

# Informed Consent, Parental Permission, and Assent in Pediatric Practice

Committee on Bioethics

*The statement on informed consent, parental permission, and patient assent has a long and extraordinary history. The first draft of this document, prepared by William G. Bartholome, MD, was presented to the original American Academy of Pediatrics (AAP) Committee on Bioethics in 1985. Bill put his soul into the manuscript and has watched over it carefully ever since. Now, a decade later, those who have worked on its continued development and urged its adoption as Academy policy applaud its publication. No one is more gratified than its primary author and champion. Those who have had the privilege to know Dr Bartholome share his sense of accomplishment, but cannot help but experience a cruel sense of irony. Just as the work Bill considers his most important contribution has become available for public appreciation, Dr Bartholome suffers from a serious illness that threatens his life.*

*Bill always wanted "the experience, perspective, and power of children" to be taken most seriously. Through the years of the statement's revisions and re-presentation within the Academy, Bill "had faith in the power of the text and the ideas it contained, . . . that its time would come." The statement embodies Bill Bartholome's dedication to children. Throughout his career, he worked to make medicine and medical research safer and more friendly for children. The AAP and its Committee on Bioethics, on behalf of all our colleagues, extend heartfelt thanks to Dr William G. Bartholome for helping us more fully appreciate that children are in the process of becoming, in his words, "intelligent, observant, capable, and responsible persons" who deserve our utmost respect.*

## AN OVERVIEW

Since the 1976 publication of an AAP policy statement on the legal concept of informed consent in pediatric practice, the concept has evolved and become more formal.<sup>1</sup> A better understanding now exists as to how physicians should collaborate with patients and parents in making these decisions. Patients should participate in decision-making commensurate with their development; they should provide assent to care whenever reasonable. Parents and physicians should not exclude children and adolescents from decision-making without persuasive rea-

sons. Indeed, some patients have specific legal entitlements to either consent or to refuse medical intervention. Although physicians should seek parental permission in most situations, they must focus on the goal of providing appropriate care and be prepared to seek legal intervention when parental refusal places the patient at clear and substantial risk.<sup>2</sup> In cases of serious conflict, physicians and families should seek consultative assistance and only in rare circumstances look to judicial determinations.

We now realize that the doctrine of "informed consent" has only limited *direct* application in pediatrics. Only **patients** who have appropriate decisional capacity and legal empowerment can give their **informed consent** to medical care. In all other situations, parents or other surrogates provide **informed permission** for diagnosis and treatment of children with the **assent** of the child whenever appropriate.

In this statement, the AAP provides an updated analysis of 1) the concept of informed consent; 2) the ethics of informed consent and the concept of the right to refuse treatment; 3) the concept of "proxy consent"; 4) the concepts of parental permission and child assent; and 5) informed consent of adolescents.

## CHANGES IN MEDICAL DECISION-MAKING

The authority to make medical decisions used to lie squarely in the hands of physicians. However, complex social changes have resulted in acceptance of the idea that patients have a right to know about their health, to know about available diagnostic and treatment options and their risks and probable benefits, and to choose among the alternatives.<sup>3</sup> Many now regard traditional practices based on the theory that "doctor knows best" as unacceptably paternalistic.<sup>4</sup> Society recognizes that patients or their surrogates have a right to decide, in consultation with their physicians, which proposed medical interventions they will or will not accept. Decision-making power or authority is increasingly seen as something to be shared by equal partners in the physician-patient or physician-surrogate relationship. For many patients and family members, personal values affect health care decisions, and physicians have a duty to respect the autonomy, rights, and preferences of their patients and their surrogates.<sup>5</sup>

## ETHICS AND INFORMED CONSENT

The doctrine of informed consent reminds us to respect persons by fully and accurately providing information relevant to exercising their decision-making rights. Experts on informed consent include

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The recommendations in this statement do not indicate an exclusive course of treatment or procedure to be followed. Variations, taking into account individual circumstances, may be appropriate.

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at least the following elements in their discussions of the concept:<sup>6</sup>

1. Provision of information: patients should have explanations, in understandable language, of the nature of the ailment or condition; the nature of proposed diagnostic steps and/or treatment(s) 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 decision(s).
4. Assurance, insofar as is possible, that the patient has the freedom to choose among the medical alternatives without coercion or manipulation.

The goals of this consent process include the development of the patient's comprehensive understanding of the clinical situation, and the timely exercise, by the patient, of active choices regarding the circumstances.<sup>7,8</sup>

#### INFORMED CONSENT AND THE RIGHT TO REFUSE TREATMENT

Health care providers should engage in the process of informed consent with patients before undertaking any medical intervention. Patients generally have a moral and legal right to refuse proposed medical intervention, except when the patient has diminished decision-making capacity or must undergo legally authorized "involuntary" treatment. Respect for competent patients' autonomy ordinarily extends even to the refusal or discontinuation of their own life-sustaining treatment.<sup>9</sup>

#### PROBLEMS WITH THE CONCEPT OF "CONSENT" BY PROXY

In attempting to adapt the concept of informed consent to pediatrics, many believe that the child's parents or guardians have the authority or "right" to give consent by proxy. Most parents seek to safeguard the welfare and best interests of their children with regard to health care, and as a result proxy consent has seemed to work reasonably well.

However, the concept encompasses many ambiguities. Consent embodies judgments about proposed interventions and, more importantly, consent (literally "to feel or sense with") expresses something for one's self: a person who consents responds based on unique personal beliefs, values, and goals.

Thus "proxy consent" poses serious problems for pediatric health care providers. Such providers have legal and ethical duties to their child patients to render competent medical care based on what the patient needs, not what someone else expresses. Although impasses regarding the interests of minors and the expressed wishes of their parents or guardians are rare, the pediatrician's responsibilities to his

or her patient exist independent of parental desires or proxy consent.<sup>10</sup>

#### PARENTAL PERMISSION AND SHARED RESPONSIBILITY

Decision-making involving the health care of young patients should flow from responsibility shared by physicians and parents. Practitioners should seek the informed permission of parents before medical interventions (except in emergencies when parents cannot be contacted). The informed permission of parents includes all of the elements of standard informed consent, as outlined previously.

Usually, parental permission articulates what most agree represents the "best interests of the child." However, the Academy acknowledges that this standard of decision-making does not always prove easy to define. In a pluralistic society, one can find many religious, social, cultural, and philosophic positions on what constitutes acceptable child rearing and child welfare. The law generally provides parents with wide discretionary authority in raising their children.<sup>11</sup> Nonetheless, the need for child abuse and neglect laws and procedures makes it clear that parents sometimes breach their obligations toward their children. Providers of care and services to children have to carefully justify the invasion of privacy and psychologic disruption that come with taking legal steps to override parental prerogatives.

#### THE DEVELOPMENT OF THE CHILD AS PERSON AND THE CONCEPT OF ASSENT

Decision-making involving the health care of older children and adolescents should include, to the greatest extent feasible, the **assent of the patient** as well as the participation of the parents and the physician. Pediatricians should not necessarily treat children as rational, autonomous decision makers, but they should give serious consideration to each patient's developing capacities for participating in decision-making, including rationality and autonomy. If physicians recognize the importance of **assent**, they empower children to the extent of their capacity.<sup>12</sup> Even in situations in which one should not and does not solicit the agreement or opinion of patients, involving them in discussions about their health care may foster trust and a better physician-patient relationship, and perhaps improve long-term health outcomes.

**Assent** should include at least the following elements:

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(s).
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. Regarding this

final point, we note that 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.

As children develop, they should gradually become the primary guardians of personal health and the primary partners in medical decision-making, assuming responsibility from their parents.

Just as is the case with informed consent, the emphasis on obtaining assent should be on the interactive process in which information and values are shared and joint decisions are made. The Academy does not in any way recommend the development of new bureaucratic mechanisms, such as "assent forms," which could never substitute for the relational aspects of consent or assent.

#### THE PATIENT'S REFUSAL TO ASSENT (DISSENT)

There are clinical situations in which a persistent refusal to assent (ie, dissent) may be ethically binding.<sup>13</sup> This seems most obvious in the context of research (particularly that which has no potential to directly benefit the patient).<sup>14</sup> A patient's reluctance or refusal to assent should also carry considerable weight when the proposed intervention is not essential to his or her welfare and/or can be deferred without substantial risk.

Medical personnel should respect the wishes of patients who withhold or temporarily refuse assent in order to gain a better understanding of their situation or to come to terms with fears or other concerns regarding proposed care. Coercion in diagnosis or treatment is a last resort.<sup>15</sup>

#### ETHICAL CONFLICT AND ITS RESOLUTION

Social forces tend to concentrate authority for health care decisions in the hands of physicians and parents and this tendency diminishes the moral status of children.<sup>12</sup> Thus, those who care for children need to provide for measures to solicit assent and to attend to possible abuses of "raw" power over children when ethical conflicts occur. This is particularly important regarding the initiation, withholding, or withdrawing of life-sustaining treatment.<sup>16,17</sup> Examples of mechanisms to resolve ethical conflicts include additional medical consultation(s); short-term counseling or psychiatric consultation for patient and/or family; "case management" or similar multidisciplinary conference(s); and/or consultation with individuals trained in clinical ethics or a hospital-based ethics committee. In rare cases of refractory disagreement, formal legal adjudication may be necessary.

#### LEGAL EMANCIPATION AND INFORMED CONSENT

The traditional notion of informed consent clearly applies to patients who have reached the legal age of majority, except when the patient has been determined to be incompetent. In addition, laws designate two settings in which minors have sole authority to

make health care decisions.<sup>11</sup> First, certain minors are deemed "emancipated" and treated as adults for all purposes. Definitions of the emancipated minor include those who are: 1) self-supporting and/or not living at home; 2) married; 3) pregnant or a parent; 4) in the military; or 5) declared to be emancipated by a court. Second, many states give decision-making authority (without the need for parental involvement) to some minors who are otherwise unemancipated but who have decision-making capacity ("mature minors") or who are seeking treatment for certain medical conditions, such as sexually transmitted diseases, pregnancy, and drug or alcohol abuse.<sup>18</sup> The situations in which minors are deemed to be totally or partially emancipated are defined by statute and case law and may vary from state to state.<sup>19</sup> Legal emancipation recognizes a special status (eg, independent living) or serious public and/or individual health problems that might not otherwise receive appropriate attention (eg, sexually transmitted disease).

#### PRACTICAL APPLICATIONS

The following illustrations may help practitioners when applying the concepts developed above. These examples are intended to provide a focus for discussion and clarification and do not suggest new legal standards for pediatric practice.

In cases involving the following kinds of medical care for infants and young children, the Academy encourages physicians to seek the **informed permission of the parents** before: 1) providing immunizations; 2) performing invasive diagnostic testing for a congenital cardiac defect; 3) beginning long-term anticonvulsant therapy to control a seizure disorder; 4) initiating serial casting to correct congenital "club-foot"; or 5) undertaking surgical removal of a "suspicious" neck mass.

Even in pressing situations, informed permission should be sought for actions such as performing a lumbar puncture to evaluate the possibility of meningitis. (In this situation, if parents deny permission for the procedure, one should obtain permission from the parents to initiate treatment based on reasonable clinical judgment, rather than delaying care or risking liability for performing the lumbar puncture without appropriate authorization).

In cases involving the following kinds of medical care for older school-age children, the Academy encourages physicians to seek the **assent of the patient** as well as the **informed permission of the parents**: 1) venipuncture for a diagnostic study in a nine-year-old; 2) diagnostic testing for recurrent abdominal pain in a 10-year-old; 3) psychotropic medication to control an attention-deficit disorder in a third grader; 4) an orthopedic device to manage scoliosis in an 11-year-old; 5) an "alarm" system to treat nocturnal enuresis in an eight-year-old; or 6) surgical repair of a malformed ear in a 12-year-old. In some cases, treatment may proceed over the objection of the patient. However, physicians and parents should realize that overruling the child may undermine their relationship(s) with the child.

In situations such as the following that involve

adolescents and young adults, the Academy encourages physicians to obtain the **informed consent** of the patient, in most instances: 1) performance of a pelvic examination in a 16-year-old; 2) diagnostic evaluation of recurrent headache in an 18-year-old; 3) a request for oral contraceptives for fertility control in a 17-year-old; 4) proposed long-term oral antibiotics administration for severe acne in a 15-year-old; or 5) surgical intervention for a bone tumor in a 19-year-old. Such patients frequently have decision-making capacity and the legal authority to accept or reject interventions, and, in that event, no additional requirement to obtain **parental permission** exists. However, the Academy encourages parental involvement in such cases, as appropriate.

Review of the limited relevant empirical data suggests that adolescents, especially those age 14 and older, may have as well developed decisional skills as adults for making informed health care decisions.<sup>20-22</sup> Ethical and legal factors, (ie, confidentiality and/or privacy), suggest that the physician involve parents after appropriate discussion with the adolescent elicits his or her permission to do so. In some cases in which the patient has no legal entitlement to authorize treatment, the physician may have a legal obligation in some jurisdictions to obtain **parental permission** or to notify parents in addition to obtaining the patient's consent. An adolescent's refusal of consent in cases such as these may well be legally (and ethically) binding. If "conflict resolution" fails, formal legal adjudication may be needed.

### CONCLUSION

A re-analysis of informed consent leads to the identification of important limitations and problems in its application to pediatric practice. Two additional concepts are needed: **parental permission** and **patient assent**. The American Academy of Pediatrics believes that in most cases, physicians have an ethical (and legal) obligation to obtain **parental permission** to undertaken recommended medical interventions. In many circumstances, physicians should also solicit a **patient assent** when developmentally appropriate. In cases involving emancipated or mature minors with adequate decision-making capacity, or when otherwise permitted by law, physicians should seek **informed consent** directly from patients.

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