

Informed Consent: The Core of Pediatric Bioethics

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The Informed Consent Process for Pediatric Patients

The core of medical ethics is self-determination. Physicians facilitate self-determination by honoring the process of informed consent, by explaining to the patient the risks, benefits and alternatives to the procedure, and by obtaining from the patient an active, voluntary, informed authorization to perform a specific plan.

In pediatrics, although parents traditionally act as the surrogate decision-makers for their children, surrogate consent does not fulfill the spirit of informed consent, which requires the patient to authorize the treatment. To acknowledge this distinction, the American Academy of Pediatrics has suggested that the proper role for the surrogate decision-maker is to provide **informed permission**, which has the same elements as informed consent but acknowledges that the parent is authorizing treatment for their child.¹

For pediatric patients, the 'rule of sevens,' provides a rough age-based guideline for approaching various decision-making abilities of children. The "rule of sevens" views children age 7 and under as incapable of decision-making capacity, children between the ages of 8 and 14 as unlikely to have decision-making capacity, and children over age 14 as presumed to have decision-making capacity.

The Best Interests Standard for Infants, Toddlers, Younger Children and Children Unable to Participate in the Informed Consent Process

Parents and physicians use the concept of best interests to guide decision-making about health care for children unable to participate in the decision-making process. This standard requires the decision-maker to select the care which is objectively the best. Using this standard, then, requires determining (1) who will make the decision and (2) what is the best care. The difficulties arise in assuming that there is always one best choice, because if there is, it should not matter who makes the decision.

In today's heterogeneous and multicultural society, parents are given extensive leeway in determining what is in a child's best interests, particularly in complex decisions about informed consent, end-of-life issues and confidentiality. Traditionally, parents who are present and capable of participating in the decision-making process are well-suited to be the primary decision-makers for their children. This is in part due to society's respect for the concept of the family, and the assumption that parents care greatly for their children. And although we can never know what a child would decide if he were capable of participating in the decision-making process, it is reasonable to assume that a child will incorporate some of the parents' values as he grows and matures, making the values of the parents a good first approximation for the future values of the child.²

Informed Assent for School-age Children and Young Adolescents

Children between ages 7 and 14 should participate in decision-making to the extent their development permits. Participation should increase as children mature.

School-age children are developing decision-making capacity, so anesthesiologists should seek both informed permission from the parent and assent and participatory decision-making from the child. School-age children are capable of using logic and reason, but they tend to be more rigid and absolute in applying rules. Older school-age children begin to develop the flexibility to understand motives and different situations. Such situations may include whether to sedate a 6 year old prior to an inhalation induction, to use an inhalation or intravenous induction of anesthesia in an 8 year old and to place an epidural for postoperative analgesia in a 12 year old.

Informed Assent for Older Adolescents

Anesthesiologists should try to fulfill the ethical requirements of consent while obtaining assent from older adolescents. Adolescents have the ability to use abstract thought, apply complex reasoning, foresee outcomes, understand probability and evaluate multiple options. These abilities do not necessarily translate into good decision-making, because adolescents may be limited by insufficient emotional development. The extent to which adolescents may make decisions is related to the age of the patient, the maturity of the patient, the ability to articulate their reasons and the risks of making a poor decision. Lower risk decisions that do not foreclose future possibilities (e.g. delaying elective surgery) may be more appropriate to honor than decisions that limit the future, such as potentially life-saving decisions.

Pro forma solicitations of opinions are harmful. The American Academy of Pediatrics speaks directly to this point, emphasizing “no one should solicit a patient’s views without intending to weigh them seriously. In situations in which the patient will have to receive medical care despite his or her objection, the patient should be told that fact and should not be deceived.”¹

Emancipated Minor Status and Mature Minor Doctrine

Some adolescents have the legal right to consent to treatment. Emancipated minors have the ability to give legal informed consent for all healthcare matters. Emancipated minor status is generally awarded to adolescents who are married, parents, in the military, economically independent and may include adolescents who are pregnant. Mature minors are legally and ethically capable of giving informed consent in specific situations as determined by a court. The mature minor doctrine generally requires adolescents to be older than 13 years old, and tends to permit less hazardous decisions at a younger age and more hazardous decisions as the adolescent nears majority.

Table: Elements of Consent and Assent as Defined by the American Academy of Pediatrics Committee on Bioethics¹

Consent

1. Adequate provision of information including the nature of the ailment or condition, the nature of the proposed diagnostic steps or treatment and the probability of their success; the existence and nature of the risks involved; and the existence, potential benefits, and risks of recommended alternative treatments (including the choice of no treatment)
2. Assessment of the patient’s understanding of the above information
3. Assessment, if only tacit, of the capacity of the patient or surrogate to make the necessary decisions.
4. Assurance, insofar as it is possible, that the patient has the freedom to choose among the medial alternatives without coercion or manipulation

Assent

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 treatment.
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).
4. Soliciting an expression of the patient’s willingness to accept the proposed care.

Table: Approaches to Pediatric Consent

This broad outline should be viewed as a guide. Specific circumstances always must be taken into consideration. When children are in the upper range of an age bracket, limited or full inclusion of a higher technique, such as the use of assent for a six year old, may be appropriate.

Age	Decision-making Capacity	Technique
Under 7 years	None	Best Interests Standard
Ages 7 – 13 years	Developing	Informed Permission Informed Assent
Ages 14 years and older	Mostly developed	Informed Assent Informed Permission
Mature Minor	Developed, as legally determined by a judge	Informed Consent
Emancipated Minor	Developed, as determined by a situation	Informed Consent

Resolving Disagreements: Informed Refusal by Parents and Adolescents

The requirements to achieve informed refusal for a procedure are similar to the requirements for informed consent in that the decision-makers should be substantially well-versed about the risks, benefits and alternatives before declining. When parents refuse what caregivers believe is necessary care for a minor who cannot participate in the decision-making process, caregivers may use the best interests standard as guide.

One way to decide what is in the best interests of the child is to define what choices fall **outside** of the range of acceptable decision-making. The continuum between unacceptable and acceptable treatment in the practice of anesthesiology provides clear extremes, but an ambiguous gray zone. For example, it is nearly always considered unacceptable undertreatment for Jehovah's Witnesses to refuse a life-sustaining blood transfusion for their child. On the other hand, parents may decline to have an epidural placed in their child for postoperative pain management, depriving the child of an optimal source of pain control. This is not considered unacceptable undertreatment, in part because the harm is limited by other adequate methods of pain control.

Anesthesiologists may best determine the appropriateness of a treatment by considering the amount of harm to the child, the likelihood of success and the overall risk-to-benefit ratio.³ Anesthesiologists challenging inappropriate health care may benefit from inviting other clinicians to review the proposed plan and to engage the parent in discussion.⁴ Pursuing legal actions to redress questionable health care decisions has significant familial and social ramifications. If all other methods fail, and anesthesiologists believe the desired therapy is outside the bounds of acceptable treatment, they should report the situation to proper child welfare authorities.

This situation is more complicated when the minor expresses significant decision-making capacity and refuses a nonemergent procedure. Anesthesiologists should respect the right of pediatric patients not to assent to a procedure, and should go out of their way to avoid coercing or forcibly making the minor have the procedure. Achieving the patient's assent may necessitate further discussions with the patient, parents, and other providers, and such discussions may best take place away from the operating room. In cases where the parent and child disagree, clinicians should seek the assistance of others experienced in conflict resolution to help resolve the dispute with a minimum of rancor.

Disagreements about appropriate therapy may be more relevant in end-of-life care. Decision-making for a child near the end of life should be based on the best interests of the child. Given improvement in medicine, clinicians should be aware that it is often hard to predict success in very young children. Further, parents tend to be very involved in the care of their children and pediatric doctors may feel a need to "protect" their patients. When both parents and clinicians are invested in the child's well-being, there is a greater possibility of disagreements causing conflict, particularly given the difficulty in defining beneficial and burdensome outcomes. The guidelines from the American Academy of Pediatrics consider benefits to include prolongation of life under certain circumstances, improved quality of life (such as reduction of pain or the ability to leave the hospital), and increased enjoyment of life. Burdens may include intractable pain and suffering, disability, and events that cause a decrement in the quality of life, as viewed by the child and parents.⁵ A useful approach to resolving conflicts has been proposed by the *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*.² In short, only if a therapy is clearly

beneficial (as in blood transfusion for anemia) may clinicians override parental preferences, and even then, out of respect, the appropriateness of the treatment and the process of decision-making should undergo an external review, which will often be medical, ethical or legal in nature.

Table: Suggested Grid for Resolving Disputes about Appropriate Care ^{2,6}

	Parents prefer to <i>accept treatment</i>	Parents prefer to <i>forego treatment</i>
Physicians consider treatment <i>clearly beneficial</i>	Treat	Provide treatment during review process
Physicians consider treatment to be of <i>ambiguous or uncertain benefit</i>	Treat	Forego
Physicians consider treatment to be <i>inadvisable</i>	Provide treatment during review process	Forego
Physicians consider treatment to be <i>futile</i>	Review	Forego

Special Situations in Pediatric Informed Consent

The Pediatric Patient and Abortion

Even though pediatric patients who are pregnant may be considered emancipated, many states require some form of parental involvement such as parental consent or notification prior to an elective abortion in an adolescent. If a state requires parental involvement, the ability of the minor to circumvent this regulation by seeking relief from a judge, known as judicial bypass, must be available. Requirements and enforcement of statutes vary from state to state.⁷ The need for parental involvement in minor abortions is not always legally straightforward and it may be best to consult with hospital counsel in determining these issues. Although this is clearly an area in which honorable people disagree, it is worth noting that both the American Academy of Pediatrics and the American Medical Association have issued statements affirming the rights of adolescents to confidentiality when contemplating an abortion.^{7,8}

Confidentiality for Adolescents

The obligation to maintain confidentiality requires physicians to protect patient information from unauthorized and unnecessary disclosure. Confidentiality is necessary for the development of a patient-physician relationship that supports an open and uncensored flow of information and concerns. A trusting alliance is particularly important in the care of adolescents who are more likely to defer needed treatment because they are concerned about confidentiality.⁹ Emancipated and mature minors have a right to complete confidentiality. For other adolescents, if the knowledge is of minimal harm to the health of the patient, physicians should encourage the patient to be forthright with parents but respect their decision not to be. If, on the other hand, withholding the information may result in serious harm to the patient, the physician is ethically justified in notifying the parents.⁹ Possible exceptions to the principle of confidentiality are

notifications required by law such as reporting statutes, parental notification, and when a patient makes a credible threat to harm another person.

The quality of the information obtained in the preoperative interview may be directly affected by the adolescent's trust of the anesthesiologist. The anesthesiologist can enhance this trust by interviewing the adolescent in private, acknowledging the adolescent's concerns about confidentiality and following through on any promises made. Inadvertent breeches of confidentiality are as harmful as intentional ones, and anesthesiologists should be aware that many disclosures take place unwittingly in public spaces or social situations.

Emergency Care

Anesthesiologists will need to perform emergent anesthetics for minors who do not have parents available to give legal consent or informed permission. In an emergency situation, the presumption is that necessary therapy is desirable and should be given.¹⁰ It is reasonable to attempt to contact the parents or surrogate, but questions about reimbursements should not hold up necessary treatment.¹⁰ Emergencies include problems that could cause death, disability and the increased risk of future complications.

This situation becomes more complex when a minor near majority refuses assent for emergency care that the parent desires. The right of the minor to refuse treatment turns on the minor's decision-making capacity and the resulting harm from the refusal of care.¹ If the harm is significant, and the patient's rationale is decidedly short term or filled with misunderstanding, it is necessary to question the minor's decision-making capacity. At this point one may revert to asking what is in the best interests of the minor.

The Impaired Parent

Parents may have impaired judgments and may be unable to fulfill surrogate responsibilities regarding informed permission, and they may be disruptive or dangerous. Caregivers should focus on the safety of the child, the impaired parent, and others, such as patients, parents and employees in the area, comply with reporting mandates and protect patient confidentiality.¹¹ As a general rule, caregivers should use the least restrictive means to decrease the risk from the impaired parent. Caregivers may wish to postpone routine treatment until legal consent can be obtained from an unimpaired parent. Anesthesiologists will have to weight the benefits of waiting with the risk that impaired parents may be less reliable and, for example, may not return for future visits. In this case, it may be in the child's best interests to proceed with a routine procedure in the situation of an impaired parent unable to give legal consent. Anesthesiologists may wish to consult legal and risk management colleagues for guidance.

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