

Session 3. Informed Consent and Assent in Clinical Pediatrics

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Overview

Decision making in pediatrics presents a multitude of challenges for children, parents, and physicians alike. The related, yet distinct, concepts of assent and consent are central to pediatric decision making. Although 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 a child should be to provide meaningful 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 both children's understanding of disclosed information and of the assent process itself, and finally, what constitutes an effective, practical, and realistically applicable decision-making model.

Instructors Guide:

- Case Summary
- Alternative Cases
- Learning Objectives
- Suggested Reading for Instructor
- Further Reading
- Case Discussion
- Conclusions and Suggestions

Case Summary

Josh, a 17-year-old, has had Crohn's disease for 5 years. Since diagnosis, Josh 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. Josh had been adherent 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 he argues with his parents about his recent weight loss and abdominal symptoms. Josh's mother reports that he minimizes his symptoms so that he can continue to play sports. Josh 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 Josh's physician, is this a decision you will allow him to make?
- How do you balance Josh's goals with those of his parents' and your own?
- How can you find a way to enable Josh's parents to allow him to transition into control of his own health care management?
- Who ultimately is responsible for Josh's care and health?
- How would this situation be different if Josh were 18 instead of 17?

Alternative Cases

1. Kathy is a 13-year-old who 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. Kathy's mother does not know that she is sexually active and Kathy emphatically demands that you treat her without telling her mother.
2. David, a precocious 12-year-old, is seen in a local emergency department with acute onset nausea, vomiting, and scrotal pain and swelling. Testicular torsion is diagnosed. The emergency room physician informs David and his parents that surgical exploration is necessary to salvage the involved testis and that the pediatric surgeon is on her way. David is visibly upset. He is quite emphatic that no "girl" touches 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, David 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 and parents' preference conflict with one another.
5. Articulate a practical decision-making model that portrays assent as a process and establishes appropriate roles for children, their parents, and physicians.

Suggested Reading for Instructor

Erlen JA. The child's choice: an essential component in treatment decisions. *Child Health Care*. 1987;15(3):156-160

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Further Reading

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Case Discussion

Josh is a 17-year-old patient with a chronic illness who 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?

Assent is an interactive and ongoing process between a child and a clinician (or a researcher) wherein developmentally relevant information is disclosed about a particular intervention. During the assent process, the child is engaged and his or her input is sought. The goal of assent is to protect children's rights¹ by allowing them to voice their preferences when it is appropriate to do so. 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.² Respecting a person means helping him or her to make choices that are as informed as possible. Above all else, assent is about respecting a child's "developing capacity."³ 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.⁴ A child should be included in medical decisions to the extent of his or her abilities and desire to be involved.⁵ 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 capacity⁶ and in doing so, promotes their values, interests, and abilities.⁷

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 to make decisions accordingly. Weithorn and Campbell showed that children 14 years and older appear to be as capable as adults in making informed treatment decisions. Common Law in some states (eg, Tennessee) adopt a similar approach based on the so-called "Rule of Sevens," by which minors 14 years and older have presumed capacity for making medical decisions (*Cardwell v. Bechtol*). Hein and colleagues suggested that children as young as 9.6 years may be competent to consent to participation in clinical research.⁸ This finding is of particular interest, as most experts agree that assent (and consent) for research participation requires a more sophisticated and nuanced decision-making capacity than assent (consent) for clinical care.⁹

Although at least one study found that children's age and intelligence were the sole determinative factors influencing ability to provide consent to clinical research (Hein 2015), age alone does not reliably identify a child's ability to understand. Knowledge, health status, anxiety, experience with decision-making, and each child's unique cultural, familial, religious background, and values all play a role in children's understanding of their situation and affect their ability to make decisions. Children who, either because of poor health (often resulting in more experiences and a greater role in decision making) or whose parents have allowed them to make "life decisions," seem better equipped to appreciate that their choices carry certain consequences and insomuch they 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 whose parents have insulated them 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/assent situations because of their physical, emotional, and financial dependency on adults¹⁰ 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.¹¹

Emerging data from the field of neurobiology has compelling implications for both children's and adolescents' ability to meaningfully participate in medical decisions.^{12,13,14,15} Although adolescents possess the *ability* for adult-like decision making, this does not necessarily translate into *actual* adult-like decisions. Utilizing imaging techniques such as functional magnetic resonance imaging (fMRI) and neuropsychological evaluations, researchers have shown that the adolescent brain differs from the adult brain in substantive ways.¹⁶ This difference is largely the result of so-called, "back-to-front" development, where the brain's limbic structures mature years before the prefrontal cortex. As a result of this neurodevelopmental process, adolescents tend to have more developed socioemotional faculties that reside in the "back of the brain" than cognitive ones that are features of frontal brain regions. In fact, the prefrontal cortex, which is responsible for executive function, planning, organization, and weighing risks versus rewards, is the last to mature and is not fully developed until the mid-to-late 20s.

As a result, adolescents are more prone to peer and parental pressure, they tend to focus on the present rather than the future, they often act impulsively and based on instinct, and they are poor judges of risk versus reward. In fact, when the stakes are high and emotions are charged, as may occur during times of an illness or when in the company of peers, evidence suggests that adolescents have a difficult time engaging the cooler and more rational parts of their brain and are more prone to act rashly, without appropriately weighing all aspects of a decision. Ultimately, this occurs as a result of a more developed limbic system and less than fully developed prefrontal cortex.

Importantly, this does not, however, suggest that adolescents are incapable of participating in medical decisions. When emotional arousal and the influence of peers is minimized, adolescents are likely as capable as adults in making medical decisions.¹³

Thus, adolescents often possess the skills to make informed treatment decisions, yet they are neurodevelopmentally constrained and may 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. Accordingly, minors must be guaranteed added protections ensuring their ability to provide voluntary and informed decisions.

Many parents believe that decisions about what to do concerning their ill child's life is theirs to make, regardless of the child's awareness or capacity.¹⁷ Some parents are not aware that it is acceptable to include their children in the decision-making process.¹⁸

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 on in discussions with families and should revisit the point periodically to assure that a child's increased decision-making parallels their developmental growth.

What criteria determine a child's decision(s) as valid?

No universally accepted standard defines decisional capacity. A wide variation in adolescent medical decision-making practice exists; for example, Portugal and Denmark allow minors as young as 14 and 15 years, respectively, to make medical decisions. In Switzerland and many parts of Canada, medical decision making by children is determined on a case-by-case basis. In the United States, individual states decide the types of medical decisions adolescents of various ages can make, with some states allowing minors as young as 14 years to make certain decisions and other states requiring a threshold of at least 18 years to participate in medical decisions.¹⁹ Whether a person possesses decisional capacity depends on the *type* of decision and the *risks and benefits* involved. What is clear is that children develop capacity in stages and children of differing ages have different abilities. Capacity is linked both to developing cognition and to prior life experiences. Depending on the gravity of the decision and its consequences, many experts agree that a threshold level of capacity is a useful framework to assist in adolescent decision making where a high threshold be utilized for particularly meaningful decisions (eg, refusing a life-saving therapy) while a lower threshold be tolerated for less consequential decisions.

Decision-making capacity by children requires that the child possess the freedom to choose, that the choice must be both reasonable and rational, and that the child must understand information that is relevant to his or her choice. Thus, prior to soliciting assent from a child, it is crucial that the physician assess the child's level of understanding, which includes an appreciation not only for the consequences of a given action, but consequences that may result by *not* acting. This is one way to ensure that assent is significant and meaningful.

Methods to assess understanding are underutilized and should be employed when evaluating the veracity of a child's decision-making prowess. These can include such techniques as the "talk-back" method wherein using her own words, the minor explains the process by which she reached a decision. Alternatively, a brief questionnaire or assessment tool may prove helpful.^{8,20} The ideal evaluation tool should account not only for the child's rational and cognitive abilities, but also for the influence of socioemotional factors.

How can an appreciation for soliciting a child’s assent help you negotiate with this teenage patient?

The process of obtaining a child’s assent requires several steps.²¹ The physician must (1) help the patient achieve awareness of his or her condition; (2) tell the patient what to expect regarding diagnosis and treatment; (3) assess the patient’s understanding; (4) assess factors influencing patient responses (ie, undue pressure); and (5) solicit the patient’s willingness to accept care.

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

How do you balance Josh’s 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.^{20,22} 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.^{6,7} Additionally, shared decision making between children and adults (parents), coined “collaborative paternalism,”²³ has been shown to yield many positive benefits including improved academic performance and less risky behaviors—for example, substance abuse and criminal activities (Partridge).¹⁶

The American Academy of Pediatrics (AAP) encourages pediatricians to evaluate each child’s capacity for assent on an individual basis.²⁴ Based on their development, children are encouraged to “provide assent to care whenever possible” (Committee on Bioethics 1995). The AAP views assent as a process that ideally incorporates *joint decision making* by all parties. The AAP 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.

As advocates for children, pediatricians have a responsibility to foster children’s evolving capacities. Accordingly, pediatricians 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 *and* to ensure that their parents will (mostly) protect them from the consequences of unwise 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 on the notion of respect for people. 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.

In research settings, unless the specific research intervention is the sole prospect for directly benefiting the child, a child's assent and dissent are more determinative than assent in clinical contexts.³⁰

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

Despite recent calls by several contributors questioning minors' abilities to make meaningful decisions,^{14,25} adolescents have *legally* been allowed to make medical decisions for specific conditions for nearly half a century. One of the reasons for the apparent disconnect between the medical and legal approaches to minors as decision makers is the prevailing wisdom among many in the medical community that emphasizes a developmental and neurobiological approach for adolescents' evolving capacity, whereas the legal community largely favors a political theory of constitutionalism.²⁶ All 50 states have legislation that permits minors to seek treatment without their parents' permission for sexually transmitted infections, sexual and substance abuse, contraception and pregnancy, and psychiatric problems.²⁷ These laws vary somewhat with regard to the specific situations and ages in which they apply.²⁸

All states also have mature minor doctrines, which allow minors who have been found by the appropriate state body to possess *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 in terms of who can make this determination and the age at which it can be made. Age plays a role in mature minor doctrine, with 16 years being the common cutoff, but in some states, minors as young as 14 years can be granted the right to consent to any medical treatment without parental consent. The process by which an adolescent may be recognized as a mature minor varies by state.

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 either (1) married; (2) active-duty military; or (3) living on their own *and* managing their own finances.

Who ultimately is responsible for Josh’s care and health?

Legally, his parents; however, as an “almost adult,” Josh should be given increasingly greater responsibility for his care as is appropriate. It might be instructive to inform Josh that he can already make certain medical decisions for himself. Doing so might empower him.

How can you find a way to enable Josh’s parents to allow him to transition into control of his own health care management?

As noted by the AAP and other professional medical organizations, parents and providers have a role in helping adolescents’ transition to become autonomous adults capable of making responsible and appropriate medical decisions.²⁹ Thus, as Josh develops an appreciation of his disease with an understanding of its consequences and as he 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 Josh were 18 instead of 17?

Were Josh 18, unless he was deemed lacking in capacity, he would be responsible for health care decisions in most states. If he lacked in capacity, then a health care surrogate would be appointed. Ultimately, many 18-year-old adolescents (and young adults) 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 his or her unique medical background and history of decision making combined with familial preferences is most appropriate.

A tangible model of assent gives children of all ages choices (King). 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 then designate a role that not only allows the child to make appropriate decisions but that also challenges their abilities.

This strategy results in one 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 the parents in a more central role while children will be “consulted” for their preferences, and finally, some decisions will be made exclusively by parents and children will be asked only to “ratify” the decision.

For example, (1) a child might have decisional priority for choosing how blood is to be drawn (ie, right or left arm; with or without a local anesthetic); (2) the child could decide at what time of day a medication is taken, but not refuse to take it; and (3) the child could approve of a life-saving intervention, but not refuse it. Giving children the option to decide respects them as people with developing autonomy, it allows them to learn from the decisions they make and to improve on future decisions, and it 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 his or her desires and concerns (Bluebond-Langer). Parents need to understand the importance that they listen to their children’s voice and consider what they say as meaningful. Children need to appreciate that decision making is a joint endeavor and while their input will be factored into the final decision, it is not theirs alone to make, nor will it necessarily be binding. Thus, the physician, by establishing ground rules and intervening when and where appropriate, is able to shoulder some of the burden, easing what is a potentially contentious and stressful time for both children and parents.

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 between child, parent, and pediatrician is a strong foundation on which to base assent.

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