and choose voluntarily. Most states have mature-minor statutes in which the minor’s age, overall maturity, cognitive abilities, and social situation as well as the gravity of the medical situation are considered in a judicial determination, finding that an otherwise legally incompetent minor is sufficiently mature to make a legally binding decision and provide his or her own consent for medical care.

In distinction, emancipated minor statutes do not address decision-making ability, but rather, the legal and social status of the minor. Adolescents living separately from their parents and self-supporting, married, or on active duty with the armed forces are generally considered legally emancipated and able to provide informed consent or refusal for their own medical care.

In all states, adolescent parents, similar to other parents, are presumed to be the appropriate decision-makers for their children and may give informed consent for

their child's medical care. This right reflects the adolescent's status as a parent. There is clearly a concerning paradox encountered when adolescents are allowed to make complex medical decisions for their child but cannot legally direct their own medical care.<sup>27</sup>

### **EMERGENCY EXCEPTIONS TO INFORMED CONSENT**

Children may present with emergency medical conditions without a parent or legal guardian available to provide consent.<sup>28</sup> In addition to common and statutory law generally supporting the provision of emergently needed care, the Emergency Medical Treatment and Active Labor Act mandates that a medical screening examination and delivery of appropriate medical care for the pediatric patient with an urgent or emergent condition should never be withheld or delayed because of problems with obtaining consent in these situations in which a parent or guardian is not available.

### **INFORMED CONSENT/ASSENT/REFUSAL IN RESEARCH INVOLVING CHILDREN AND ADOLESCENTS**

In distinction from clinical practice, there are clear federal mandates in research to obtain assent from the child research subject and informed permission from a subject's parent(s). A minor's dissent from study participation is also respected. Although assent is mandated, guidelines for how to obtain assent for research and at what age are not explicit. Similar to concerns raised regarding adolescent refusal of life-saving therapy in the clinical arena, the institutional review board can provide a waiver from requiring assent if the research has the potential for an important direct benefit that is only available in the context of research.<sup>29</sup>

### **RECOMMENDATIONS**

1. Physicians should involve pediatric patients in their health care decision-making by providing information on their illness and options for diagnosis and treatment in a developmentally appropriate manner and seeking assent to medical care whenever appropriate.
2. Parents should generally be recognized as the appropriate ethical and legal surrogate medical decision-makers for their children and adolescents. This recognition affirms parents' intimate understanding of their children's interests and respects the importance of family autonomy.
3. Surrogate decision-making by parents or guardians for pediatric patients should seek to maximize benefits for the child by balancing health care needs with social and emotional needs within the context of overall family goals, religious and cultural beliefs, and values.
4. Physicians should recognize that some pediatric patients, especially older adolescents and those with medical experience because of chronic illness, may possess adequate capacity, cognitive ability, and judgment to engage effectively in the informed consent or refusal process for proposed goals of care.
5. The dilemma of an adolescent treatment refusal is ethically and emotionally challenging. Instances in which treatment burdens may outweigh benefits and fail to achieve a curative end should mandate thoughtful guidance from the physician, with continued communication among the patient, surrogates, and health care team to clarify values and treatment goals. Knowledge of individual state laws on adolescent treatment refusals is critical in these situations.
6. Physicians have both a moral obligation and a legal responsibility to question and, if necessary, to contest both the surrogate's and the patient's medical decisions if they put the patient at significant risk of serious harm.
7. Physicians must realize that informed consent/permission/assent/refusal constitutes a process, not a discrete event, and requires the sharing of information in ongoing physician-patient-family communication and education.
8. Physicians must have access to and understanding of their specific state statutes governing the care of sexually transmitted infections, provision of contraceptive and abortion services, mental health and substance abuse treatment, and the definition and care of the emancipated minor and adolescents who possess decision-making capacity (mature minors). These statutes may not include protection of adolescent confidentiality.
9. Physicians who are involved in clinical research must understand both the special place of assent in the process of enrolling children in clinical research trials and the specific additional protections that regulate the participation of children and adolescents as research subjects.

### **LEAD AUTHORS**

Aviva L. Katz, MD, FAAP  
Sally A. Webb, MD, FAAP

### **COMMITTEE ON BIOETHICS, 2015–2016**

Aviva L. Katz, MD, FAAP, Chairperson  
Robert C. Macauley, MD, FAAP  
Mark R. Mercurio, MD, MA, FAAP  
Margaret R. Moon, MD, FAAP

Alexander L. Okun, MD, FAAP  
Douglas J. Opel, MD, MPH, FAAP  
Mindy B. Statter, MD, FAAP

### CONTRIBUTING FORMER COMMITTEE MEMBERS

Mary E. Fallat, MD, FAAP, Past Chairperson  
Sally A. Webb, MD  
Kathryn L. Weise, MD

### LIAISONS

Mary Lynn Dell, MD, DMin – *American Academy of Child and Adolescent Psychiatry*

Douglas S. Diekema, MD, MPH – *American Board of Pediatrics*  
Dawn Davies, MD, FRCPC, MA – *Canadian Pediatric Society*  
Sigal Klipstein, MD – *American College of Obstetricians and Gynecologists*

### FORMER LIAISONS

Kevin W. Coughlin, MD, FAAP – *Canadian Pediatric Society*  
Steven J. Ralston, MD – *American College of Obstetricians and Gynecologists*  
Monique A. Spillman, MD, PhD – *American College of Obstetricians and Gynecologists*

### LEGAL CONSULTANTS

Nanette Elster, JD, MPH  
Jessica Wilen Berg, JD, MPH

### STAFF

Florence Rivera, MPH  
Alison Baker, MS

### ABBREVIATION

AAP: American Academy of Pediatrics

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