Session 4. Informed Consent and Assent in Pediatrics

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Overview
Decision-making in pediatrics presents a multitude of challenges for children, parents, and physicians. The related yet distinct concepts of assent and consent are central to pediatric decision-making. While informed consent is largely accepted as a worthwhile principle in adult medicine, assent has been and continues to be mired in controversy. Unanswered questions include the actual definition of assent, how old children should be to assent, who should be involved in the assent process, how to resolve disputes between children and their parents, the relationship between assent and consent, the quantity and quality of information to disclose to children and their families, how much and what information children desire and need, the necessity and methods for assessing children’s understanding of disclosed information and the assent process itself, and finally, what constitutes an effective, practical, and realistically applicable decision-making model.

Participants will learn the components of assent and how it differs from informed consent or permission. Learners will identify the requirements for decision-making capacity and barriers that may influence a child’s ability to participate in decisions. Participants will recognize limitations on children’s decision-making rights as well as specific circumstances in which minors are the primary decision-makers related to their care. Learners will discuss approaches to balance disputes when children’s and parents’ preferences are in conflict. Participants will articulate a practical decision-making model that views assent as a process and establishes appropriate roles for children, their parents, and physicians.

Instructor’s Guide
- Case Summary
- Alternate Cases
- Learning Objectives
- Suggested Reading for Instructor
- Further Reading
- Case Discussion
- Conclusions and Suggestions

Case Summary
A 17-year-old has had Crohn’s disease for 5 years. Since diagnosis, he has had 3 flares, each manifesting with abdominal pain, bloating, oral intolerance, and intermittently bloody diarrhea. Flares have successfully been treated with mesalamine and corticosteroids. He had been compliant with maintenance medication (6-mercaptopurine) and with his treatment regimen until 3 months ago when he joined the varsity basketball team. He no longer takes his medication regularly and argues with his parents about his recent weight loss and abdominal symptoms. His mother reports that he minimizes his symptoms so that he can continue to play sports. He says he
just wants to “be a normal kid.” He does not think he needs any chronic medications to control his disease and asks that you respect his decision.

- As his physician, is this a decision you will allow him to make?
- How do you balance his goals with those of his parents and your own?
- How can you find a way to enable his parents to allow him to transition into control of his own health care management?
- Who ultimately is responsible for his care and health?
- How would this situation be different if he were 18 years old instead of 17?

Alternate Cases
1. A 13-year-old presents to your continuity clinic for the second time with a sexually transmitted infection. During the course of obtaining a thorough medical history she relates that she has had consensual sex with “many” sexual partners. Additionally, she admits to a history of sexual abuse by her mother’s former live-in boyfriend. Her mother does not know that she is sexually active and she emphatically demands that you treat her without telling her mother.

2. A precocious 12-year-old is seen in a local emergency department with acute onset nausea, vomiting, scrotal pain, and swelling. Testicular torsion is diagnosed. The emergency department physician informs him and his parents that surgical exploration is necessary to salvage the involved testis and that the pediatric surgeon is on her way. The child is visibly upset. He is quite emphatic that no “girl” touch him “down there.” Additionally, he does not want a lifelong scar and is afraid it will (sexually) disadvantage him in the future. Despite his parents’ insistence that he go ahead with the surgery, the child adamantly refuses. He states that forcing him to have surgery against his wishes is “assault” and he threatens to do “whatever it takes,” including physically resisting and calling a “lawyer” if necessary.

Learning Objectives
1. Understand the components of assent and how it differs from informed consent or permission.
2. Identify the requirements necessary for a child to possess decision-making capacity and barriers that may influence a child’s ability to participate in decisions.
3. Recognize limitations on children’s decision-making rights as well as specific circumstances in which minors are the primary decision-makers related to their care.
4. Discuss approaches to balance disputes when children’s and parents’ preferences conflict with one another.
5. Articulate a practical decision-making model that views assent as a process and establishes appropriate roles for children, their parents, and physicians.

Suggested Reading for Instructor


**Further Reading**


Spinetta JJ, Masera G, Jankovic M, et al. Valid informed consent and participative decision-making in children with cancer and their parents: a report of the SIOP working committee on
Case Discussion.

A 17-year-old patient with a chronic illness has requested that you respect his decision not to take required daily medication. In other words, he has asked that you recognize his capacity to make a medical decision. What is assent and how does it relate to decision-making capacity?

The goal of assent is to protect children’s rights (Erlen). The assent requirement, traced to the concept of respecting children as individuals, calls for the need to recognize and respect the wishes of children as they develop cognitively and mature (National Commission). Respecting a person means helping them to make choices that are as informed as possible. Above all else, assent is about respecting a child’s developing capacity (Bartholome). For assent to work, the physician must truly know the individual child. This demands an appreciation of the child’s developmental stage and recognition of his or her basic preferences. Parents possess knowledge of their child’s preferences and developmental stage and are ideally situated to assist the physician in acquiring information.

Understanding or capacity is a critical component of assent; a second and equally important facet of assent is the child’s desire to make decisions (Spinetta et al). A child should be included in medical decisions to the extent of his or her abilities and desire to be involved (Unguru et al, 2008). Children need to be encouraged by parents and physicians to communicate openly so that they may be active participants in the assent process. Shared decision-making empowers children to the extent of their capacity (Geller et al).

Capacity for decision-making is not an all or none phenomenon but rather a process that matures with time and experience. No single child experiences life, health, or disease in exactly the same way, and each child’s personal experiences with decision-making is unique. These experiences contribute to the child’s unique capacity for decision-making. Children of varying ages possess varying abilities to synthesize information and make decisions accordingly. Weithorn and Campbell showed that children aged 14 years and older are as competent as adults in making informed treatment decisions. Age alone does not indicate a child’s ability to understand. Knowledge, health status, anxiety, experience with decision-making, and each child’s unique values and cultural, familial, and religious background all play a role in children’s understanding of their situation and affect their ability to make decisions. Children who have made life decisions because of poor health (often resulting in more experiences and a greater role in decision-making) or because their parents have allowed them to seem better equipped to appreciate that their choices carry certain consequences and may have a greater understanding of what is required to assent to participate in medical (and research) decisions than a healthy child or a child who has been insulated from making decisions.
What are some of the barriers influencing a child’s ability to participate in decisions?
For assent to be valid, it must be voluntary. Children are particularly vulnerable to influences in medical consent or assent situations because of their physical, emotional, and financial dependency on adults (Grodin and Alpert) and because of their relative inexperience with health care–related decisions. Subsequently, rather than act with developing autonomy, minors may regress to dependency on significant others (Weithorn and Scherer, 1994). Although adolescents may possess the skills to make informed treatment decisions, they often lack perspective and life experience. As such, they are more likely to act impulsively and to focus on their current situation rather than the future. Minors must be guaranteed added protections ensuring their ability to provide voluntary and informed decisions.

Many parents feel that decisions concerning their ill child’s life belong to them, regardless of the child’s awareness or capacity (Bluebond-Langer et al). Some parents are not aware that it is acceptable to include their children in the decision-making process (Angst and Deatrick). Thus, it becomes the physician’s responsibility to broach the topic of children participating in decisions about their care. Ideally, physicians need to do this relatively early in discussions with families and should revisit the point periodically to ensure that a child’s increased decision-making parallels his or her developmental growth.

What criteria determine a child’s decision(s) as valid?
No universally accepted standard defines decisional capacity. Whether a person possesses decisional capacity depends on the type of decision and the risks and benefits involved. Capacity is linked to developing cognition and prior life experiences.

Decision-making capacity by children requires that the child possess the freedom to choose, the choice be reasonable and rational, and the child understand information that is relevant to the choice. Thus, prior to soliciting assent from a child, it is crucial that the physician assess the child’s level of understanding. This is one way to ensure that assent is significant and meaningful.

How can an appreciation for soliciting a child’s assent help you negotiate with this teenaged patient?
The process of obtaining a child’s assent requires several steps (American Academy of Pediatrics). The physician must help the patient achieve awareness of his condition; tell the patient what she can expect regarding diagnosis and treatment; assess the patient’s understanding; assess factors influencing patient responses (eg, undue pressure); and solicit the patient’s willingness to accept care.

This patient does not want to take medication because in his mind this is not what “normal kids” do. One way to help this patient is to help him to recognize that to be an effective player he needs to be healthy, and therefore he must take his medicine and adhere to his treatment plan.

How do you balance his goals with those of his parents and your own?
Children recognize their role in decision-making as intertwined with that of their parents and respect their parents’ input (Rossi et al; Unguru et al, 2010). Most children do not expect to make
decisions on their own; rather, they want to be involved (in the process) and for their opinions be respected. Shared decision-making helps children to clarify values and preferences (Geller et al).

The American Academy of Pediatrics (AAP) Committee on Bioethics encourages pediatricians to evaluate each child’s capacity for assent on an individual basis. Based on their development, children are encouraged to “provide assent to care whenever possible.” The AAP views assent as a process that ideally incorporates joint decision-making by all parties and endorses the view that discussion leads to the development of a meaningful relationship between a child and physician, and it is this aspect of assent that is paramount in the process.

Clinicians should make every effort to provide parents with the tools to allow their children to think independently. Doing so enables children to make reasoned and valid age-appropriate decisions knowing that they can rely on their parents to support these decisions. Children learn to make good, sound decisions with practice and by relying on those they trust. Parents and children may not be in a position to fully recognize the extent to which their relationship may serve to limit a child’s ability to make free or voluntary decisions. Thus, it is the physician’s responsibility, as the child’s advocate, to serve as a facilitator and to ensure that this process occurs.

**How does assent differ from consent?**

Informed consent is grounded in the notion of respect for persons. Autonomy is the right of a rational person to make his or her own decisions and provides a moral justification for the doctrine of informed consent. Capacity to consent requires the legal ability to form a valid contract and the psychological or developmental ability to make sound decisions. Hence, minors cannot give valid consent, but they may give assent. Assent empowers children to the extent of their capacity.

Consent for adults is based on the principle of autonomy, which in turn focuses on competence, a legal term. Assent, on the other hand, is better viewed as focusing on capacity, a developmental term.

Assent differs from consent in that while the willingness of a minor to accept treatment is an important consideration, it is exactly that—a consideration. Treatment often may proceed against the minor’s wishes if his or her parents consent. Thus, parental permission may trump assent and is legally binding.

**Are children ever allowed to make medical decisions on their own without parental oversight?**

Yes. Adolescents have legally been allowed to make medical decisions for specific conditions for nearly half a century. Legislation, referred to as medically emancipated minor acts, permits minors to seek treatment without parental permission for the diagnosis and treatment of sexually transmitted infections, sexual and substance abuse, contraception and pregnancy, and psychiatric problems (Sigma). States vary with regard to the extent of these exceptions and age at which they apply.

Minor treatment statutes, known as the mature minor doctrine, allow minors with adequate decisional capacity and understanding of their medical condition, the right to consent to treatment without parental permission. This doctrine applies only to specific medical decisions.
and varies by state. Age plays a role in mature minor doctrine, with 16 years being the common cutoff, but in some states minors as young as 14 are granted the right to consent to any medical treatment without parental consent.

Finally, minors who meet criteria for emancipation may consent to all aspects of their care and do not require parental permission. Emancipated minors include children who are married, active-duty military, or living on their own and managing their own finances.

**Who ultimately is responsible for this patient’s care and health?**
Legally, his parents are responsible. However, as an “almost adult,” he should be given increasingly greater responsibility for his care as is appropriate. It might be instructive to inform him that under the mature minor doctrine he can already make certain medical decisions for himself. Doing so might empower him.

**How can you find a way to enable his parents to allow him to transition into control of his own health care management?**
As he develops an appreciation of his disease with an understanding of its consequences and starts to take ownership of his care (as evidenced by improvement in medical parameters), his parents should start to relinquish certain aspects of his care while still remaining involved in an oversight capacity. Decision-making involving older children requires the patient’s assent and parental permission.

**How would this situation be different if he were 18 years old instead of 17?**
An 18-year-old is responsible for his health care decisions unless he is deemed lacking in capacity. If he lacks capacity, a health care surrogate is appointed. Ultimately, many 18-year-olds desire parental involvement in matters of health and as such, seek their parents’ input.

**What would a practical decision-making model with appropriate roles for children, their parents, and physicians look like?**
A strategy that accounts for a child’s developmental level as well as her unique medical background and history of decision–making, combined with familial preferences, is most appropriate.

A tangible model of assent gives children of any age choices (King and Cross). As children age and gain experience with decision-making, they are to be involved to a greater extent in decisions. Parents and physicians should evaluate a child’s decision-making prowess and designate a role that not only allows the child to make appropriate decisions but challenges her abilities.

This strategy results in 1 of 3 decision-making roles determined by the gravity of the decision to be made and the child’s capacity. Some decisions will be made exclusively by the child with minimal to no parental input; some decisions will place parents in a more central role while children will be “consulted” for their preferences; and finally, some decisions will be made exclusively by parents with children asked only to “ratify” the decision. For example, a child might have decisional priority for choosing how blood is to be drawn (eg, right or left arm, with or without a local anesthetic); the child could decide at what time of day a medication is taken but not refuse to take it; or the child could approve of a lifesaving intervention but not refuse it.
Giving children the option to decide respects them as persons with developing autonomy, allows them to learn from the decisions they make and improve on future decisions, and provides them with a sense of control and ownership that comes with making decisions related to one’s health.

Children, parents, and physicians need not be equal in status. Instead, it is vital that each party voice their desires and concerns (Bluebond-Langer et al). Parents need to understand the importance of listening to their children’s voice and consider what they say as meaningful. Children need to appreciate that decision-making is a joint endeavor. While their input will be factored into the final decision, it is not theirs alone to make, nor will it necessarily be binding. Thus, physicians, by establishing ground rules and intervening when and where appropriate, are able to shoulder some of the burden, easing what is a potentially contentious and stressful time for children and parents.

**Suggested Reading for Instructor**

**Conclusions and Suggestions**
Children’s understanding and their preference for being included in decisions about their care are essential components of assent.

Shared decision-making among children, parents, and pediatricians is a strong foundation on which to base assent.

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