



# Informed Consent in Decision-Making in Pediatric Practice

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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 their 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. This technical report, which accompanies the policy statement "Informed Consent in Decision-Making in Pediatric Practice" was written to provide a broader background on the nature of informed consent, surrogate decision-making in pediatric practice, information on child and adolescent decision-making, and special issues in adolescent informed consent, assent, and refusal. It is anticipated that this information will help provide support for the recommendations included in the policy statement.

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 is now 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, the revised policy statement<sup>3</sup> affirms that patients should participate in decision-making commensurate with their development; they should provide assent to care whenever reasonable.

Although some aspects of decision-making in pediatrics are evolving in response to changes in information technology, scientific discoveries, and legal rulings, recent reports have noted that change can be slow. Despite the long-standing stance of the AAP that older children and adolescents should be involved in the medical decision-making and consent process, there still has not been widespread understanding and endorsement among practitioners of the concept of pediatric assent or refusal.<sup>4-6</sup>

## abstract

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The discordance between current clinical practice and previously published guidance may reflect the gradual evolution of change within the culture of medicine or perhaps suggests a need to build on the discussion of informed consent, assent, and refusal for children and adolescents. The purpose of this technical report is to provide a firm grounding of the concept of informed consent, addressing both the legal and philosophical roots, to provide information on a variety of standards applicable for decision-making by surrogates for pediatric patients and to discuss how issues of assent, refusal, and consent affect the care of children and adolescents in a variety of clinical and research settings.

For purposes of this report, we will define and use the following terms: a pediatric patient or a minor who has not reached the legal age of majority (in most states, 18 years of age) is a patient younger than 18 years; an adolescent refers to a person in the transition between childhood and adulthood, classically defined as 13 to 18 years of age; a child refers to a person from the ages of 1 through 12 years; and an infant refers to a person in the first year of life.

## HISTORY AND NATURE 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 right of an autonomous agent to make decisions as guided by his or her own reason.<sup>7</sup> As a brief description, informed consent incorporates 2 duties: disclosing information to patients and their surrogates and obtaining legal authorization before undertaking any interventions. The historical shift in US medical practice from paternalism to respect for individual

autonomy was shaped by events in the 20th century, such as the distrust of the medical profession after the Nuremberg trial of Nazi doctors, widespread publicity regarding research ethics violations, the turbulence of the civil rights and women's rights movements, and the long-standing American characteristic of individualism. This long-standing American emphasis on individualism correlated with an increased interest in and attention to the issue of informed consent.<sup>8,9</sup>

Autonomy (from the ancient Greek *autos* [self] and *nomos* [rule or law]) can be seen as derived from Kantian moral philosophy, with key elements of liberty, the capacity to live life according to your own reasons and motives, and agency, the rational capacity for intentional action. A formulation of Kant's categorical imperative notes that we are obliged to act out of fundamental respect for other persons by virtue of their personal autonomy. This imperative forms the moral basis to respect others and ourselves as moral equals and provides moral support for the concept of informed consent. Although many, if not most, patients in pediatric practice lack the agency required to be truly autonomous agents, this framework remains important in providing the background for continued respect of their moral potential.

In pediatrics, the duties to protect and promote health-related interests of the child and adolescent by the physician are also grounded in the fiduciary relationship (to act in the best interest of the patient and subordinating one's own interests) between the physician and patient, but these duties may conflict with the parent's or patient's wishes and set up tensions either within the family or between the family and the physician. Most believe that parents have an ethically parallel fiduciary obligation to protect and promote both the health-related and

the non-health-related interests of their child or adolescent, with the pediatrician and the parents acting as "co-fiduciaries" for health matters.<sup>10</sup> This provides a conceptual framework for moving the discussion from parental rights to parental responsibility when considering pediatric medical decision-making and informed consent.

Appropriate decisional capacity and legal empowerment are the determinants of decision-making authority in medicine. A reliance on individual liberties and autonomy in the pediatric patient is not realistic or legally accepted, so parents or other surrogates provide "informed permission" for diagnosis and treatment, with the assent of the child as developmentally appropriate.<sup>2</sup> However, 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 similar in the pediatric and adult population and are grounded by the same ethical principles of beneficence, justice, and respect for autonomy. As we will discuss further, in pediatric care we often need to expand our understanding of autonomy to recognize the autonomy of the family unit, allowing respect for both the privacy of the family unit, within limits, and parental authority and responsibility for medical decision-making.

Although the requirement of "simple" consent by patients for surgical procedures dates back to 18th-century English law, it was only in the 1950s that the American courts began to develop the doctrine of true "informed" consent from patients through disclosure of facts by physicians. The term "informed consent" is derived from the ruling in *Salgo v Leland Stanford Jr University Board of Trustees* in 1957.<sup>11</sup> This term was adopted verbatim from an *amicus curiae* brief filed by the

American College of Surgeons: "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent... in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent."

The judgment in this case identified the need for a full disclosure of the facts necessary to form an informed consent. Later cases (*Mitchell v Robinson*, *Natanson v Kline*)<sup>8,9</sup> shaped our modern understanding of the required elements of disclosure during the consent process by mandating disclosure of risks, the nature of the medical condition, details of the proposed treatment, the probability of success, and possible alternative treatments. The standard of what information must be included in discussions leading to informed consent or informed refusal of treatment has evolved over time and varies somewhat from state to state.<sup>9</sup>

## THE PROCESS OF INFORMED CONSENT

Several different but common standards for the physician's disclosure obligation have emerged. The professional community standard defines adequate disclosure by what the trained and experienced physician tells his or her patient. The objective, reasonable person standard requires the physician to disclose information that a reasonable person in the patient's condition would need and want to know.<sup>9</sup> A small minority of states use the subjective standard of what a particular patient would need to know to make a decision to evaluate the extent of disclosure. Physicians should make substantial efforts to craft disclosures that maximize understanding by all surrogates or patients regardless of developmental maturity, severity of illness,

educational limitations, or language barriers.

Pediatricians should be adept at explaining information to their young patients in an age-appropriate and descriptive manner. This vital skill, if not a standard, enhances the assent and permission process in pediatrics. Although the ability of the child or adolescent to provide assent or consent changes along with cognitive development and maturation, disclosure of the medical condition and the anticipated interventions in a developmentally appropriate manner demonstrates respect for the patient's emerging autonomy and may help enhance cooperation with medical care. The pediatrician and pediatric medical subspecialist should have an understanding of the spectrum of intellectual disability encountered in childhood and adolescence and should be prepared to provide the individualized support needed to maximize understanding of the disease process and therapeutic options.

The content of the informed consent discussion is closely linked with professional experience. Disclosure of risks may differ between physicians in community and academic settings, between younger and older physicians, or among those who perform minimally invasive compared with open procedures.<sup>12</sup> During disclosure to the patient and/or the surrogate regarding treatment options, many believe it is important for the physician to disclose his or her or the facility's own experience with the proposed intervention and periprocedural complications. The issue of disclosure of surgeon-specific outcome data has been addressed recently in the surgical literature.<sup>13,14</sup> Although the potential advantages of this disclosure may include enhanced patient autonomy and understanding during decision-making, some critics contend the accuracy of surgeon-specific performance rates is often illusory because of a variety of

limitations and generally not truly available for thoughtful discussion in the informed consent process.<sup>13</sup> Transparency and honesty in discussing provider experience with patients and families are critical, and there is case law on this issue, with the court finding that, in certain instances, physician-specific data may be material in allowing a fully informed consent.<sup>15</sup>

Although informed consent is usually thought of as linked to surgical or invasive interventions in health care, the same process of disclosure of potential diagnosis, options for evaluation and treatment, likely outcomes, and potential associated risks is also necessary to ensure that medical decision-making for routine or noninvasive clinical treatments is transparent to patients and families.

## SEEKING INFORMED CONSENT

Knowledge about a medical condition is critical to making informed health care decisions by and for adults, adolescents, children, and infants. Informed consent is not satisfied by merely obtaining a signature on a form but is a process of dialog with a patient about a planned course of action. The first part of that dialog is determining whether the patient and/or his or her family/surrogate are capable of understanding the information one discloses. The terms "capacity" and "competence" are frequently blurred in medical discourse. Capacity is a clinical determination that addresses the integrity of mental abilities, and competence is a legal determination that addresses society's interest in restricting decision-making when capacity is in question.<sup>16</sup> Pediatricians can determine whether an adolescent is capable of making health care decisions, and the courts generally determine competence. It is also important to understand that an individual can still have decision-making capacity while

being declared legally incompetent. This situation is typically illustrated when an adult with newly diagnosed dementia is still able to participate and make health care decisions but is incompetent to manage financial affairs, as determined by the courts. It is critical to recognize that capacity is not an all-or-none phenomenon and is relatively task specific.

A patient may have the capacity to participate in certain areas of medical decision-making but may not have the capacity to contribute in more complex discussions, such as end-of-life decision-making. In addition, it is important to recognize that neither capacity nor competence is permanent and may fluctuate over time and should be reassessed over the course of illness, as indicated.

As informed consent and, more recently, assent in pediatrics have evolved over the 50 years since the Salgo case, certain elements of the process listed as follows serve as the framework for conversations with our patients and their families.<sup>2</sup> It is vital that throughout the process, the health care professional understands that providing information and obtaining permission, consent, or assent are 2 different, although linked, functions.

1. Provision of information: patients and their surrogates should be provided explanations, in understandable, developmentally appropriate language, of the nature of their illness or condition; the nature of the proposed diagnostic steps and/or treatments and the probability of their success; the existence and nature of the risks and anticipated benefits involved; and the existence, potential benefits, and risks of potential alternative treatments, including the option of no treatment.
2. The patient's and/or surrogate's understanding of the above information should be assessed.

3. Because decisional capacity is a critical requirement in providing consent, the capacity of the patient and/or surrogate to make the necessary decisions should be assessed (often, assessment of the capacity to make decisions and the understanding of the pertinent medical information occurs simultaneously).
4. There should be assurance, insofar as is possible through ongoing dialog, that the consent is voluntary and that the patient and/or surrogate has the freedom to choose among the medical alternatives without undue influence, coercion, or manipulation. This condition recognizes that we are all subject to subtle pressures in decision-making and that medical decision-making cannot occur in isolation from other concerns and relationships.

The process of informed consent requires participation by the physician or health care provider of record. In teaching hospitals or clinics, it is ethically and legally inappropriate to permit medical students to obtain informed consent from parents or patients without the support and involvement of more senior, knowledgeable staff. Medical students lack the comprehensive medical knowledge required to provide adequate information for a truly informed consent. Junior house staff may also not have sufficient knowledge to satisfy condition number 1 listed above and will need education from more experienced physicians to assist in the dialog with patients and surrogates. Both medical students and junior house staff benefit from opportunities to observe attending physicians engage patients and families in informed consent discussions and may assist in providing initial information to patients and families and by answering questions that fall within their level of understanding.<sup>17,18</sup>

Patient or surrogate comprehension of procedural consent has been reported to be <50% in the adult surgical literature.<sup>19</sup> Similarly, studies of recall and comprehension by parents and pediatric research subjects after informed consent discussions reveal that parents and subjects have far greater understanding of their research rights than the clinical implications of the interventions.<sup>20</sup> New strategies to improve patient literacy and recall during consent are being developed and include multimedia presentations, requirements for "repeat back" elements of the proposed interventions, and trying to increase the time spent in the informed consent discussion.<sup>19,20</sup>

How one shares this information is also crucial to building a successful, trusting relationship with children, adolescents, and their parents/guardians and is critical to achieving the goals of treatment. The event model, in which discrete interventions are seen as a one-shot encounter and patients and their surrogates are left to accept or reject a physician-formulated plan, is inferior to the process model, in which medical decision-making is a longitudinal process over time, with information shared between the physician and the patient/surrogate.<sup>9</sup> This process model, which recognizes that a multitude of decisions are made throughout the medical course as new information emerges, fosters better communication and understanding between clinicians and patients/surrogates. An example of the importance in framing medical decision-making as a longitudinal process that takes shape over time is the care of a critically ill child undergoing resuscitation and stabilization in the ICU. A broad discussion of the many elements that may be required for resuscitation is clearly required, but individualized consent for each element, especially in the likely condensed time frame



is not, as long as there has been an overarching discussion and agreement on the goals of care and an understanding of the likely intensity of interventions required. A more interactive role for the decision-maker and/or patient in informed consent and pediatric assent may improve understanding and ownership of the medical condition and its management and often improves compliance with recommended care.

### **STANDARDS FOR SURROGATE DECISION-MAKING FOR CHILDREN AND ADOLESCENTS**

A deeper understanding of the issue of assent and consent in childhood is facilitated by distancing oneself from the potentially confrontational and legalistic approach of respect for individual autonomy as an overarching principle in pediatrics. A more nuanced approach, incorporating respect for the pediatric patient's medical experience, for family dynamics, and for emerging data on adolescent cognitive development and decision-making, allows for alternative models for both child and surrogate decision-making.

Before discussing models and standards for decision-making in pediatrics, it is helpful to appreciate the complexity of how decisions are made by parents and surrogates. A recent literature review of 55 research articles on the process of treatment decision-making noted that decisions are influenced by such things as provider relationships, previous knowledge, changes in a child's health status, emotions, and faith.<sup>21</sup> Parental distress presents a challenge for good informed decision-making. Parents who receive new diagnoses of cancer or other life-threatening illnesses in their children report burdensome emotional and psychological stress that can interfere with

decision-making.<sup>22-24</sup> Parental coping mechanisms and their perceptions of undue external influence by clinicians or family members on decision-making may result in hostile and uncertain feelings about treatment goals for their seriously ill children.<sup>24</sup> Clinicians should be aware of the effects of stress and uncertainty on autonomous parental decision-making and choose effective communication strategies to limit these negative effects.

When compared with surrogate decision-making that uses substituted judgment for adults who have lost the capacity to make their own medical decisions, surrogate decision-making for infants, children, and adolescents draws from different constructs, such as the best-interest standard, harm principle, constrained parental autonomy, and shared, family-centered decision-making. With substituted judgment, a standard often used in surrogate decision-making for incapacitated adults who previously had the capacity for medical decision-making, surrogates "substitute" their understanding of the patient's known preferences and values in determining goals of treatment. It is important to note that this is an uncommon decision-making model in pediatrics, because most children and many adolescents cannot or have not stated known preferences that are based on their level of understanding and are reflective of core values that an adult with capacity may have had an opportunity to share. In cases in which adolescents, usually those with chronic debilitating diseases, have had the capacity to express wishes about goals of care before deterioration of cognitive function or the onset of overwhelming illness, the substituted judgment standard should be respected by families and the health care team. The opportunity to provide this guidance about their future medical care should be discussed with adolescents 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 family and make appropriate, caring decisions regarding their children's health care. This parental responsibility for medical decision-making in caring for their child or young adult is not an absolute right, however, because the state also has a societal interest in protecting the child or young adult from harm and can challenge parental authority in situations in which the child or young adult is put at risk (the doctrine of *parens patriae*).

Pediatric health care providers have legal and ethical duties to provide a standard of care that meets the pediatric patient's needs and not necessarily what the parents desire or request. 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. It is important to note that parental authority regarding medical decision-making for their minor child or young adult who lacks the capacity for medical decision-making is constrained compared with the more robust autonomy in medical decision-making enjoyed by competent adults making decisions regarding their own care. By moving the conversation from parental rights toward parental responsibility, clinicians may help families minimize conflicts encountered in the course of difficult medical decision-making. It is important to recognize that just as there may be conflict between the family and the health care team, there may also be conflict between the patient's parents. Conflict between parents may predate the current health care concern or crisis or may reflect a different understanding of

what medical intervention is in the best interest of their child. These issues must be acknowledged and addressed in the process of medical decision-making for the patient.

Since publication of the 1995 AAP statement, several frameworks providing guidance for pediatric decision-making have emerged in the literature. Historically and legally, medical decision-making in children has centered on the best-interest standard, which directs the surrogate to maximize benefits and minimize harms to the minor and sets a threshold for intervention in cases of abuse and neglect.<sup>25</sup> The focus is on the pediatric patient rather than on the interests of the caregiver and, as philosophers Buchanan and Brock<sup>26</sup> defined it, “acting so as to promote maximally the good of the individual.” Confusion and concern regarding the use of this standard occur if it is interpreted this rigidly, asking the parent to consider the child’s absolute best medical interest in isolation, without considering other interests such as finances or family.<sup>25,27</sup> A broader approach for using the best-interest standard acknowledges the pediatric patient’s emotional, social, and medical concerns along with the interests of the child’s family and strives to maximize benefits and minimize harms within this framework. Best-interest determination in this “ideal” framework may help establish *prima facie*, rather than absolute, duties to children. Another option is to view best interest as a standard of reasonableness wherein the benefit to burden ratio is balanced such that most rational people would agree with the choice of action.<sup>25</sup>

The harm principle may be seen as a more realistic framework to apply in pediatric surrogate medical decision-making, especially when there is a concern about the child’s safety. The goal here is not to identify a single course of action that is in the child’s best interest or represents 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>27</sup> In addition, when considering intervention, the potential harm to the child by the parental decision must be serious and imminent and a greater threat than the potential harm from state intervention. Diekema<sup>27</sup> stated that if a parental refusal places the child at significant risk of serious harm (eg, refusing a potentially life-saving therapy or a critical therapy of proven efficacy), other questions should be asked to justify state interference: Do the projected benefits of the proposed intervention outweigh the burdens more favorably than the parents’ option? Would another option that is less intrusive to parental autonomy prevent the harm? Can state interference be generalized to all other similar cases? Would the public agree that state interference is reasonable? Proponents of the harm principle note that it is a more appropriate standard for determining when to interfere with parental decisions than the best-interest standard, because parents often make decisions that conflict with a child’s best medical interest, and this situation is generally tolerated within the context of the overall care of the child and family. These concerns would also apply in considering parental decision-making for young adults who lack the capacity to participate in their own medical decision-making.

The model of constrained parental autonomy<sup>28</sup> allows parents, as surrogate decision-makers, to balance the “best interest” of the minor patient with their understanding of the family’s best interests as long as the child’s basic needs, medical and otherwise, are met. Rather than best interests, there is the promotion of basic interests, with medical care as a basic

interest. This model reinforces that a parent’s authority is not absolute but is constrained by their caring and responsibility for the child. An important focus in this model is family autonomy, with the goal of promoting long-term autonomy for the child throughout his or her development within the family setting.

Shared decision-making is a central tenet of the family-centered medical home, especially with respect to children with chronic health conditions. Shared, family-centered decision-making is an increasingly used process for pediatric medical decision-making.<sup>29</sup> This process is dependent on collaborative communication and the exchange of information between the medical team and the family. In addition to the medical team providing information about the patient’s disease process and the risks and benefits of treatment options, it is important for family members to share information regarding their goals and values so that care decisions can meet these needs and address each stakeholder’s perception of the disease process.

## **CULTURAL AND RELIGIOUS INFLUENCE ON DECISION-MAKING**

Medical decision-making in pediatrics is informed by the cultural, social, and religious diversity of physicians, patients, and families. Understanding this tenet and embracing culturally effective pediatric health care may allow for better incorporation of family values in the informed consent process.<sup>30</sup> Occasionally, parental decisions based on culture or religion may conflict with the medical recommendations. Low health literacy in non-English-speaking families can lead to unfavorable health outcomes. The use of appropriately trained interpreters during the informed consent process is vital to obtain

and share relevant information in an easily understandable fashion and to optimize medical treatment of pediatric patients.<sup>30,31</sup>

Other examples of the potential impact of religious and cultural beliefs on medical care include the risk associated with religious-based refusals, such as the refusal of blood transfusions as a life-saving therapy by patients who practice the Jehovah's Witnesses faith, and the refusal to seek medical care when medically necessary, or declining interventions, even in the face of serious illness, by patients who are Christian Scientists. Although adults with the capacity for medical decision-making have the freedom to make decisions that reflect their faith and religious values, even at the risk of serious harm or death, there is clearly a competing state interest in protecting a child from significant risk of serious harm, as noted in the 1944 US Supreme Court ruling *Prince v Massachusetts*.<sup>32</sup> The AAP statement on religious objections to medical care<sup>33</sup> endorses that children, regardless of parental religious beliefs, deserve effective medical treatment when such treatment is not overly burdensome and is likely to prevent substantial harm, serious disability, or death. Clinicians must balance the need to work collaboratively with all parents/families, respecting their culture, religion, and the importance of the family's autonomy and intimacy, with the need to protect children from serious and imminent harm. Clinicians must recognize that failure to provide appropriate care may constitute abuse or neglect, and this situation should not be unreported because of perceived state or federal exemptions for religious groups. This protection is extended until children are able to make such religious decisions for themselves, recognizing that some mature adolescents may either endorse or reject the tenets of their parent's faith over time.

## THE CHILD/ADOLESCENT AS MEDICAL DECISION-MAKER

The value of involving children and adolescents in their own medical decision-making is increasingly recognized around the world.<sup>34-37</sup> The respect owed to pediatric patients as participants in the medical decision-making process is dependent on several factors, including cognitive abilities, maturity of judgment, and the respect owed to a moral agent, which may not all proceed to maturation along the same timeline. Children and adolescents are dependent on their parents for most aspects of their daily life and usually have limited experience with making any medical decisions. Although the child or adolescent should be recognized as a moral being with all of the appropriate dignity and rights, they are more vulnerable decision-makers than adults, in significant part because of both inexperience with decision-making and the slow process of maturation of judgment, as reviewed below.

Developmental research in the 1980s concluded that many minors reach the formal operational stage of cognitive development that allows abstract thinking and the ability to handle complex tasks by midadolescence.<sup>38,39</sup> During that time, the Tennessee Supreme Court, in deciding *Cardwell v Bechtol* in 1987,<sup>40</sup> used the "rule of sevens" to uphold the presumption of decision-making capacity for a 17-year-old girl receiving spinal manipulation. This "rule" stated that no capacity exists for children younger than the age of 7 years, a lack of capacity is presumed but may be rebutted with appropriate evidence between the ages 7 and 14 years, and capacity is presumed but may be rebutted at age 14 years and older. Newer insight into brain structure and function now makes the determination of which minors possess the maturity for decision-making much less clear-cut.

For more than a decade, considerable neurobiological research in animals and humans has focused on the complex interaction of brain development and remodeling with social, emotional, and cognitive processes during adolescence. Although the size of the brain nearly reaches its adult size in early childhood, we know from structural MRI studies that much of the brain has continued dynamic changes in gray matter volume and myelination into the third decade of life.<sup>41-44</sup> The prefrontal cortex, where many executive functions are coordinated, including the balancing of risks and rewards, is among the last areas of the brain to mature, with these functions continuing to develop and mature into young adulthood.

Neuropsychological research to link adolescent behaviors such as sensation seeking and risk taking to brain structure and function is ongoing but still speculative in many areas.<sup>45-47</sup> One theory is that adolescents have a dual-systems model of decision-making.<sup>48,49</sup> A "socioemotional" system located in the limbic and paralimbic brain regions is believed to develop around puberty, with increased dopaminergic activity, and manifests as reward-seeking behavior. The "cognitive control" system, which promotes self-regulation and impulse control, is in the prefrontal cortices and gradually develops into the third decade of life. This temporal imbalance or gap between the 2 systems can lead to the risky behavior seen in adolescence and has been analogized to starting a car engine without the benefit of a skilled driver.<sup>50</sup> Or, in other words, the circuitry of reward-related behavior develops earlier than the control-related brain regions.

Other contributors to the risky choices that some adolescents may make include peer pressure and highly complex or stressful situations. Although pubertal changes

do affect behavior, as has been mentioned, all changes cannot be attributed to “raging hormones.”

On the positive side, late adolescence is also a period during which youth develop a coherent sense of identity, with an increased understanding of their individual beliefs, values, and priorities.<sup>51</sup> The path toward autonomy in the journey from adolescence to adulthood is linked to both intellectual maturity and moral functioning.<sup>52</sup> Early life experiences are paramount in the shaping of moral functioning. With normal development, the integration of emotions, reasoning, and self-reflection with physical and social experiences helps determine the degree of moral intelligence in the transition to adulthood. A coherent sense of identity and stable, deep-seated values are key to making reflective, autonomous decisions required for true informed consent.

Some youth navigate this complex developmental process quite well despite the complex interactions of biology and social context. However, the research to date articulates that, in general, adolescents make decisions differently than adults do, and although they may have cognitive skills, they are more likely to underutilize these skills.<sup>45,53,54</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. As clinicians, we should look for evidence of stable, internalized values in adolescent medical decision-making that is reflective of the patient’s cognitive maturation. These values are key to the decision-making process and, in difficult situations, may help provide a foundation in developing goals of care.

Some adolescents and young adults with cognitive impairments and

special health needs may never develop the capacity to allow meaningful participation in medical decision-making. Parents will need to continue to serve as surrogate decision-makers for these patients, even as these adolescents turn 18 years of age and become adults. The legal issues involved in securing guardianship are beyond the scope of this report.

### **ASSENT IN PEDIATRIC DECISION-MAKING**

Pediatric practice is unique in that the developmental maturation of the child allows for increasing longitudinal inclusion of the child’s voice in the decision-making process. Assent from children even as young as 7 years for medical interventions may help them become more involved in their medical care and can foster moral growth and development of autonomy in young patients.<sup>2,55-59</sup> The 1995 AAP statement on informed consent endorses pediatric assent in decision-making. However, the definition and application of assent have lacked consistency in both clinical and research arenas.<sup>55,56</sup> A strict interpretation of assent requires that the child meet all of the elements of an adult informed consent, a requirement that challenges obtaining assent at younger ages. Others seek a developmental approach that would require different levels of understanding from children as they age.<sup>57</sup> At the very least, assent should include the following elements<sup>2</sup>:

1. helping the patient achieve a developmentally appropriate awareness of the nature of his or her condition;
2. telling the patient what he or she can expect with tests and treatments;
3. making 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); and

4. soliciting an expression of the patient’s willingness to accept the proposed care.

Note that one should not solicit a child’s assent if the treatment or intervention is required; the patient should be told that fact and should not be deceived. A child is not the final decision-maker, the parent or surrogate is. Many recommended medical interventions come with the likelihood of associated pain, invasive procedures, or at a minimum, inconvenience. Parents should balance the anticipated benefits with the level of burdens and risks of such treatments when making decisions for their children about pursuing therapy. If the likely benefits of treatment in conditions with a good prognosis outweigh the burdens, parents may choose a treatment plan over the objections or dissent of the child. A common example of this situation is an appendectomy for acute appendicitis. Regardless of the child’s degree of participation in and/or disagreement with the care plan, he or she should still be given as much control over the actual treatment as possible: for example, in determining the location for intravenous catheter placement.

Dissent by the pediatric patient should carry increased weight when the proposed intervention is not essential and/or can be deferred without substantial risk or discomfort to the patient or family. A perceived dilemma with assent is that parents and clinicians may resist incorporating assent into their practice when the stakes are too high if the child dissents, as in the case of an appendectomy for acute appendicitis. In 1 recent survey example, the majority of pediatricians would ignore an adolescent’s refusal of treatment when parents are in favor and the prognosis



is good.<sup>4</sup> As stated previously in this report, maintaining honesty in communications with patients and families helps to minimize this concern; information should always be provided in a developmentally appropriate manner, but assent should only be solicited if some element of refusal will be respected. In situations with a poor prognosis and interventions associated with a heavy patient burden, more consideration should be given to the adolescent's opportunity to provide assent or refusal.

Encouraging the patient to actively explore options and take on a greater role in his or her health care may promote empowerment and compliance with a treatment plan.<sup>60</sup> There is core philosophical and developmental support for the notion that we all need the opportunity to make choices to create ourselves as moral agents and create a coherent sense of identity.<sup>61</sup>

### **SPECIAL ISSUES IN ADOLESCENT INFORMED CONSENT/ASSENT/REFUSAL**

There are 3 broad categories of circumstances in which 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 (STIs) and provision of contraceptive services, prenatal care, and abortion services, has expanded over the past several decades. This change is not specifically related to an acceptance of the adolescents' abilities in medical decision-making. Rather, this is a public health decision and reflects both the concern that adolescents will not seek care for issues that reflect sexual activity if required to involve their parents for consent and an extension of the broad US

Supreme Court rulings regarding the constitutional right to privacy for all on these matters. It is important for the clinician to note the significant variability between states in how the statutes are worded regarding access for these services. The Guttmacher Institute ([www.guttmacher.org](http://www.guttmacher.org)) is an excellent resource for reviewing state policies on sexual and reproductive health and can be accessed electronically.<sup>62</sup>

Although all states allow access to treatment of STIs, the protection of the adolescent's confidentiality is less widespread. Some states permit the practitioner to disclose information to parents/guardians if they believe it is in the minor's best interest. Many states, insurers, and electronic medical record systems do not make provisions for deferred billing and/or payment for STI services, thus endangering an adolescent's desire for confidentiality. Practitioners are best advised to become familiar with their state statutes and to consider promoting changes in legislation to improve adolescent confidentiality protection where appropriate.<sup>63</sup>

Human papillomavirus (HPV) infection is the most common STI, and several strains of HPV are known to cause cervical cancer, with new data also linking this virus to oral cancers. Primary prevention is available in the form of vaccination, which is recommended for both boys and girls ages 11 through 12 years by the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. It is unknown whether most states will include the HPV primary prevention vaccination in the category of protected STI treatment or general vaccination for which minors may not provide consent.

The majority of states allow some or all adolescents 12 years or older access to contraceptive services and usually do not require parental notification. In contrast,

minor consent to abortion without parental involvement is uncommon: currently, 37 states require parental involvement, although, in general, there is a mechanism by which the minor can petition the court for access to abortion services without parental knowledge or consent.

There is similar variability among the states regarding adolescents' access to mental health and substance abuse prevention and treatment services. The majority of states do allow adolescents to consent to treatment of substance abuse, and importantly, programs receiving federal funding are governed by federal confidentiality regulations that prohibit sharing information regarding treatment without the patient's consent.<sup>64</sup>

The mature minor doctrine recognizes that there is a subset of adolescents who have adequate maturity and capacity to understand and appreciate an intervention's benefits, risks, likelihood of success, and alternatives and can reason and can choose voluntarily. Under the mature minor doctrine, the age, overall maturity, cognitive abilities, and social situation of the minor 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 contrast, legally emancipated minor statutes do not address decision-making ability but rather the legal status of the minor. Adolescents who are living separately from their parents and are self-supporting, married, or on active duty with the armed forces are generally considered legally emancipated and competent to make their own decisions and provide consent for medical care.

Although there are significant limitations on adolescents' legal right to consent to their own medical care, all states presume adolescent parents

to be the appropriate surrogate decision-makers for their children and allow them to give informed consent for their child's medical care. This right reflects the adolescent's status as a parent, rather than his or her decision-making capacity as a mature or emancipated minor. There is clearly a significant and concerning paradox encountered in allowing adolescents to take responsibility for complex medical decision-making for their infants and children while, in general, "protecting" adolescents from providing assent and directing their own medical care, even in more controlled, low-risk situations. The case of early adolescent parents of critically ill infants is particularly difficult with regard to consent. These parents, often the mother alone without the involvement or support of the infant's father, are generally charged with the responsibility of making important medical decisions for their infants that they would never be permitted to make for themselves or for other relatives.<sup>65,66</sup>

Although this arrangement meets the legal responsibility of recognizing and respecting the adolescent's status as a parent who has a right and responsibility for decision-making for his or her child, it does not appropriately address the ethical issues raised by young adolescent decision-making nor the physician's ethical responsibility to both the adolescent and his or her child. Adolescent parents are in a very vulnerable situation, facing the need to care for a child while still completing important developmental tasks for themselves. Many pediatricians and neonatologists seek permission from the adolescent parent to involve an adult relative, often the maternal grandparents, in crucial decisions regarding the care of the infant. This adult, selected by the mother as her co-decision-maker, can provide mentoring in shared decision-making to the adolescent

parent and may help safeguard the rights and well-being of the infant. Although not required by law, physicians should provide support for the adolescent mother, as needed, in selecting someone to help her provide informed permission for her infant's care.<sup>65,66</sup>

The informed consent process surrounding relatively higher risk, yet elective procedures, such as pectus excavatum repair and bariatric surgery, highlights the complex issue of adolescent medical decision-making. Surgery to repair pectus excavatum is most commonly undertaken in adolescent patients. The evidence to support significant physiologic improvement in cardiorespiratory function as a result of the surgery is limited, and the most common indication for surgery is distress regarding the appearance of the chest wall. Although the surgery is most often completed in a minimally invasive manner, it is not without the risk of complications, including significant postoperative pain, an extended period postoperatively of limitation of activities, the potential for recurrence of the pectus excavatum appearance, and rarely, the risk of cardiac injury and hemorrhage.<sup>67-69</sup> These can be extremely difficult concerns for the adolescent, especially the younger adolescent to consider and balance, because this deliberation includes the need to consider both acute and long-term risks and benefits. In this situation, the surgeon and the health care team must undertake thoughtful, developmentally appropriate conversations with both the adolescent patient and his or her family to provide the medical information needed to make an informed medical decision. In addition, the surgeon and the health care team must work to elicit from the family, but especially from the adolescent patient, their beliefs and concerns about the surgery and their cognitive understanding

of the associated risks and benefits and how these issues affect their medical decision-making. With this process, which includes input from both the family and the health care team, the adolescent should be able to be supported in making either an informed assent or refusal of the surgical procedure. This procedure provides an excellent example of a situation in which a major medical decision must be made but is best made by carefully supporting the adolescent's opportunity to provide assent or refusal, because only he or she can truly weight the risks and benefits as they apply to him or her. Throughout this process, the surgeon and the health care team must also be aware of balance between coercion by the family or health care team as well as the opportunity to support developmentally appropriate decision-making. A considered refusal of surgery by the adolescent should be respected, given the elective nature of the procedure and the associated postoperative pain and risks. Parental requests for surgical intervention must include the adolescent in the discussion, and the need to include the adolescent and respect his or her concerns must be discussed with the family. The surgeon and the health care team may also find themselves in the situation in which the adolescent is anxious to proceed with surgery, while the family/parents are reticent to provide consent. Continued discussion directed at having all participants clarify their goals for the surgery and their understanding of the risks may allow for a decision that all can respect.

#### **INFORMED REFUSAL OF TREATMENT BY ADOLESCENTS**

Adolescents or older children who have experienced serious and/or chronic illnesses often have an enhanced capacity for decision-making when weighing the benefits and burdens of continued treatment,

especially when the likelihood of a good outcome is low.<sup>70</sup> Refusal of life-sustaining therapy by such an adolescent should be given careful consideration by parents and the health care team. The pediatrician should work with the health care team, patient, and family in a collaborative approach to resolve any conflicts between the parents and adolescent, and the clinicians should generally advocate for the adolescent's wishes if they reflect an ethically acceptable treatment option. When conflicts about the goals of treatment persist, the health care team should enlist the involvement of secondary consultants, an integrated palliative care team, ethics consultation, psychologists, psychiatrists, or chaplains. Seeking legal intervention should be a last resort.

In general, it is also reasonable to respect an adolescent's refusal of nonurgent, non-life-threatening care as long as efforts are directed toward helping the physician and the family understand the basis of the refusal and providing appropriate education for any misconceptions.

Although age provides a clear legal definition of majority, there is still no bright line demarcating when a minor becomes "mature" enough to independently demonstrate the capacity for informed consent or refusal. Courts have weighed in on this issue with a variety of outcomes, detailed below. Recent pressure to generalize functional MRI neurobiological research to individual adolescents to prove criminal culpability is disturbing, because the science still struggles to separate social and environmental influences from biological determinants of behavior.<sup>45</sup>

One of the first mature-minor doctrine cases to rule on whether an adolescent has the right to make decisions about life-sustaining treatments is *In re E.G.* (1989).<sup>71</sup> In this case, the Illinois Supreme

Court ruled that a 17-year-old with leukemia and who was a member of the Jehovah's Witnesses faith was mature and had the right to refuse blood transfusions. Importantly, her mother agreed with her decision. The judges observed that the age of majority "is not an impenetrable barrier that magically precludes a minor from possessing and exercising certain rights normally associated with adulthood." A second case, *Belcher v Charleston Area Medical Center* (1992),<sup>72</sup> heard by the West Virginia Supreme Court of Appeals, also recognized the mature-minor doctrine and directed physicians to seek input from a mature minor before treatment. In this case, a physician wrote a do-not-resuscitate order for a 17-year-old with muscular dystrophy without discussion with the patient, despite the family's request that he do so. The patient, Larry Belcher, later had a cardiac arrest and died without resuscitation.

Case law continues to evolve on the issue of a minor's right to refuse medical treatment. A recent case<sup>73</sup> involved 13-year-old Daniel Hauser and his mother, Colleen Hauser. Daniel was found to have a very treatable form of Hodgkin lymphoma, with an estimated survival of 80% to 95% after standard chemotherapy and radiation therapy. Despite receiving an initial course of chemotherapy, Daniel and his mother refused further recommended chemotherapy, insisting instead on using "holistic" medicine based on Native American healing practices. One important aspect of this case was Daniel's inability to meet elements of informed assent/consent, because his limited cognitive abilities and illiteracy hampered his ability to comprehend his medical condition and its recommended treatments. A 2009 Minnesota court order in this case considered both a parent's right to raise a child free of interference and the constitutionally protected

right to religious belief but found both less compelling than the state's need to protect the child and to proceed with necessary medical therapy for a treatable, life-threatening illness.

This legal decision is in contrast to previous decisions, such as the case of Dennis Lindberg.<sup>74</sup> Dennis was a 14-year-old with leukemia who practiced the Jehovah's Witnesses faith and was allowed to refuse a blood transfusion after a 2007 court ruling by a Mt Vernon, Washington, judge who found him to be a mature minor. Although Dennis' biological parents objected to this ruling, his long-time guardian, who had raised him in the Jehovah's Witnesses faith, supported his refusal of transfusions. He died within hours of the ruling. In another prominent case in 2006, Abraham Starchild Cherrix, a 16-year-old with lymphoma, successfully deferred standard therapy for his lymphoma, supported by a Virginia court ruling. This ruling centered on the patient's maturity, understanding of his illness, and parental support of his refusal and quickly resulted in Virginia's 2007 "Abraham's Law" that allows adolescents 14 years of age and older a decision-making role in life-threatening conditions.<sup>75</sup>

Despite the legal rulings and ethical guidance, there is still much controversy about informed refusal by adolescents of life-sustaining treatments.<sup>5,76-80</sup> A recent statement from the Confederation of European Specialists in Pediatrics clearly states that pediatric patients may not refuse life-saving treatment.<sup>35</sup> Although the Confederation of European Specialists in Pediatrics references the United Nations Convention of the Rights of the Child, citing article 12, which provides for "the view of the child being given due weight in accordance with the age and maturity of the child," and finds that this clearly applies to medical treatment, they state that the physician has a

duty to act in the best interest of the child.

Many bioethicists support limiting a child's or adolescent's short-term autonomy by overriding a treatment refusal to preserve long-term autonomous choice and an open future.<sup>28,54</sup> Although adolescents may possess the capacity for decision-making, as discussed earlier, it may be limited by lack of perspective or real-life experiences. Some also argue that parental responsibility in promoting and protecting their child's life does not abruptly end when an adolescent has decision-making capacity. They should not cede sole decision-making authority to their minor child.<sup>77</sup> Instead, parental authority and decision-making are constrained to identify and protect the best interests of their child when he or she refuses medical care.

In general, adolescents should not be allowed to refuse life-saving treatment, even when parents agree.<sup>34,54,78</sup> However, in circumstances of a life-limiting terminal illness when only unproven, overly burdensome or likely ineffective treatment options exist, some adolescents may make an informed choice to forgo interventions to address their underlying disease and instead focus on measures that provide comfort and support.

The dilemma of an adolescent treatment refusal is ethically and emotionally challenging. Pediatricians must ascertain the capacity of the minor for decision-making while recognizing that the "science" of that determination is still evolving. The presence of chronic illness can either enhance a child's decisional skills or contribute to regression, emotional immaturity, and anger when facing a choice. The involvement of psychiatric counselors, ethicists, child life specialists, social workers, or other consultants, such as an integrated

palliative care service, may help the patient, family, and clinical team resolve conflict.

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

Parental consent is usually required for the evaluation and medical treatment of pediatric patients. However, there are situations in which children may present with emergency medical conditions and a parent or legal guardian is not available to provide consent. The AAP policy statement "Consent for Emergency Medical Services for Children and Adolescents"<sup>31</sup> recommends that a medical screening examination and appropriate medical stabilization of the pediatric patient with an urgent or emergent condition should never be withheld or delayed because of problems with obtaining consent. Although clinicians, courts, and parents may differ on what constitutes an emergency, this standard should apply when urgent interventions to prevent imminent and significant harm are necessary and when reasonable efforts to find a surrogate are unsuccessful.

Clinicians should also be aware that current federal law, under the Emergency Medical Treatment and Active Labor Act, mandates a medical screening examination and, if indicated, treatment and stabilization of an emergency medical condition, regardless of consent issues, in any hospital that receives federal funding. If an emergency medical condition is not identified with a screening examination, then Emergency Medical Treatment and Active Labor Act regulations no longer apply and the physician should seek proper consent or assent before further nonurgent care is provided.<sup>31</sup>

There also may be situations in which practitioners seek consent by proxy for nonurgent care (eg, a babysitter brings a 6-year-old to the doctor's office). Guidance for clinicians in

this area is found in the AAP policy statement "Consent by Proxy for Nonurgent Pediatric Care."<sup>81</sup>

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

The informed consent process for both research and clinical care shares similar ethical foundations and also encounters similar problems in ensuring consistency across institutions and practices. Informed consent and assent obtained from children involved in research are clearly mandated, in contrast to the "recommended" guidance in place in clinical care. This process has been closely scrutinized for >3 decades since the publication of the *Belmont Report* in 1978.<sup>82</sup> Produced by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the *Belmont Report* formed the basis of much of the work on informed consent in the research setting. Institutional review boards (IRBs) have incorporated the *Belmont Report*, the *Report and Recommendation: Research Involving Children*,<sup>83</sup> the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects,<sup>84</sup> and the appropriate federal guidelines (the "Common Rule" [45 CFR §46, 1991]) into the rules balancing the risk/benefit ratio that guide the review of research protocols including children as research subjects. The informed permission of the child subject's parent(s) must be obtained before enrolling the subject in the research protocol. In a distinction from the usual clinical practice, there are also clear guidelines on the need to obtain assent from the child subject in research and to respect a minor's dissent from study participation, with limited exceptions.

Although assent is mandated, federal guidelines on how to obtain assent



and at what age are not explicit. This situation results in variability in requirements of local IRBs of the age at which assent should be obtained and what elements of the traditional informed consent process are required from children and adolescents.<sup>2,55–59</sup> Although the AAP and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research recommend assent for children >7 years, there is still wide variation in the inclusion of children in the assent process.<sup>85</sup> The ability of the capable mature minor to consent to medical research depends on individual state laws, but generally, risks must be minimal and the research aim should center on a medical condition for which the minor can legally give consent. More detailed information is found in the AAP clinical report “Guidelines for the Ethical Conduct of Studies To Evaluate Drugs in Pediatric Populations.”<sup>86</sup>

Most research into the assent or consent process has occurred in the pediatric oncology population, because up to 80% of pediatric patients with cancer are also enrolled as subjects in clinical research trials. Oncologists may neglect to include adolescents in the decision-making process because of perceived inability of the adolescent to comprehend information when facing a life-threatening situation and the presumed sufficiency of parental permission.<sup>87</sup> Children enrolled in clinical trials very often have limited awareness and appreciation of the research trial, do not recall having a role in deciding whether to enroll, and do not feel free to dissent.<sup>59</sup> Observational studies have noted variations in how often the physician addressed the child versus the parent during the assent/permission discussion.<sup>70,88</sup> Observed decision-making approaches during discussion of enrollment include patient-centered, parent-centered, or joint child-parent decisions. The

latter or partnering approach may be the most successful in meeting the criteria for parental permission and child assent but may not be possible when families or physicians exercise authority over the child. A strong push toward endorsing a developmentally appropriate assent process in research may encourage more joint decision-making.

The IRB can provide a waiver from requiring assent if greater-than-minimal-risk research has the potential for an important direct benefit that is only available in the context of the research or the research carries only minimal risk and could not be carried out without the waiver.<sup>89</sup> This is a critical difference from the child’s input into decision-making in the clinical world.

## CONCLUSIONS

Informed consent should be seen as a constitutive part of health care practice; parental permission and childhood assent is an active process that engages patients, adults, and children in the health care process. Pediatric practice is unique in that developmental maturation of the child allows for increasing longitudinal inclusion of the child’s opinion in medical decision-making in clinical and research practice. Although new research has shown that neurologic maturation continues into the third decade of life, seeking assent from children and adolescents for medical interventions can foster the moral growth and development of autonomy in young patients and is strongly recommended. Surrogate decision-making by parents or guardians for pediatric patients should seek to maximize the benefits for their child by balancing health care needs with social and emotional needs within the context of overall family goals, cultural beliefs, and values. Physicians should recognize that some pediatric patients, especially older adolescents and

those with medical experience because of chronic illness, are minors with enough decision-making capacity, moral intelligence, and judgment to provide true informed consent, or, in non-life-threatening settings, informed refusal, for their proposed care plan. Clinicians have both a moral obligation and a legal responsibility to question and, if necessary, to contest surrogate and/or patient medical decisions that put the patient at significant risk of serious harm. Adolescent treatment refusals remain controversial and are ethically and emotionally challenging for families and clinicians.

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## ABBREVIATIONS

AAP: American Academy of Pediatrics  
HPV: human papillomavirus  
IRB: institutional review board  
STI: sexually transmitted infection

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