American Academy of Pediatrics
Bioethics Resident Curriculum:
Case-Based Teaching Guides

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ACKNOWLEDGMENTS

The idea for this curriculum was originally conceived in a brainstorming session within the American Academy of Pediatrics (AAP) Section on Bioethics Executive Committee. When the idea of a case-based teaching guide for residency training programs was initially presented to the Committee on Bioethics it was wholeheartedly and enthusiastically embraced. So from its earliest inception this has truly been a collaborative effort within the AAP. As editors, we are deeply grateful to each of the authors for their willingness to work with us and for their stimulating cases and thoughtful discussions. Without their commitment to addressing the critical need for resources in bioethics education, we would not have been able to develop this teaching guide.

We are truly grateful for the wonderful editorial help received from Brenda Mears, MD, FAAP. In addition to all the other work Brenda does for the Section on Bioethics, she gave untold hours to assist with editing and also included hyperlinks to AAP policies and wherever possible the references cited in this curriculum. Her work has significantly enhanced the ease with which instructors can get to reference material they need.

This project would not have gone forward without the administrative assistance of Anjie Emanuel, AAP staff contact for the Section on Bioethics, and Alison Baker, AAP staff contact for the Committee on Bioethics. They kept us on task, providing superb organizational support and timely and helpful advice whenever we needed it.

Mark would like to thank his wife, Anna, for her support, patience, and encouragement that made this and so many other professional projects possible. Doug would like to thank his wife, Susan, for her support and encouragement, and his children, Nathan and Katie, for their inspiration and patience. Mary would like to thank her husband, Rod, for his support and encouragement that allowed her the flexibility to pursue this project in the midst of transitioning their lives and work to Africa.

Suggested Citation

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Dear Educators,

The American Academy of Pediatrics (AAP) Section on Bioethics and Committee on Bioethics have together responded to the need for bioethics education in pediatric training programs. We have developed a case-based modular curriculum designed to function as a how-to resource for residency and fellowship training programs. These instructor guides are aimed at assisting pediatric faculty in helping trainees develop basic competencies in bioethics.

The modules review relevant resources and identify current debates important in the teaching of bioethics to medical trainees. Each module contains references to AAP policies with links to these documents. References are separated into “Suggested Reading for Instructor” and “Further Reading,” allowing instructors to efficiently identify pertinent resources on the topic. No specific order of priority is intended. Instructors should feel free to pick and choose topics to fit their individual institution’s needs. Redundancy within and among these modules is intentional.

We recognize that the demands of medical training dictate that residents are unlikely to be available to attend all the sessions. Therefore, important concepts are repeated with a different emphasis. For example, many of the concepts in Session 4, “Informed Consent and Assent in Pediatrics,” are repeated in Session 10, “Autonomy, Beneficence, and the Rights of Parents and Children: Exploring the Application of Ethical Principles in Pediatrics.” However, in Session 10, the focus of informed consent and the principle of respect for persons are set in the context of adolescent decision-making.

Many modules have alternate cases listed. Most of these alternate cases do not contain a question-by-question discussion. This is intentional. Alternate cases are presented to provide potential material for faculty wishing to dig deeper into the topic or pursue additional perspectives. The discussion presented in the question-and-answer format of the primary case yields sufficient material to provide a background if faculty wish to use alternate cases.

There are multiple analytic methods or theoretical models available in clinical ethics. These teaching guides use a variety of different analytic methods for the different cases. These different analytic methods serve as a starting point for ethical reflection and can assist in organizing the medically and morally relevant questions intrinsic to any ethical inquiry. Familiarity with different approaches is useful, and a variety of different approaches are used in different modules. The approaches include but are not limited to principle-based ethical theories like the Beauchamp and Childress framework of autonomy, beneficence, nonmaleficence, and justice, or the European approach to principlism that emphasizes the primacy of patient welfare, patient autonomy, and principle of social justice. Non–principle-based ethical theories are also used in some modules. Examples include the ethics of care, which evaluates the moral dimension of relationships with others; communitarian ethics, which places a value on the health of the community and can override autonomy; virtue-based approaches that place more emphasis on the character of the person preforming the action than on the action itself; and feminist ethics, which uses the ideas of feminist theory to evaluate ethical issues from a gender-based perspective. All analytic methods have some value in helping elucidate aspects of a case. Even though some modules use only one theoretical model in the discussion, it is not our intention to present any single analytic method or theoretical model as the only right way to approach ethical issues.
Individual faculty may wish to use these teaching guides to inform and develop active participation opportunities for trainees. We wholeheartedly support this! The case-based teaching guides use a question-and-answer format that easily facilitates the development of learner-centered small group activities. Active participation ideas include role-plays, interactive lectures, small group discussions, and brainstorming sessions. Using these teaching guides to develop and implement active participation may provide trainees valuable opportunities to examine their own attitudes and values. It is helpful for trainees to determine the degree to which they have potential to be coercive or disrespectful to a family who holds a different opinion from their own. This potential for personal examination is particularly relevant in cases found in Session 2, “Religious, Cultural, and Philosophical Objections to Care,” and Session 14, “Maternal-Fetal Conflict,” but can certainly be identified in every module. Using these teaching guides to develop active learning opportunities for the practice of skills necessary for ethical discourse with families and colleagues is encouraged. Role-plays could even be used to assess a resident’s ethical competency in post-learning evaluation. That said, we recognize each institution has needs that are unique; therefore, the presentation of the material in each module is structured to be a self-contained unit to allow maximum flexibility in implementation.

No student guide has been developed at this time. However, we think the material, as it is presented, is accessible to residents and medical students who want to grow in their understanding of bioethics. The addition of other topic areas is the first priority of the section and committee. We see this compilation of topics as a first step, not the final step, in providing resources to training programs.

These modules and cases presented in them are not intended to direct outcomes in resolving ethical dilemmas instructors or trainees encounter. In addition, case discussions do not represent a consensus opinion of the AAP. They have been authored and edited by various members of the AAP Section on Bioethics, resulting in some degree of stylistic and analytic variation. Cases are meant to provide a platform for discussing important principles and build a foundation for ethical reflection. Many cases are provocative and those with whom you work and teach may have different impressions of what the best outcome would be. This is realistic because the questions we face in the practice of pediatrics are not simple. Ethical engagement in real life requires decision-making in the face of medical uncertainty as well as moderating conflicts between interested parties who may have different opinions on what the most desirable outcome is.

We trust you will find these modules beneficial as we work together to incorporate bioethics into pediatric education.

Sincerely,

The Editors
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Session 1. Ethics Education and Available Resources

Douglas J. Opel, MD, MPH, FAAP

Overview
Bioethics is relevant to every practicing clinician. Whether it is in the form of a doctor’s duty to his or her patient to maximize benefit and minimize harm or including a patient’s or family’s values in clinical decision-making, medical practice includes a moral component. Bioethics education has therefore been made a priority in medical training programs, and faculty are often called on to give formal and informal ethics teaching. How should bioethics education be approached? What are the goals of bioethics education? What bioethics resources are available to attending pediatricians to help facilitate and promote bioethics education among residents and fellows?

This module highlights the importance of bioethics education in pediatric training and the resources needed to become involved in ethics education. It reviews the goals of bioethics education and discusses research that has evaluated bioethics educational interventions. Participants will learn general approaches to bioethics curricula for pediatric residents and fellows. Participants will also review the available resources in bioethics and identify current debates in the teaching of bioethics to medical trainees.

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

Case Summary
You are the primary preceptor for several residents in a busy outpatient primary care clinic. Over the course of several years, despite what you perceive as an increased prevalence of ethical issues in the clinic setting, you feel that the residents are less attuned to them. Instead, you have noticed that the residents’ focus has shifted to cases about death and dying and other tragic scenarios in the inpatient setting. You decide that you would like to develop an outpatient ethics curriculum for your residents that would explore ethical issues in everyday clinic encounters.

- Is this time well spent? Don’t residents get more than enough ethics education?
- What bioethics educational resources are available to help develop a curriculum?
- Are there models for effective bioethics curricula?
- What should the general goals be for bioethics education?
• Will this make a difference? What outcomes have been improved as a consequence of bioethics education?

Alternate Cases
1. The chief pediatric resident asks you to join her in leading a session with a number of residents who have been involved in the care of an 18-year-old girl with anorexia. The residents are frustrated with how to handle this patient’s continued refusal of recommended treatment. You have been the emergency department attending the last few times this patient has come in, and the chief resident would like you to provide a synopsis of the ethical dimensions of this case to start off the discussion. The meeting is tomorrow and you are on the night shift tonight. Furthermore, you don’t feel very qualified to give an ethics talk. How and where do you begin?

2. You are the coordinator for the pediatric resident noon conference lecture series. The residency director e-mails you in a panic asking for your help in meeting the Accreditation Council for Graduate Medical Education (ACGME) core competency for professionalism. The ACGME site visit at the institution is next month. You agree to help, but despite your interest in resident education, you have no experience developing a formal ethics curriculum.

Learning Objectives
1. Understand the goals and outcomes of bioethics education.
2. Describe the current state of bioethics education in pediatric residency training.
3. Identify current bioethics curricula for pediatric residents.
4. Describe 2 aspects of bioethics education that are presently being debated.

Suggested Reading for Instructor


Further Reading


Case Discussion

What is the current state of pediatric resident education in bioethics? What is the current state of fellowship bioethics education?

Despite the existence of an ACGME requirement since 1997 that all residency programs must provide educational experiences for residents to demonstrate knowledge, skills, and attitudes in professionalism—as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population—45% of pediatric residents queried in a 2004 study rated their ethics education as fair to poor (Kesselheim et al). This finding is even more surprising in light of the fact that most pediatric residency training programs have standardized bioethics curricula. Informal discussions with supervising attending physicians were rated by pediatric residents as being the most influential on their ethics education; however, more than half of the residents surveyed also found formal ethics teaching conferences to be influential (Kesselheim et al). There are little data on the extent to which bioethics education exists in pediatric subspecialty fellowship programs, but there is increased recognition among neonatology fellowship programs that formal ethics curricula are needed (Salih and Boyle).

Why is bioethics education considered to be important?

Focus here on the moral component of medicine. Every physician–patient encounter has a moral dimension (Carrese and Sugarman). For instance, clinical decision-making involves the consideration of patient and family values. Recognizing these values and incorporating them into decision-making requires knowledge and skill in ethics. Other examples of the intrinsic nature of ethics in medicine include the physician’s ethical and professional duties. Physicians take an oath
to “do no harm.” In doing so, they are obligated in every clinical situation to provide care that benefits the patient and minimizes harm. This too requires ethical sensitivity.

**It would be important to first understand what the goals of a bioethics curriculum should be. Besides meeting the ACGME core competency requirement in professionalism, what other goals should one consider?**

Emphasize education goals that include acquisition of knowledge of analytic methods and skills as well as awareness of ethical issues encountered in medicine and pediatrics. There are published goals for ethics education that include these goals and provide additional ones, such as understanding the core ethical principles and values of the medical profession, demonstrated competence in core bioethics behavioral skills, appreciation of cultural diversity and its relationships to bioethics, and willingness and ability of faculty to teach clinical bioethics to medical students and trainees in clinical settings in real time (Carrese and Sugarman).

There are several analytic methods or theoretical models available in clinical ethics. None has been deemed the “right” approach and all have value. It might be helpful for clinicians to familiarize themselves with one of the analytic methods in bioethics and use it consistently. One common approach is called the 4-box method (Jonsen et al). This approach draws on 4 features of the case in question to help clarify underlying ethical issues: medical indications, patient preferences, quality of life considerations, and contextual features.

**If I’m looking to develop a bioethics curriculum, it would be nice to have a starting point. What bioethics curriculum models are available?**

There are published curriculum models for pediatric resident ethics education. The first published curriculum was from the pediatric training program at the University of Washington School of Medicine (Diekema and Shugerman). Other published examples include the curricula of Children’s Hospital Boston and the University of California, Davis. For members of the American Society for Bioethics and Humanities, the Syllabus Exchange Project of the Task Force on Graduate Medical Education on Bioethics and Humanities has posted several other curricula (www.asbh.org/membership/task_force/asbh.html).

**What are some other available bioethics resources to help develop the content of a curriculum?**

Medical literature contains numerous empirical and conceptual articles on bioethics topics; see “Suggested Reading for Instructor” for a few related to bioethics education. The American Board of Pediatrics offers an annotated bibliography of bioethics references, updated regularly, intended to promote familiarity with bioethics topics and problem solving. This bibliography is available for download (https://www.abp.org/ABPWebSite/resident/bioethics.htm). There are numerous other Web-based bioethics resources. Recommended links include the following:

- American Academy of Pediatrics Section on Bioethics (www.aap.org/sections/bioethics/default.cfm)
- Bioethics Research Library at Georgetown University (http://bioethics.georgetown.edu)
- The American Journal of Bioethics (http://bioethics.net)
- Pediatric Ethics Consortium (www.pediatricethics.org)
Does bioethics education actually make a difference? What positive outcomes have been associated with bioethics education?

Despite the aforementioned reference that found residents to be dissatisfied with their ethics education, education interventions in ethics have proven to be successful in improving several measurable outcomes. For instance, investigators performed a randomized trial comparing the effects of 3 ethics education interventions (control versus ethics lecture series versus ethics lectures series plus case discussions with an ethicist in attendance) involving 85 internal medicine residents and found that residents who received ethicist-mediated educational intervention were more confident addressing ethical issues and procedures with ethics dimensions (Sulmasy et al). In other studies, awareness and knowledge of ethics issues as well as ethical decision-making have all been shown to improve with ethics educational interventions.

What are some current debates about how to teach bioethics?

Bioethics teaching has historically focused on tragic cases encountered in the inpatient setting (Liaschenko et al). Not as much attention has been focused on the ethical dilemmas that arise in less dramatic settings, such as in routine encounters in a primary care clinic. There has been a movement over the last few years to not only better understand everyday ethics issues that pediatric residents encounter (Moon et al) but develop approaches that help residents learn how to navigate these ethical issues. Another interesting debate concerns the effectiveness of using instructor-generated cases versus resident-generated cases. Many curricula use instructor-generated cases, but there may be utility to increasing the number of resident-generated cases in curricula (Kon).

Conclusions and Suggestions

Bioethics education is an important part of pediatric residency training. There are numerous resources and curricula available to help in the development and augmentation of bioethics educational interventions.

This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 2. Religious, Cultural, and Philosophical Objections to Care

Douglas S. Diekema, MD, MPH, FAAP

Overview
Responding to a parent’s refusal of medical care based on religious, cultural, or ethical considerations presents complex challenges. Physicians must balance respect for the parent’s wishes and legal rights with the child’s well-being. What are the limitations on a parent’s right to refuse treatment for a child? What are the steps a physician must take to justify involving state agencies to compel treatment? How does a physician resolve conflicts between the parent’s values and those of the medical profession?

This module will explore the ethical issues that arise when the values of parents and health care professionals come into conflict over health care decisions. Participants will learn the components of informed consent or permission and understand the limitations of a parent’s right to refuse treatment for a child. Participants will discuss the steps to take to justify involving state agencies to compel treatment for a child and identify strategies to resolve conflicts between the values of a parent and the medical profession.

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

Case Summary
A 4-year-old presents to the emergency department with a 3-cm laceration sustained while walking around in a friend’s backyard. The wound is moderately dirty. The child’s mother agrees to have the wound irrigated and sutured. She says she believes in naturopathy and will not permit antibiotics or immunizations. The child has had no tetanus immunizations.

- Is this a decision that you will permit the mother to make?
- How do we decide when it may be necessary to interfere with a parental decision?
- If you decide that a parental decision places a child in danger, what are your options?
- Under what conditions would you feel compelled to call child protective services or obtain a court order to compel treatment?
- Does it matter if the basis for the parental decision is religious, cultural, or something else?
Alternate Cases
1. Jeffrey Beagley and his wife, Marcie, belong to a small religious sect called the Followers of Christ church. They believe in divine healing and do not seek medical care for their children when illness strikes. Instead, they spend much time in prayer and, for serious illnesses, may use anointing or laying on of hands.

The Beagleys have 3 children and they take good care of them. Marcie did not receive prenatal care from a physician, and the children have not seen a physician. Their oldest daughter is married. In early 2008, their only son, 16-year-old Neil, began to experience symptoms that included lassitude, decreased appetite, and occasional nausea and abdominal pain. These symptoms were intermittent. Neil’s parents gave him the option of seeing a physician, but he refused on the grounds that his faith would be sufficient to heal him. Neil felt considerably worse in June, leading his family to begin a vigil with church members that involved prayer and laying on of hands. One night in June, after spending 2 days in bed and amidst nearly constant prayers, Neil suddenly became unconscious and died. An autopsy revealed a very advanced stage of chronic renal disease that was probably the result of untreated posterior urethral valves.

2. A 5-year-old Hmong child has a cleft palate causing severe speech impairment. The family refuses surgical repair. The pediatrician considers this neglect and is seeking a court order. (Should cultural differences be respected in decisions about health care for children? Is this different from a Christian Scientist refusing treatment for meningitis?)

Learning Objectives
1. Understand the components of informed consent or permission.
2. Understand the limitations of a parent’s right to refuse treatment for a child.
3. Identify the steps one must take to justify involving state agencies to compel treatment of a child.
4. Recognize the conflict between the parent’s values and those brought to the situation by medical professionals and identify strategies for resolving this conflict.

Suggested Reading for Instructor


Further Reading


**Case Discussion**

**What is best for the patient?**

This patient has sustained a wound that you would consider dirty and at risk of tetanus. Normally this would result in a recommendation for tetanus vaccine and immunoglobulin. Given the contamination of the wound, you would also recommend antibiotics. The child’s mother declines all of those treatments because of her naturopathic beliefs. Should she be allowed to make that decision?

Emphasize that simply having established what you think is best for the patient does not establish that a parent who disagrees with you can have her refusal of treatment overridden. The first question is about what you think is best for the child. The second question is about what authority you have to interfere with the choice of a parent.

**What is your authority in this situation?**

Except in emergency situations in which a child’s life is threatened imminently or a delay would result in significant suffering or risk to the child, a physician cannot do something to a child without the permission of the child’s parent or guardian. Touching (or administering a medication or vaccine) without consent is considered battery under the law.

**Assuming you have not been successful in changing the mother’s mind, what are your options?**

Only the state can order a parent to comply with medical recommendations. The physician’s options include tolerating the parent’s decision (while continuing to try to convince her to act otherwise) or involving a state agency. This can take different forms but most frequently includes involvement of child protective services (ie, making a claim of medical neglect) or a court order. Both of these will generally be perceived as adversarial by parents and may permanently alter the physician’s relationship with the family.

**How do we decide whether a parent has exceeded her authority in making a medical decision for her child? What are the limits of parental authority to refuse a medical intervention? In**
other words, what is the threshold for when we should involve state agencies in a case like this?
When a parent’s decision places a child at *significant* risk of *serious* harm, the parent has exceeded her authority.

**How much risk is too much for a parent to subject a child to? Does it matter how great the potential harm is?**
Harm must be more than trivial. Generally, harm must be serious.

**Does it matter how likely the harm is?**
Risk of harm must be significant, not simply a possibility. The threshold in this case is lower if this is a grossly contaminated wound as opposed to a cut with a clean kitchen knife.

**Does it matter how imminent the harm is?**
In this case, the harm is not imminent in the sense that something needs to be done immediately. But there is a time beyond which immunization and immunoglobulin administration would no longer be effective in preventing tetanus. Thus, in this case we have a day or 2 to try to work with this family but not much more than that.

**Does it matter whether the recommended treatment is accompanied by the potential for significant toxicity or side effects or risks?**
It does matter because it is the overall balance between harm and risk of the proposed intervention that must be considered. If a treatment is accompanied by significant risk of serious harm, the threshold for seeking state power to administer the treatment against parental wishes becomes higher and requires a higher likelihood that the intervention will result in an important benefit to the child.

Compelling any treatment should also require that one demonstrate evidence that it is likely to benefit the child. There is an important difference between proven efficacy (data-based) and convention (“it’s standard of care”) when one is attempting to force parents to accept an intervention.

The usual ethical concepts of harm, benefit, and best interests are value-laden. What seems to be minimal harm to many medical professionals may seem like a huge harm to those with different belief systems. What counts as significant is very personal.

Judgments in medicine about efficacious care are often based on minimal data and can change with time. Some evidence-based standard of likelihood of benefit should be required to override a parent’s assessment of what would be best for the child.

**Would it matter if the parents were Christian Scientists and they were refusing immunization, immunoglobulin, and antibiotics because consent would violate their religious belief (in contrast with a nonreligious belief like naturopathy)?**
The constitution requires that the government not interfere with religious practice or endorse particular religions. The government also has an interest in protecting children and innocent third parties.
Freedom of religion does not permit a child to be harmed, neglected, or abused through religious practices. In *Prince v Williams*, the US Supreme Court said, “Parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves.”

While the constitution does not appear to allow parents to martyr their children for religious beliefs, it is important to recognize that our reasons for interfering with parental decision-making are not because the parents have a religious belief but because their decision places a child at substantial risk of serious harm. That standard remains the same whether the parents’ reason for refusing an intervention arises from religion, culture, or some other source.

In the case of routine vaccination, the American Academy of Pediatrics does not believe parental refusal should be viewed as child neglect. However, under conditions in which the level of risk from being unvaccinated rises to dangerous, such a refusal could be considered medical neglect. The example provided by this case—a grossly contaminated deep wound—might be such a case with regard to the tetanus vaccine.

*Are there other important considerations? Is there a series of questions physicians should ask to help decide if they should seek state action to overturn parental refusal of a recommended medical intervention?*

Conditions for justified state interference with parental decision-making include

1. By refusing to consent, are the parents placing their child at significant risk of serious harm?

2. Is the harm imminent, requiring immediate action to prevent it?

3. Is the intervention that has been refused necessary to prevent the serious harm?

4. Is the intervention that has been refused of proven efficacy and therefore likely to prevent the harm?

5. Does the intervention that has been refused by the parents not also place the child at significant risk of serious harm, and do its projected benefits outweigh its projected burdens significantly more favorably than the option chosen by the parents?

6. Would any other option prevent serious harm to the child in a way that is less intrusive to parental autonomy and more acceptable to the parents?

7. Can the state intervention be generalized to all other similar situations?

8. Would most parents agree that the state intervention was reasonable?

**Conclusions and Suggestions**

Remember that parents who disagree with their physician believe they are doing what is best for their child.
It is important to maintain an atmosphere of respect and concern for the child in disagreements with parents. Respectful persuasion is far preferable to attempts at coercion.

Attempting to interfere with a parental decision is not appropriate if prognosis is grave even with treatment or if the treatment in question is not clearly efficacious and beneficial.

This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 3. Training Issues for Residents and Students: Ethical and Professional Conflicts in the Context of Valued Learning Opportunities

Alex Okun, MD, FAAP, and Waseem Hafeez, MBBS, FAAP

Overview
As outlined by the American Board of Pediatrics, medical professionalism invokes the principles of honesty and integrity, reliability and responsibility, commitment to lifelong learning, self-awareness, and knowledge of limits.

Residency training requires learners to expand their medical knowledge, acquire essential skills, and work in teams with shared responsibilities. In this teaching module, we will explore ways that the current hierarchic model of training can foster challenging disagreements on important medical care decisions between team members at different levels of training and experience. We focus on tensions that arise from ethical and professional conflicts imbedded in valued experiential learning opportunities that approach the limits of the trainee’s competence or other boundaries of permissible work. Discussion of a broad range of issues in ethics and professionalism that commonly challenge trainees can be found in the references by Bercovitch and Long and McDougall and Sokol in “Further Reading.”

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

Case Summary
A 7-year-old girl with hydrocephalus and a ventriculoperitoneal (VP) shunt presents to the emergency department with headache, vomiting, and a flurry of generalized tonic-clonic seizures. After lorazepam is given, the seizures stop, but the girl becomes hypoxic. As a junior trainee, you suspect VP shunt malfunction; your attending physician agrees. The technicians at computed tomography (CT) scan want the patient there now. You would like to accompany her in the event that emergent resuscitation is required because you will be the senior resident on the inpatient service in a few months and could use the experience.

- Should a trainee in this situation ask permission to accompany the patient to CT scan?
- Should you be allowed to participate in a procedure with this level of risk, which may be beyond your level of experience?
Given the risk of respiratory depression, should you be allowed to go alone with the patient?

Does it make a difference that you will be the resident on the floor in a few months and could benefit from the experience?

Alternate Cases
1. As a junior trainee, you examine a 5-year-old girl who fell and suffered a laceration on her face. The laceration needs to be sutured and your attending physician allows you to do it. You have sutured lacerations before, but never on a child’s face. When you tell her father that the cut will need sutures, he asks who is going to do it and expresses his desire that his daughter not “be a guinea pig.”

- What do you tell the dad?
- Do you need to let him know that this is your first time doing this particular repair?
- Do the wishes of the parent override a trainee’s need to learn in a teaching hospital setting?
- If the father had not asked, would it have been your responsibility to inform him of your lack of experience?
- Would you handle this situation differently if you had never performed suture repair before?
- Is supervision by another senior resident acceptable if the attending physician is busy in an emergency?
- Even if it is your first repair, when asked if you can do it, would you consider saying “yes” to impress an attending physician from whom you might later want a letter of recommendation for fellowship?
- Would you approach this in a different manner if the child’s parent were a relative of your colleague?

2. A 14-year-old boy with acute lymphocytic leukemia in relapse is transferred to the pediatric intensive care unit with septic shock. During his monthlong hospitalization, you develop an unusually strong bond with him and his family. He is dying, and you would like to stay after your shift on call has ended to learn from the attending physician how to give bad news and to be with the family during this frightening and distressing time.

- Should you be involved in this meeting, which will require a significant time commitment, after the end of a shift?
- If so, should you ask permission first?
- If participating violates duty-hour rules, should you face consequences?
- If the attending physician were to suggest that you stay for the purposes of learning and providing support to the family, does this change anything?
• What would you say if a trainee wanted to stay after duty hours to take advantage of a rare opportunity to participate in an unusual and exciting technical procedure highly pertinent to his or her future career plans?

Learning Objectives
1. Reconcile potential harm that can come to patients by having less-experienced trainees perform needed procedures with the future good that comes to others from having well-trained professionals and the benefits to trainees provided by challenging experiential learning.
2. Negotiate the potential conflict that arises between a trainee’s obligation to be truthful to a patient and his or her caregivers about the limits of the trainee’s experience with the harm and loss of confidence that can result by full disclosure and the loss of opportunity for learning.
3. Understand and explore the rationale for double standards that may exist in the degree of responsibility trainees are given to provide care to patients from different backgrounds. For example, would you approach this in a different manner if the patient was at a county hospital versus a private hospital?
4. Explore the basis for mandated duty-hour limits and reconcile the professional obligation to adhere to these limits with
   a. Obligations to patients and their families
   b. Obligations to take advantage of experiential learning opportunities that are unusual or unique and highly valued but are not readily available to learners by other means such as reading or simulated exercises
   c. Obligations for self-care that may be met or hindered by participation in learning opportunities after shift hours
   d. Risks associated with taking part in experiential learning in a state of significant fatigue

Suggested Reading for Instructor


Further Reading

Case Discussion

Should a trainee in this situation ask permission to accompany the patient to CT scan?
Yes. In determining a trainee’s preparedness to attempt any procedure, the trainee and attending supervisor share the responsibility to review the trainee’s background knowledge and experience and assess the condition of the patient and associated risks. This is based in professionals’ duties to ensure that the patient’s best interests are promoted.

Should you be allowed to participate in a procedure that may be beyond your level of competence?
Trainees should not conduct a procedure beyond their level of competence in the absence of direct supervision. In assessing your preparedness to accompany the patient to CT scan, the attending physician should review potential complications and emergency developments with you, in the interest of best care for the patient and as continuing assessment of your readiness. These demands are difficult to meet in all situations when simultaneous emergencies or calls to urgent clinical situations strain staffing availability.

Because there is risk of life-threatening respiratory depression, should you be allowed to go alone with the patient?
If you are judged to be adequately prepared to begin emergency interventions and help is available quickly, it may be appropriate for you to go to CT scan alone with the patient.

Does it make a difference that you will be the resident on the floor in a few months and could benefit from the experience?
Anticipating future responsibilities should motivate trainees to put extra effort into mastering areas of learning and clinical skills out of professional obligation to pursue clinical excellence. A trainee’s personal goals for learning should not influence the assessment of his or her preparedness and suitability to accompany a patient alone to CT scan because the patient’s safety and welfare are of prime importance.

Alternate Case 1

What do you tell the dad?
Honesty about proposed treatments is mandatory. Professionals need to be aware that many individuals from populations that have traditionally been underserved or exploited by society in general, or the health care system in particular, are likely to feel apprehensive when approached with important treatment proposals or suspicious that they are not receiving quality care.
Trainees are not obligated to volunteer explicit information about their lack of experience but must answer truthfully, if asked.

**Do the parents or patient have a role in this decision?**
Parents have a limited role in deciding how their child’s care is delivered in that they can expect that their requests and preferences will be heard, if not fully honored, and they should be encouraged to advocate for the care they feel is appropriate. They are owed a sensitive explanation of the system by which care is rendered, including by trainees in supervision, and, out of respect for their autonomy, should be offered reasonable alternatives to that system of care.

**What is the best compromise concerning training needs and the rights of patients and their parents to receive optimal care?**
You should assure the parent that the procedure will be done under the guidance of an experienced physician and follow through with the promised plan. Your mastery of new skills advances medical knowledge as you become able to teach others in the future but holds no special benefit for the child being treated. Likewise, this child has no interest in enabling you to perform procedures more skillfully or independently in the future by providing a learning experience. Trainees should be aware of the limitations of their own knowledge and technical skills. If the trainee and supervising attending would not render treatment in the same way for the child of a colleague, the suitability of the trainee performing the procedure on this patient is called into question.

**Is supervision by another senior resident acceptable if the attending physician is busy in an emergency?**
Even if the senior resident has the competency and willingness to teach the skill, the approval of the attending physician is required.

**Even if it is your first repair, when asked if you can do it, would you consider saying “yes” to impress an attending physician from whom you might later want a letter of recommendation for fellowship?**
Some trainees may not recognize their lack of expertise and may attempt procedures beyond their scope of competence. They may be motivated by the opportunity to practice new skills or the chance to impress their supervisors. In this case, it would demonstrate a lapse in judgment, limited self-knowledge, and disregard for the welfare of the patient to proceed enthusiastically against a base of no prior experience. The impression that your enthusiasm might make could turn out to be negative once the attending learns more about your preparedness.

**Alternate Case 2**
*Should you be involved in this meeting, which will require a significant time commitment, after the end of a shift?*
Although you might be in a position to advance your learning to a significant extent and provide special support that has meaning for the child, family, and you, fulfilling this fiduciary obligation to the patient would also violate the professional requirement to uphold standards of predetermined work limitations. Duty-hour restrictions are intended to enhance patient safety and promote wellness and self-care for trainees. In certain situations, it is possible that the weight
given to these relative virtues would favor violating working hours because of the importance of the benefits that may result.

**Should you ask permission first?**
Absolutely. If a supervising physician prohibits a trainee from staying after a shift is over, the trainee has the opportunity to appeal to a higher level of authority.

**If participating violates duty hours, should you face consequences?**
If there are consequences established in the training program for violating working hours, a trainee is responsible for knowing them and should be apprised or reminded of them. Trainees are responsible for the actions they take facing difficult decisions to stay after duty hours, regardless of how they value different considerations inherent in the choice.

**If the attending suggests that you stay for the purposes of learning and providing support to the family, does this change anything?**
If the attending physician suggests you stay, the suggestion provides support for pursuing this unusual opportunity to learn highly valued material and meet obligations to accompany the patient and family at this difficult time. At the same time, such a request has the potential to exert pressure on trainees to not appear to be shirking responsibilities or displaying disinterest in the attending physician’s teaching agenda. An attending physician who violates rules by requesting trainees stay past duty hours may compromise his or her status as a positive role model.

**What would you say if a trainee wanted to stay after duty hours to take advantage of a rare opportunity to participate in an exciting technical procedure highly pertinent to his or her future career plans?**
In the previous instance, there was little risk that the trainee’s fatigue would lead to critical errors because the trainee was remaining with the child and family to provide emotional support, learn about the nature of the dying process, and watch a potential role model provide care. If a trainee were merely to observe a rare procedure pertinent to his or her future plans, no benefit or harm would come to the patient and family, but potential good could come to future patients for whom the trainee cares. It could place the training program at risk, however, if the violation of duty-hour limitations were discovered. One of the primary rationales for duty-hour restrictions is to prevent medical errors, as strong evidence exists that the judgment and performance of fatigued trainees are impaired. An elevated risk of harm exists from trainees’ active participation in procedures after hours, undermining our commitment to nonmaleficence.

**Conclusions and Suggestions**
Training opportunities in medicine commonly place learners in situations they have rarely or never experienced before. Professionals have a lifelong obligation to pursue learning and master skills to improve the care they provide. Special opportunities may encroach on the limits of the learner’s competency or permitted scope of work. When trainees take advantage of such opportunities without clear permission and close supervision, the primacy of patient welfare may be threatened.
Session 4. Informed Consent and Assent in Pediatrics

Yoram T. Unguru, MD, MS, MA

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.

This instructor’s guide was developed by Mary Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 5. Minors as Decision-Makers

Joel E. Frader, MD, MA, FAAP, and Erin Flanagan, MD

Overview
Some empirical evidence suggests that on average, 14-year-olds have cognitive or reasoning capacity equivalent to 20- to 22-year-olds. However, information from social psychology studies indicate that as a group, teenagers have at least 3 characteristics that may limit the quality of decisions they make: 1) teens have a high tolerance for risk; 2) they attend primarily to short-term consequences of their actions; and 3) they are more easily influenced by others (eg, peers, parents) than they will be when somewhat older. In addition, neuropsychological studies have begun to show that brain capacity does not mature until approximately 25 years of age.

Our society, for complex social and political reasons, permits independent decision-making for most matters, including health care, at age 18 years. Despite accumulating science indicating caution about this arbitrary age cutoff, we generally uphold 18 as the age of majority. Further complexity enters into this because some minors, though by no means all, with chronic medical conditions and considerable experience in the health care system seem mature beyond their years. Arguably, such medically mature minors should have decision-making authority well before their 18th birthdays.

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

Case Summary
Jane was diagnosed with cystic fibrosis (CF) at age 9 months because of failure to thrive and a recurrent cough. Now 16 years old, her lung function has deteriorated to the point of consideration for lung transplantation. Jane has been in the intensive care unit (ICU) for mechanical ventilation 3 times. Two of those episodes of respiratory failure required more than 3 weeks each of mechanical ventilation, though the most recent lasted only 4 days. At a pulmonology clinic visit Jane tells her physician and parents that she does not want a transplant. She indicates that transplantation would likely require weeks to months in the hospital and much more time in the ICU on a ventilator, and after thinking about it and talking with her pastor she feels she wants palliative care and no more trips to the ICU. Jane, well aware of her failing lungs, does not wish to undergo lung transplantation despite the potential of the procedure to add years to her life. She feels that the rigors of surgery and subsequent ICU care and medications would mean a poor quality of life no matter how much longer she would survive. Her parents and
physicians, surprised by her announcement, do not know how to best respond to what Jane has said.

- Are adolescents capable of making their own health care decisions, especially major ones like refusing transplantation?
- Under what circumstances would a minor be legally allowed to make autonomous health care decisions?
- How does a physician address conflict between the patient’s desired course of medical action and the parents’?

**Alternate Cases**

1. Tom, at 17 years of age, smokes marijuana 3 to 4 times a week. A talented painter, Tom defends the practice on the grounds that it enhances his artistic abilities. Hospitalized for injuries he incurred while driving stoned, Tom refuses to meet with a substance abuse professional.

2. Ginny, at 15 years of age, is about to graduate from high school and enter a state university program for gifted youth. A model daughter until now, she has entered a rebellious phase and despite knowing better, fails to prevent becoming pregnant. Ashamed, she tells her parents of her condition and requests their help obtaining pregnancy termination. Based on their strong religious convictions, Ginny’s parents insist she carry the baby to term and give it up for adoption.

3. Steve, a 16-year-old, has isolated growth hormone deficiency. He has received recombinant growth hormone (rGH) injections daily for the last 7 years and a recent bone age radiograph indicates he has approximately 15 months of additional potential linear growth with continued rGH. A serious musician—he plays first violin in a statewide youth orchestra—he feels no need to grow taller than the 5 feet 4 inches he has attained. He hates the daily injections and wants to stop.

4. Carole, a 14-year-old, develops a sore throat, fever, a headache, and abdominal pain. The result of a rapid group A beta-hemolytic streptococcus test in her pediatrician’s office is positive. Carole knows that she and her mother routinely fail to complete prescribed treatment regimens, and the teen requests an injection of penicillin rather than have to take pills for 10 days. Carole’s mother refuses on the grounds that insurance will pay for the oral penicillin but not the $50 for intramuscular penicillin.

5. Andy and Steve are identical 15-year-old twins. Andy has developed hemolytic uremic syndrome induced by *Escherichia coli* followed by acute, then chronic renal failure. Andy’s kidney specialist tells the family that Andy will need a kidney transplant. On his own, Steve researches the situation and discovers he is the ideal immunologic donor for his brother. He tells his family that Andy should not go on the cadaver kidney transplant list because he (Steve) will donate a kidney. Undergoing the operation will mean Steve has to give up his chance to become the state wrestling champion in his weight class, a goal Steve and his dad have had for years.
Examples From Case Law
1. Case of BA (1998): A 15-year-old male refused immunosuppressive medications after his second liver transplant because of severe side effects and poor quality of his life. The family supported the teen’s decision. Physicians filed charges of medical neglect. The judge ruled in favor of the patient, who died 1 month after immunosuppressive medications were stopped.
2. Case of EG (1987): A 17-year-old female and her family refused transfusions as part of necessary supportive care for newly diagnosed acute myeloblastic leukemia. The court initially rejected EG’s petition for mature minor status and authorized transfusions. This decision was reversed years later, and mature minor status was granted to EG to make decision to refuse transfusions. This decision did not help the patient in question but established a precedent for future cases.

Learning Objectives
1. Define the circumstances under which a minor would be legally allowed to make autonomous health care decisions.
2. Discuss how the adolescent and brain development literature influences the approach to minors as decision-makers.
3. Identify key questions to guide conflict resolution in settings in which an adolescent and the parents disagree with the best course of medical action.
4. Examine the rational for court intervention.

Suggested Reading for Instructor


Further Reading


**Case Discussion**

*What factors should be considered in allowing a minor to refuse medical treatment (in this case, transplantation)?*

1. Issues related to basic informed consent
   - How, if at all, would these differ for our patient from considerations for a 35-year-old making a similar decision?
   - Does the patient have the *cognitive capacity* to understand information presented to her, process it appropriately, and make an adequate decision?
   - Does the patient appear to *weigh risks and benefits* of the proposed treatment based on the medical information and personal (patient goals of care) factors?
   - Is this decision consistent with prior decisions the patient has made and *with the patient’s values and priorities*?

2. Why is the patient really refusing treatment?
   - Before we consider compelling treatment for an adolescent, we need to make absolutely sure we have explored all aspects of the patient’s decision.
     - Have her family and involved clinicians worked to maximize the patient’s quality of life and control any pain or other symptoms?
     - Are there hidden underlying issues the patient is struggling with, such as unrecognized fears, not wanting to impose financial or psychological burdens on her family, spiritual distress, or a special wish that could not be realized if plans for transplantation continue, such as attending a special event in another country?

3. Efficacy of treatment
   - What evidence can we find about the chances for successful outcome with the proposed transplant?
   - How high a chance of success would lead us to attempt to overcome Jane’s refusal to be listed?
   - Would a 50% chance of 5-year survival suffice to justify trying to override Jane’s decision?
   - How does Jane’s age figure into the efficacy discussion?
There are conflicting views among pediatric pulmonologists about long-term survival and quality of life among children with CF who undergo transplantation, compared with those who receive nonsurgical care.

4. Morbidity and mortality of treatment
   - Can we justify a treatment that may prolong her life but ruin her quality of life in the short or long term?

5. Morbidity and mortality of disease
   - What are the options for continued medical management of her disease and what effect would they have on the quality of Jane’s life in the short or long term?

*If the adults responsible for Jane’s care conclude that she does not have the maturity to make a fully autonomous decision against additional ICU care and transplantation, what measures could one justify using to ensure future mechanical ventilation or preparation for transplantation? Or, if both parents support Jane’s view, should her doctors seek court-ordered treatment on the grounds that such intervention would serve her best interests?*

Defining the legal age of majority at 18 years is an attempt to create conditions in which most patients can participate in the traditional notion of informed consent. This does not imply, however, that no one younger than 18 years can participate in their own health care decision-making. Although most adolescent patients younger than 18 years cannot legally provide informed consent, they can and should provide their assent in decisions that affect their health, life, and death. Parents, physicians, ethics consultants, chaplains, and all involved in conflict surrounding medical decision-making for a minor should do all they can to preserve the integrity of the patient’s participation and the relationships among the patient, family, and members of the health care team. Involving the court system in these cases should always be a last resort. Court intervention disrupts the integrity of the physician-family-patient relationship, affects family privacy, and may hinder future attempts at shared decision-making among the minor, parents, and physician. Moreover, clinicians and the court would have to consider the practical and psychological effect of forced treatment. If Jane resisted surgery, would they find physical or pharmacologic restraint acceptable?

*Are there special circumstances in which minors can be legally allowed to make autonomous health care decisions?*

1. The emancipated minor
   Under certain circumstances, depending on state legislation and precedent-setting court decisions, minors are deemed emancipated and thereby have sole authority to make health care decisions. These circumstances typically include

   - Minor is living independently and self-supporting.
   - Minor is married.
   - Minor is pregnant or a parent.
   - Minor is in the military.
   - Minor is declared emancipated by a court as described under the mature minor section.

2. Specialized consent statutes
Many states give adolescents independent, confidential, decision-making authority for special health circumstances such as

- Diagnosis and treatment of sexually transmitted infections
- Pregnancy
- Substance abuse
- Mental health services

The nature and scope of these specialized consent statutes vary from state to state.

3. The mature minor
In circumstances in which a minor wishes to make an autonomous decision against the wishes of parents or medical professionals, courts may grant the minor total or partial emancipation (mature minor status) to make decisions. Such court actions are based on existing case law, state statutes, or common law practices and will vary state to state.

What do we know about adolescent development that helps address the dilemma Jane and her caregivers face?
Some data (Weithorn and Campbell) suggest that normal 14-year-olds have reasoning power, when considering hypothetical medical situations, equivalent to those legally entitled to make their own decisions at age 21 to 22 years. Other social psychological data (Scott et al) suggest that on average, adolescents have a high tolerance for risk, consider short-term consequences of their acts rather than longer-range ones, and are highly influenced by others, making “independent” mature decisions questionable. Some more recent neuroimaging (Sowell et al) and neuropsychological studies indicate that brain maturation continues well beyond adolescence into the third decade of life.

Does brain development literature suggest that we should not allow adolescents to make medical (or other important) decisions?
Brain development in normal situations may not reflect what happens physiologically or psychologically to patients with chronic diseases and with particular medical experiences, such as multiple ICU stays. Some studies (Freyer) suggest a bimodal population of adolescents with life-threatening illness—those who mature beyond their years and those emotionally infantilized by their illnesses. In addition, even if cognitive and emotional development do not fully mature until, say, age 25 years, that does not automatically mean we should prevent decision-making much earlier (Johnson et al). Clinicians should undertake careful individual assessments of cognitive and emotional functioning when asking if any particular child should have decision-making authority.

This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 6. Availability and Use of Pediatric Enhancements

Ferdinand D. Yates, Jr, MD, MA, FAAP

Overview
The advent of enhancements has introduced options and challenges. Verbal parameters in this conversation must be presented carefully and defined unambiguously. Perhaps the most helpful and yet demanding designation is the issue of whether an enhancement is to be therapeutic or nontherapeutic. If the former, the enhancement is designed and purported to be a replacement for a part or function that no longer functions well; if the latter, the enhancement is designed to exceed initial limitations. In essence, the enhancement can indeed be an option that makes the child’s body “better than well.”

Personal autonomy enjoys considerable endorsement, and even a minor child asking for a particular enhancement to make him faster, smarter, or stronger will likely enjoy a thoughtful—and perhaps even sympathetic—response. As such, the use, misuse, and abuse of enhancements in the pediatric population should be of great concern to the parent and physician. Off-label use raises the particular concern of the safety profile of the drug (or procedure) as well as the ethics of such utilization. Of considerable importance with respect to the development of enhancements and enhancing procedures is the notion of allocation of resources and distributive justice.

Instructor’s Guide

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

Case Summary
A 24-year-old mother of 3 is your former patient. You recall she was an attractive and well-rounded teenager who excelled in many aspects of her high school life. Specifically, she was an accomplished gymnast with particular ability in the uneven parallel bars. In addition, she had stellar grades and on graduation from high school, was accepted into an Ivy League college with aspirations of entrance into law school. You remember that she demanded increased doses of amphetamines and, from time to time, seemed to require extra prescriptions. Reluctantly, at that time, she had admitted to you that she was taking extra doses of medications as she felt that it had helped her to concentrate better in gymnastics in addition to noticing that her study time was more efficient. She had transferred her medical care to an internist some time ago. However, you had noticed her impressive legal career escalate as she had represented some high-profile plaintiffs in
malpractice litigation. She now asks that you become the new pediatrician for her 4-year-old daughter. Apparently, her child shows promise in Suzuki string lessons, but she does not seem to have the temperament for prolonged practice times and becomes easily discouraged from lack of progress. She is confident that you will understand her predicament.

- Is this a situation in which the physician may have become morally complicit?
- The physician legitimately expects historical repetition—is there a protective obligation that should be offered to the young daughter?
- Does this constitute a violation of the principle of justice?

Alternate Cases
1. The parents of a short 12-year-old boy seek your endorsement of growth hormone treatment for their son. They are convinced their own short stature has been a substantial hindrance to personal job promotion. The boy is presently free of relapse from acute lymphocytic leukemia recurrence for 5 years, and his growth has tracked at or below the third percentile for height over the past 6 years. The boy’s parents have seen a recent infomercial extolling the benefits of increased final height in genetically short children. They plead with you for a referral to a local endocrinologist who has a reputation for being sympathetic to the use of growth hormone in marginal medical situations.

- How does parental pressure affect the care of a pediatric patient?
- How should the pediatrician ensure that there is informed consent?
- Does the pediatrician have a responsibility to help ensure the appropriate use of expensive medical resources?

2. A 21-year-old long-standing patient of yours is the lead alto saxophone for a local jazz group. The group has been offered a gig at a prestigious nightclub and a recording contract is a real possibility. Your patient must finance his own college education; to that end, has a day job he must maintain. He has always required considerably more sleep than most teenagers. He informs you that the performance gig will be for an extended period and that he has taken “uppers” provided by the group’s percussionist. Your patient has heard anecdotal stories about fatigued airplane pilots taking prescription medication to help keep them awake on long flights. He begs you to provide this medication for him so that he will “not let down” the other members of his group.

- Must the pediatrician necessarily acquiesce to the request of personal autonomy?

Learning Objectives
1. Understand the allure of enhancements in the pediatric population.
2. Recognize the potential complicity of parents and physicians in a pediatric request for enhancement.
3. Understand how the traditional goals of medicine may be in conflict with requests for off-label use of “lifestyle drugs.”
4. Recognize that the prescription and use of enhancements embody an allocation of resource issue that will affect the distributive justice of medical resources.
5. Be aware of the indications and controversies regarding the use of growth hormone.

**Suggested Reading for Instructor**


**Further Reading**


Case Discussion

**In considering the use of enhancements, the physician needs to consider the goals of medicine and the purpose of various treatment modalities.**

The primary goals of medicine are to assist in preventive health, the process of healing and recuperation back to normalcy, and in the case of lost capacity due to illness, disease, or injury, to assist in restoring as much of normal function and ability as possible. To this end, we may freely consider such items as eyewear, dentures, prostheses, and even hairpieces. Treatment modalities that are designed to make the patient better than well are not consistent with the goals of medicine and fall outside the purview of medical care in the Hippocratic tradition. In addition, the American Academy of Pediatrics (AAP) has observed that the intentional use of performance-enhancing substances is morally and ethically indefensible, the use of such enhancements may pose a health risk to the patient, and the use of enhancements tends to devalue the principles of sound physical training and good health care.

**How does (and should) the physician assess whether an enhancement is therapeutic or nontherapeutic?**

If the physician is operating under the traditional goals of medicine, the distinction between therapeutic and nontherapeutic becomes appropriate and necessary. A therapeutic enhancement would be consistent with traditional goals; a nontherapeutic enhancement takes a different position, as these modalities typically are requested (or expected) to make an individual stronger, faster, smarter, or taller than others. Bostrom noted that an enhancement is “an intervention that improves the functioning of some subsystem of an organism beyond its reference state; or that creates an entirely new functioning or subsystem that the organism previously lacked.” This enhancement is designed and expected to help the individual exceed the inherent normal and genetic entitlements. Germane to this consideration is the intent of the requesting individual; that is, is the intention to purposely excel beyond what would be obtainable under routine circumstances?

**The physician has considerable involvement in these situations, and it would not be unusual for a conflict of interest to arise.**

Pediatricians are trained to provide routine and extraordinary care. Coupled with this education is the experience to know when the differing levels of care are appropriate. In addition to wanting the patient to flourish, the physician must help maintain the patient’s health and well-being. Inherently, one of our goals is to provide a consistent level of care to all of our patients. We recognize that from time to time, certain patients will require more extraordinary care (ie, time and resources) to return to their prior state of good health, and
this is a routine part of pediatric care. However, a purposeful request from a patient or parent for a specific enhancing treatment to exceed normalcy may (and perhaps even should) create some angst in the heart of the routine busy pediatrician. The actual conflict of interest may arise at several different levels: parental preferences for a minor child who may have incomplete comprehension and cannot execute informed consent; the physician who may have control over the distribution of resources and does not want to be pressured into acquiescing in the provision of resources; and physician desire to help the patient flourish and accomplish goals, and yet not know the long-term health issues of a particular enhancement.

*When a parent requests treatment for a minor child, how does the physician balance the issues of parental authority and the best interests of the child?*

The pediatrician’s primary goal must be the health and well-being of the child, and our advocacy for the child should be unswerving. Parental authority deserves respect and proper consideration, and in most cases the request stemming from this authority aligns with the best interest of the patient or is no worse than value neutral (ie, no foreseeable harm for the patient). However, if a supplement or enhancement requires repeated injections or blood tests, the physician should seek age-appropriate, reasonable assent for the elective actions being performed.

*In agreeing to provide treatment, is it possible that the physician has become complicit and is violating the principles of justice?*

Chesire has observed that there are 3 types of justice: commutative, social, and distributive. The pediatrician should be familiar with each category because care for our patients may intersect with each of the classifications. Commutative justice suggests that there should be fairness in competition. Enhancements augmenting our patients may well place others at a selective disadvantage. The principle of social justice is satisfied when patients take medication for cognitive disorders such as attention-deficit/hyperactivity disorder to restore mental capabilities to the point of full participation in society. Distributive justice ensures that there is equitable allocation of limited resources—medications, supplements, and procedural treatments—along with qualified professionals to distribute and monitor ongoing therapeutic modalities. Alternatively, in encouraging the use of enhancements, Greely et al noted that the safety profile should not be different for off-label usage, there should be freedom to use enhancements without coercion from any perspective, and the fairness doctrine should not apply to the use of medications any more than it applies to the use of private tutoring. The primary observation that a primary care physician makes is that comparable (needy) patients may lack access to care (enhancements) because of their personal financial circumstances. It is, therefore, possible that the pediatrician may become complicit with violation of the principles of justice while never intending to do so.

*How does the issue of informed consent affect the use of enhancements?*

The notion of informed consent involves the triad of having adequate information, decisional capacity, and the opportunity to make a decision without coercion. In addition, having the ability to make decisions implies that one can understand and repeat the information, process the information by understanding the pros and cons, and balance the pros and cons to make an actionable decision and be able to explain the decision. Informed consent is appropriate in the use of enhancements because frequently there will be a
financial cost at some level (most often to the patient and family) and often there will be unknowns relative to future medical effects of the proposed or desired enhancement.

**Does the physician have a duty to consider the issue of allocation of resources?**
The pediatrician has the responsibility of being a good steward of the medical resources at his or her disposal; there is a simultaneous fiduciary accountability to the patient individually and to society at large. Because there is also a covenantal agreement with the patient, the pediatrician’s primary allegiance is to the patient and family. Nonetheless, this allegiance must be juxtaposed to the utilitarian responsibility to society, and the physician must be cognizant of future availability of resources.

**Under what circumstances can the physician refuse to provide the requested enhancement?**
The physician certainly has the endorsement of the AAP in refusing to participate in many of these treatment requests. The health of the patient is of primary importance. Issues of justice and fairness will always present themselves in these discussions, and the physician needs to be cognizant that the use of an enhancement in a particular patient will quite naturally affect the circle of individuals with whom the patient is involved on a regular basis. Right of conscious issues also often come to bear, and the experienced physician may well feel a discomfort in prescribing when the stated intent is to have a selective advantage over the competition. The physician also needs to be aware that once started on this path, it will be very difficult to discontinue the provision of the enhancement.

**Conclusions and Suggestions**
The availability and use of pediatric enhancements will necessarily affect the medical, ethical, legal, and social aspects of the society in which we live and work. If the use of enhancements is allowed—and perhaps even encouraged—in nontherapeutic situations, medical care will attempt to alleviate what was once recognized as part of the human condition, thereby obscuring the goals of medicine, jeopardizing the safety of our patients, and devaluing personal accomplishments of the future.

*This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.*

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Session 7. Iatrogenesis: Exploring Ethical Obligations

Tomas J. Silber, MD, FAAP

Overview
Iatrogenesis may be defined as any adverse condition in a patient resulting from the application of a treatment by a physician, health care professional, or member of the medical team. These events contribute significantly to patient morbidity and mortality (Kohn et al). A substantial percentage of iatrogenic events are preventable. Iatrogenic events may or may not be the result of medical errors (Sharek and Classen; Klugelman et al). Harm may come to patients due to known complications of treatments such as chemotherapy as well as from failure of a patient to get appropriate care, from getting unnecessary care, from poor or impaired medical judgment, or from a physician failing to put the good of the patient ahead of his or her own. Iatrogenic events may be minor or life-threatening. Institutional or system failures, such as insufficient enforcement of standards for hand washing resulting in appropriately high rates of health care–associated infections, may also result in iatrogenic events that harm patients.

Physicians and other health care professionals have a duty to do no harm. In settings where patients are at risk or are harmed, what are the responsibilities of the ethical physician to the patient? This module will discuss how the physician and health care system can demonstrate integrity and respect for persons as well as carry out their fiduciary responsibilities. It will provide ethical reflection on what levels of transparency and disclosure are appropriate. In addition it will explore the options available for an apology and identify avenues for repair of the relationship.

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

Case Summary
A 7-year-old boy, with a relapse of acute myelocytic leukemia (AML), did not respond to any of his cancer treatments, including a bone marrow transplant (BMT). He was hospitalized to implement a research protocol with a new investigational drug for AML. A thorough process of informed consent and assent was followed and signed by the child and parents.

During the first 3 days of chemotherapy treatment the child had significant side effects including high fever and neuropsychiatric symptoms. The mother became very alarmed that something was wrong. On the fourth day the principal investigator was informed the entire study drug supply
had been given, contrary to the protocol instructions. Subsequent investigation revealed the pharmacy had received a new batch of the drug with the same appearance but a different concentration. A labeling error then led to administration of an excessive and nephrotoxic dose of the drug. The end result was cessation of any further experimental therapy. The child lost his “last-chance treatment.” He died a few weeks later in another hospital. Review of this event identified an error caused in part by insufficient staffing of the research pharmacy and failure to recheck medications prepared there.

This young child and his distraught parents had negotiated their way through the vicissitudes of daunting AML treatments, including BMT, only to see their hopes for recovery dashed by this iatrogenic event.

- What are the moral and legal implications of iatrogenesis?
- Was this iatrogenic event the responsibility of an individual or the result of a failure of systems within the hospital?
- What is the role of apology and repair in the setting of iatrogenesis?

Alternate Cases
1. A 17-year-old Hispanic girl was hospitalized for headaches and fever. She had an unremarkable neurologic examination. Subsequently it was noticed she had third cranial nerve palsy with diplopia. A computed tomography (CT) scan of the brain was read as compatible with cysticercosis; her spinal tap showed low blood glucose and mild pleocytosis. Cultures were negative, chest radiograph was normal, and her purified protein derivative was negative. Consultations were obtained with infectious disease specialists and a neurologist, and treatment for cysticercosis was begun. The patient’s headaches worsened; she developed nystagmus and fever followed by seizures. She was transferred to the critical care unit, where she died. That same day a cerebrospinal fluid culture report came back positive for *Mycobacterium*, subsequently identified as *M. bovis*. Posthumously, it was discovered that she had consumed unpasteurized milk in Mexico.

2. A 3-week-old, recovering from pneumonia, is about to undergo surgery for a tumor that is partially obstructing the left main bronchus. The anesthesiologist reads the chart and examines the child. He then shakes his head and sighs. The frightened teenaged mother observes his unspoken actions in petrified silence.

3. It is New Year’s Eve. A 4-year-old arrives at the emergency department with abdominal pain. After a tentative diagnosis of acute appendicitis is made, the on-call attending surgeon arrives. He confirms the diagnosis and prepares for immediate surgery. As he is scrubbing, the nurse notices his agitation and alcoholic breath. She now must decide how she will respond.

Learning Objectives
1. Identify iatrogenic events and give examples resulting from individual errors and system malfunctions.
2. Describe individual and system responsibilities in the disclosure of iatrogenic events.
3. Discuss physician responsibility to demonstrate professional integrity, duty to warn, and transparency interface with disclosure.
4. Examine the role of apology and relationship repair in the setting of iatrogenesis.
5. Consider related legal and moral implications of iatrogenic events

**Suggested Reading for Instructor**


**Further Reading**
Berlinger N. *After Harm: Medical Error and the Ethics of Forgiveness.* Baltimore, MD: The Johns Hopkins University Press; 2005


**Case Discussion**
*Is there a general duty to disclose iatrogenesis?*
The disclosure of a medical error is based on the principle of truth telling. This, in turn, is based on the human survival value provided by trust. Without such trust a civilization suffers and eventually anarchy and disillusionment prevail. This is made more salient in dangerous situations, when one’s life and well-being are placed in the hands of professionals (eg, doctors, attorneys, police, financial advisors). Hence the ethical concept of a fiduciary relationship, one in which the interest of the patient or client is to be considered above that of the professional.
How does a physician’s ethical responsibility to demonstrate professional integrity, a duty to warn, and transparency interface with disclosure?

The origin of a disclosure obligation is established by the privilege of being granted a license to get intimately involved in the lives of others as part of a curing and healing enterprise. Based on truth telling, trust, and the special nature of the physician-patient relationship, it is appropriate to consider that a patient’s right to know about iatrogenic events trumps the physician’s desire for privacy. From the perspective of professionalism, clinicians are therefore expected to do their utmost to prevent errors, alert systems to actual or potential iatrogenesis, and disclose errors when they occur.

What is the basis of the ethical obligation a physician has toward a patient when an iatrogenic event occurs?

These ethical obligations inherent to the physician-patient relationship are an extension of and grounded in the more basic principle of respect for persons. The implication of this principle is inescapable. Every person is entitled to be informed about the important things that can directly affect them.

The professionalism of the individual is still the cornerstone of the right behavior. Systems are in place to ensure its flourishing. There is a clear duty to warn when another member of a health care team is impaired (potential iatrogenesis). Health care systems need to address this potential through a system of preceptors, supervisors, and administrators who have authority to intervene. It is essential for all on the health care team to know their duty to the patient and promptly report incidents of unprofessional behavior including on-duty alcohol or drug use. Prevention of iatrogenesis is an obligation that extends to everybody, from the highest authority in a system to the humblest beginner.

Identify iatrogenic events and give examples that result from a single individual error as well as those related to system malfunctions.

Iatrogenesis is frequently related to systematic issues. Examples include insufficient staffing of the research pharmacy or a lack of double-checking of the medications prepared there. Iatrogenesis may include improper supervision of consultants, especially where a history of substance abuse is known. Nevertheless, the dimension of personal responsibility cannot be overlooked.

How are individual accountability and system responsibility addressed when iatrogenic events potentially include both aspects?

Constructive approaches to iatrogenic events must consider the possibility that training has been insufficient (eg, the body language in the alternate case 2) or that supervision has been lax (eg, alternate case 3). Personal contributions to errors need to always be considered in the context of the systematic issues that might facilitate them. The current no-blame paradigm has been questioned in a patient safety improvement article that suggests the adoption of explicit punitive approaches to poorly performing physicians (Wachter and Pronovost). An opposing view was expressed in a longitudinal study in a large facility, which found that penalties did not deter undesirable behavior. Instead, penalties drove underground the evidence of noncompliance and encouraged people to conceal their errors (Dekker and Laursen).
If one accepts that iatrogenesis often occurs as a result of system failures, one needs to conclude that there is an ethical obligation to identify and correct those systems that contribute to error. Methods to address system errors include debriefing, morbidity and mortality conferences, and performance improvement reviews. Iatrogenesis also affects each individual in the system, requiring personal reflection and commitment to improvement as well as studying, documenting, and communicating well with all those involved. All health care personnel need to exhibit the professional integrity to disclose medical errors and the moral courage to interrupt potential iatrogenesis (duty to warn) and fulfill professional ethical obligations. When it occurs, an episode of iatrogenesis needs to be openly addressed, the documentation transparent, and the incident followed by disclosure, apology, and amends.

**What approaches can be identified to facilitate apology and relationship repair in iatrogenesis?**
Clinicians involved in iatrogenesis (and their team, if necessary) need to explain to the patient and family in understandable language what happened or, if necessary, what will be done to understand what happened. Physicians should express their heartfelt regrets and apologize for the error incurred. Physicians and senior members of the health care team need to inform patients and families how this type of problem will be remedied and specifically what can be done to help a patient when harm has occurred.

Patients who have been harmed deserve an apology. For such an apology to be ethically significant, it needs to be clear about its content, recognizing what went wrong and how it happened; express the heartfelt sorrow that it caused in all involved and the regrets that followed; and include any amends or repair that can be offered.

The case of the child with AML illustrates the value of approaches that combine full investigation, complete disclosure, apology, and repair. The parents were given a copy of the medical record and a report that explained exactly what had happened, outlining step-by-step what caused the confusion, where it occurred, when it was identified, and the corrective steps taken. The oncologist met with the parents and could not help but tear up as she disclosed the event. Her tears spoke more eloquently than any words about the sadness and suffering that was generated by this error, as she recognized that any hope of rescuing this child from AML had been extinguished. Involvement of the legal system was necessary. Lawyers for both sides collaborated toward a settlement, which included a central feature—an endowed grand rounds devoted to the topic of safety and prevention of iatrogenesis.

**Is there a legal approach to iatrogenesis?**
The legal risk management approach to iatrogenesis exists in parallel with ethical considerations. It takes into account that such an event may lead to a malpractice suit. In the mind of many professionals it is best to “not make waves,” meaning to not mention the event, not document or release details—indeed, not “make it worse” by disclosing it to those affected. Nothing could be further from the truth.

While this teaching guide cannot serve the purpose of giving legal advice, it endorses the current state of the art in risk management, which favors clear documentation, transparency, and the completion of incident reports. While it is important to avoid finger-pointing, a description to the patient or family about the sequence of unfortunate events and its aftermath is mandatory. The
reality is that the public does understand malfunction of systems and human errors, even if they do not want to be at the end of such misfortune. Most malpractice cases have more to do with gaps in communication and adversarial relationships, with perceived secrecy and defensiveness, than with the medical events involved.

**Does the legal approach differ from the moral approach to iatrogenesis?**

There can certainly be congruence between the ethical and legal approaches to iatrogenesis. Both incur obligations toward the institution in which the episode occurred. Both need to be incorporated into the search for a resolution. In the end the old dictum should prevail—good medicine makes good ethics. To this we can add, good ethics make for the best possible legal outcome.

**What are the harms and implications of more subtle forms of iatrogenesis?**

Iatrogenesis usually implies actual damage to health. However, it is valuable to stress that there is an area of more subtle iatrogenesis that deserves strong consideration. This form of iatrogenesis means that a physician’s ill-chosen words or body language can be a source of distress and have a great effect on the emotional state and well-being of those depending on his or her care. The alternate case of the teenaged mother who is frightened by the anesthetist’s nonverbal communication is but one example. Because physicians are often unaware of this form of iatrogenesis, the author’s personal experience may be instructive: “While on rounds I experienced excruciating back pain that radiated to my groin. In agony, I walked toward the emergency department of the hospital near my children’s hospital. There, I developed hematuria and fainted as I was completing my insurance check-in. Still in my white coat, I was placed on a gurney and rolled in to be seen by the urology resident. I couldn’t have been happier, thinking that I would receive rapid relief from the searing pain that the displacing kidney stone was causing me. I was greeted by the enthusiastic urologist who, recognizing me as a doctor, gleefully shared his thoughts with me: ‘We will get a CT scan right away to check if you have kidney cancer.’” Insensitivity, verbal and nonverbal, has the potential to harm.

**What is the appropriate way to support physicians and members of the health care team in cases of iatrogenesis?**

The events in the cases in which the patient had a fatal outcome resulted in enormous emotional pain to the clinicians involved. This emotional pain may manifest in the form of guilt, insomnia, anxiety, depression, or self-doubt. On occasion, errors lead to a painful self-imposed end of a professional career. The remorse and regret a clinician feels may become overwhelming (Hilfiker). This is a time for support and solidarity with our afflicted colleagues, who have been rightly referred to as “the second victim.”

On the other hand, the real victims often suddenly see very little of their physicians. This may be because of professional embarrassment, fear, or misguided legal advice. It needs to be remembered that the victims of iatrogenesis merit priority over anything else. The first thing to do is to maintain human contact with them, as hard as this will be, so they do not feel abandoned in addition to experiencing the consequences of an error.

**Conclusions and Suggestions**

Iatrogenesis is common and may range from known complications of treatment, to errors on the part of an individual physician, to problems within systems. The physician’s ethical and legal
obligations to the patient in the setting of iatrogenesis function in tandem. When an episode of iatrogenesis is identified it needs to be openly addressed and clearly documented, and followed by disclosure, apology, and amends to the extent possible.

This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 8. Malpractice and Disclosure of Errors

Sadath A. Sayeed, MD, JD, and Robert D. Truog, MD, FAAP

Overview
Clinical errors that result in patient injury often raise concerns about medical malpractice. At its core, medical malpractice law presents a socially constructed means to compensate parties harmed in the course of receiving health care using the apparatus of the civil judicial system. However, this tort mechanism of steering individuals and institutions into adversarial, opposing roles in which the end process may be a litigated trial before a jury of peers is recognized by all close observers as imperfect. Many wrongly harmed patients never receive due compensation, and many competent and capable health care professionals are harmed by even a threat of legal complaint. The negative consequences to almost all stakeholders (patient, physician, and hospital) are not trivial. Moreover, the current system sets up perverse incentives and encourages a widespread distortion of priorities.

Historically, the threat of being sued and the serious difficulties that often followed from having to legally defend one’s clinical conduct have inclined most in the medical profession to a conservative posture regarding disclosure of clinical errors. This normative pattern of behavior has recently begun to shift as a growing body of empirical data suggest that regardless of whether aggrieved patients intend to pursue civil litigation, they consistently voice a desire for honesty and transparency when it comes to revelations of medical error. Within the medical profession, there is increasing awareness that it is difficult to ethically justify maintaining veils of silence when errors occur.

This module will review some of the issues that arise in cases of medical error that might result in a future malpractice claim.

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

Case Summary
A pediatrician is about to see a 3-year-old boy in follow-up for an elevated blood lead level. Two weeks ago at his regular checkup, a test was ordered based on parental concerns, and it came back at 55 μg/dL (normal <10 μg/dL). Before entering the room, the physician was flipping through the boy’s chart and saw in the laboratory printouts a result from a level ordered at his routine 2-year visit—30 μg/dL. She cannot recall ever seeing these results.
• Should the physician tell the parents the results of the earlier test during this visit? If so, how should the oversight be communicated?
• Should a formal apology be offered? If not, why not? If not now, when, if ever, should the error be communicated to the parents?
• If the error should not be reported to the parents, why not?

Alternate Cases
1. An 18-month-old girl is admitted to the general pediatrics ward for intravenous antibiotics for urosepsis. The handwritten order for her antibiotics is misread and she is given 10 times the requested dose. She appears to have had no immediate adverse effects and is likely to have a full recovery. Should the parents be informed of this error?

2. Earlier this evening a 16-year-old student with signs of meningitis and septic shock is admitted to the hospital. After intubation, placement of a central line, fluid resuscitation, and inotropic infusion, the student was initially stabilized and sent to radiology for a head computed tomography (CT) scan. He completed the CT scan, but moments after being moved from the scanner to his stretcher, he became hypotensive. Resuscitation was attempted but he never responded, and eventually he was pronounced dead. As he was being prepared to be brought back to the emergency department, his disconnected central venous line was found in the bed sheets. None of his infusions or resuscitation medicines had actually been administered. His CT scan showed some cerebral edema and midline shift but not clear evidence of herniation. It is unclear how the patient would have fared had he survived. Should the parents be told about the problem with the central venous line?

Learning Objectives
1. Understand and critically reflect on the reasons why medical errors often go undisclosed.
2. Discuss the range of possible consequences to individuals and institutions when an open disclosure policy is adopted.
3. Understand and reflect on the role of apology in the course of communicating medical errors to patients and families.

Suggested Reading for Instructor


Further Reading


Case Discussion

When a medical error has occurred, what are the ethical obligations to the family? How should the error or oversight be communicated? If an error should not be reported, why not?

In this case it is clear that a medical error has occurred that may have a lasting negative health consequence for the child. Not surprisingly, when asked, adult patients and parents of pediatric patients almost universally express a desire to receive information about medical errors despite its unsettling nature. Further, a solid body of research shows that an overwhelming majority of surveyed physicians believe serious errors should be disclosed to patients and families. However, ideals do not match practice. Several studies collectively sampling thousands of physicians have demonstrated that while nearly all respondents acknowledge serious errors as such, significantly fewer appear prepared to disclose the same specifically as “error” to patients and families. There is a temptation in cases like this to jump to conclusions that would hedge on the question of whether the physician should disclose based on concerns about a torrent of negative immediate and long-term consequences to the physician, including but not limited to risk of
liability. The focus here should be on the basics, the “right thing to do” question. One way of getting at the ethical concern is to ask participants to ask themselves, “If you were a parent of this child, what would you think is reasonable to expect to be told?”

Most agree that, as an ethical matter, physicians ought to disclose medical errors to patients and their families, especially when there is any basis to be concerned about lasting harm. Yet it is the case that most practitioners initially hesitate in their willingness to be forthcoming and transparent. Why might physicians hesitate to disclose medical errors?

The framing of the basic problem is important. If the primary narrative that a physician or institution selects to understand medical error is one that casts medical error in terms of risk of legal liability, a resolute nondisclosure policy quite predictably follows. The physician’s or institution’s posture is immediately defensive. In this approach, adopting a “circle the wagons” mentality is common; as such, any patient-supportive activity that might increase the risk of malpractice exposure will be discouraged.

Numerous explanations have been offered for the professional wall of silence that relate to and are distinct from fear of legal liability. It is important to acknowledge that the current system of tort-based compensation is dysfunctional. It can and does occasionally unfairly devastate a physician’s career, and it costs insurers and institutions money. Even though civil litigation is generally not organized to be punitive, it can have that effect on clinicians forced into defending themselves. Formal findings of malpractice potentially have negative downstream consequences in terms of credentialing, obtaining hospital privileges, and securing affordable insurance coverage. As such, clinicians quite naturally might focus on how the error affects them personally, rather than thinking of disclosure as a respectful, patient-centered, professional duty.

What structural, sociologic, and psychological barriers exist that make breaking the wall of silence difficult?

Physicians are acculturated into a system that poorly prepares them to deal with their mistakes; the training of medical professionals takes place in a hierarchical system, within which trainees must perform to the satisfaction of their superiors. Trainees are socialized early to use certain coping mechanisms in the face of error, such as denial, discounting, and distancing. Acknowledging vulnerability and the possibility of mistakes is not encouraged or rewarded. This often translates into a need to project confidence, even in the face of uncertainty, and appear objective, even in situations that engender confusion and distress. Thus, it becomes easier not only to hide errors from patients and colleagues but also to develop strong psychological defense mechanisms and not recognize them as such as time goes by. Admitting error becomes akin to acknowledging a personal failing, which risks triggering strong feelings of inadequacy, let alone guilt and remorse. There is also a preoccupation with professional perfection, which sets up a false expectation that clinicians who are well-trained cannot and do not make mistakes. Some believe that imagining the physician as infallible may provide comfort to a vulnerable patient, but there is an important difference between appropriately having confidence in a professional’s competency and mistakenly believing doctors are infallible.

Are the collection of potentially serious negative consequences (legal and nonlegal) to medical professionals enough to partially or complete justify nondisclosure in cases of clear medical error on the part of individuals or systems?
What is important is to notice that rather than being a given, it is debatable whether any of the accurate descriptive explanations mentioned previously are adequate to serve as ethical justification. There is a clear conflict of closely held and important values. On the one side are the professional self-interests of physicians and health care institutions; on the other are patients’ claims to be treated with respect (ie, honesty and transparency). For the purposes of case discussion, participants will hopefully recognize that the harmful consequences that may flow to individual physicians are in competition with best patient care practices, and these latter considerations deserve much more attention than they typically receive.

Offering an apology after one has played a causal role in an accident or error that harms something of value to another person not only seems polite and courteous, it also expresses respect and empathy. Typically, it is the decent thing to do. Yet in cases of medical error in which a patient is harmed, as in this case, many physicians feel ambivalent about offering an apology. Why is this so?

An apology need not be an admission of guilt or causal responsibility, though it is hard to control whether it is interpreted as such. For this reason, it may be useful to distinguish saying, “I’m sorry for what has happened to you,” from an apology that entails personal or institutional accountability for error. Arguably, the act of saying, “I’m sorry,” allows physicians to reclaim their natural capacity for caring and kindness. Of note, numerous state legislatures have passed so-called apology laws that are intended to encourage formal acknowledgment while simultaneously insulating such statements from use in subsequent malpractice litigation. However, it is at least possible that such laws actually detract from the perceived sincerity of an apology in this context.

What evidence exists concerning the effect of apologies or admissions of error on risk of liability?

The data are equivocal. Several small lines of evidence suggest that an open disclosure policy may reduce the risk of liability under the current tort system and save hospitals and insurers money. The most impressive example of this comes from the University of Michigan. There, it was found that poor communication and a failure of accountability were the root causes of initiating local malpractice suits. In 2002, the hospital adopted a new approach that included acknowledging cases in which a patient was hurt because of medical error and quick and fair compensation of those patients, defending cases thought to be without merit, and studying adverse events to determine how procedures could be improved. In a 4-year time frame, the university was able to demonstrate a drop in its annual litigation costs from $3 million to $1 million and a drop in the number of claims and lawsuits from 2001 to 2005 from 262 to 114 (Clinton and Obama).

On the other side, there is an obvious concern that if more patients and families are informed about potentially actionable errors, more will decide to sue. The basic point is that there are a huge number of claims out there that have never been filed because patients were never made aware of them. Once this can of worms is opened, even if only a minority of patients end up suing, the potential overall costs to the system may increase. One group of investigators has concluded based on its modeling studies that a widely adopted open disclosure policy would at least double the number of claims and lawsuits, open disclosure would reduce the size of awards by an average of 40%, and the overall effect of disclosure would be an increase in compensation costs from $5.8 billion to $7.0 billion per year (Studdert et al).
Even if overall malpractice claims and costs rise, is that a sufficient ethical reason to discourage the practice of open disclosure?

This is a final opportunity to challenge the participants to think through the range of negative financial, professional, and personal consequences that might follow from being sued or losing a civil suit in court, and ask if all of those undeniable bad outcomes are enough to warrant nondisclosure of errors or prevent an apology that is heartfelt and empathetic and need not amount to an admission of guilt.

What approaches might be reasonable in this specific case of medical error?

Most participants should agree that disclosure is obligatory in this case. There may, however, be a genuine debate about the optimal timing of the disclosure. Because the physician is just about to see the family, it may seem reasonable to wait to disclose until a follow-up visit. More information might be useful to gather, including determining how the error occurred. Discussion of a possible medical error could distract the parents from attending to the immediate medical needs of their child at this time. Because the immediate need is to make a treatment plan for the elevated lead level, it may make sense to address the issue of the missed laboratory result in a separate, dedicated meeting with the parents.

Alternatively, one could disclose the laboratory result at this visit, perhaps after a plan for workup has been developed and agreed on. The physician could say something like, “There is something else I need to tell you. Before I came in the room today I noticed that the screening lead level we performed last year was also elevated. I’m really sorry about this; I don’t know why I didn’t see it, and indeed at this time I can’t even be sure that there wasn’t an error in labeling the result such that it is not even yours. But in any case, I wanted you to know this as soon as possible, and I will follow up and have more information for you as soon as I am able to gather it. This is a priority for me, and I also want to prioritize arranging to have your child seen by the appropriate developmental pediatric specialist as soon as possible.” However uncomfortable this approach may initially seem, it also has some advantages—it establishes with the parents that you are taking this problem seriously and that you are immediately responding to it as best as you are able.

Conclusions and Suggestions

Disclosing medical error with an apology remains a thorny problem for physicians despite little disagreement about the ethical merit of such activity. The threat of medical malpractice litigation and its host of negative consequences clearly influence professional behavior and present a formidable social and structural barrier to opening better lines of honest and empathetic communication between stakeholders. There is increasing empirical evidence to suggest that genuine acknowledgments of mistake and regret, coupled with diligent efforts to compensate those harmed, offer a path forward that can mitigate the risk of legal liability.

This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 9. Pediatrician-Parent-Patient Relationship: Obligations of Veracity, Fidelity, and Confidentiality

Mary B. Adam, MD, MA, PhD, FAAP

Overview
Over the last few decades there has been a shift in the medical decision-making approach from a paternalistic to a shared decision-making paradigm, one that recognizes that all parties involved in the medical decision bring essential elements to the therapeutic relationship. Shared decision-making requires a willingness to trust by all parties. Parents need to trust physicians to have skill and competence; children need to trust their parents to have their best interests at heart; and pediatricians need to trust that families know their children and have a true understanding of their capacities and limitations. This shift in the decision-making process to a shared paradigm also overlays a developmental trajectory in which the wishes of the child are increasingly relevant.

The development of a trusting relationship between a pediatrician, parent, and child is at the center of the American Academy of Pediatrics (AAP) conceptualization of the medical home. Yet multiple barriers to the development of trusting therapeutic relationships exist. These include an increasingly mobile population, health insurance shifts, and settings where a new relationship must be forged rapidly because of a medical crisis. In a therapeutic relationship a pediatrician assumes the obligations of veracity, fidelity, and confidentiality. These obligations can be simply defined. **Veracity** is a devotion to the truth or truthfulness. **Fidelity** is understood as being faithful and trustworthy. **Confidentiality** is an implicit or explicit promise by the physician to not divulge a patient’s personal information without his or her permission. By assuming these duties physicians create a solid foundation for effective communication. Communicating with families is a skill that can be developed and will increase a physician’s ability to address medical problems.

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

Case Summary
A 12-year-old female is referred to you for primary care by an infectious disease specialist at the university medical school. The patient is HIV positive; she does not know her diagnosis, and her parents do not want you or any of the staff to discuss her diagnosis with her. She was adopted as an infant and her HIV status was not known by the adoptive parents until sometime after the
adoption. The patient knows her mother died when she was a toddler and that those life circumstances meant her biological mother was unable to care for her, though she wanted the best for her child. The patient was recently in the hospital with respiratory problems and though she improved, she is asking specific questions about her health status.

- How does a physician balance the competing and sometimes conflicting goals of confidentiality, veracity, and fidelity?
- How do you resolve conflicts between the parents’ values and those of the medical profession?
- When is it acceptable for a physician to deny a parent authority over what information to give a child?
- What are the goals of medicine, and are the goals of the child, parent, and physician the same?

Alternate Cases
1. A 15-year-old female is the daughter of family friends and a patient you are following for obesity and hypertension. She was seen by a colleague on your day off and was found to be pregnant. She does not want her parents to know. Given her hypertension and the pregnancy she is at some medical risk, but she promised to follow up on all her obstetric appointments and will tell her parents at some later time. You see her parents at least once a week in a social setting.

2. You are caring for a child with asthma and his mother brings him in because he is wheezing. The parents are divorced. He was with his father over the weekend and he now has a cough, cold, and some wheezing. The mother is convinced he is worse because the father, a smoker, was smoking around him. She accuses the father in front of the child and wants your help to get sole custody. Mom wants you to inform the court that the father is medically negligent by continuing to smoke around their son and therefore putting the child at increased risk.

3. A 12-year-old new patient is brought in by his parents with a past history of several episodes of wheezing. The father looks uncomfortable while you are asking about any family members with asthma and asks to speak to you in private. There, the father tells you that the child was born via donor insemination and states that he does not want his son to know.

Learning Objectives
1. Discuss the basis of the duty of medical confidentiality, veracity, and fidelity and its application to the patient and family.
2. Address a parent’s right to direct care as well as the physician’s responsibility to function as a moral agent.
3. Recognize situations in which these respective duties are potentially in conflict (eg, when a family wants information withheld from an older child, when a child and parent disagree on the course of action that should be taken).
4. Identify strategies for preventing or resolving these conflicts.

Suggested Reading for Instructor
http://aappolicy.aappublications.org/cgi/content/full/pediatrics;101/5/938. Accessed May 12, 2011


**Further Reading**


(This special section of *The Journal of Clinical Ethics* contains commentaries by leading ethicists that explore the many facets of this question. This is a must read for all clinicians, generalists, and subspecialists.)


Case Discussion
Analysis of the Duties
In this case, the duty of confidentiality to the parent is in potential conflict with the duty to tell the patient the truth. This highlights a challenge in pediatrics in which the pediatrician has a legal obligation to the parents (or legal guardian) and a moral obligation to the patient. A failure to answer a patient’s direct questions and to respect a parent’s understanding of what is in the best interest of the child have the potential to put the therapeutic relationship at risk.

Is truth telling a moral imperative or a virtue?
One physician’s personal moral values may view an element of deception as therapeutic and justifiable in this setting. For another physician, any deception is wrong no matter what the consequences. The social, legal, and economic climate can influence a physician’s personal values. The importance of individual autonomy as a highly valued good, especially in Western society, combined with the legal role of informed consent, has altered physician practices more in favor of recognition of patient rights of self-determination and truthful disclosure. The move toward a pediatric patient’s right of self-determination is especially prominent as adolescence approaches, and most states have legislation to protect adolescents’ independent decision-making in areas like reproductive health.

What is the justification for lying to the patient or willfully hiding the truth?
In this case, the parents feel that the emotional and cognitive burden of knowing she is HIV positive will damage their daughter’s memory of her mother and further distance her from meaningful relationships with peers. The stigma associated with HIV is so significant and the prevailing paradigm in the United States is that of high-risk sexual behavior (e.g., homosexual, prostitution). The adoptive parents believe she will suffer from the association—even though it is incorrect—that she is a prostitute or gay. Middle school students as a group are known for their ability to form cliques and exclude those who are different.

Her parents have told her she has a blood disease and she is compliant with treatment. Her biological mother died from the disease and while the daughter knows she is adopted and her mother is dead, the parents do not wish to discuss that the child has the same disease as her mom or that it is fatal. In addition they wish to avoid a discussion of transmission. The parents have tried to portray the biological mother as a caring woman who wanted what was best for her child, especially after the mother knew she was sick. Because HIV is likely to be discussed at school in health class and information is available on the Internet, all of these facts would likely come to light if her disease were to be formally named.

Should physicians always tell the truth, the whole truth, and nothing but the truth?
Physicians often inform patients of some but not all risks of a procedure or medication. In doing so they make judgments about what information is salient and what they convey to the patient. In this sense, withholding some information is common in the practice of medicine. Historically, physicians were felt to be ministers of hope and comfort to the sick. When diagnostic options
were extremely limited and treatment options relatively nontoxic, doctors often felt that comforting and caring for the sick and suffering was more important than full disclosure and were known to withhold specific stressful information. In certain cultural contexts and frequently with children, withholding stressful information or controlling the way a severe medical illness is presented to a child is considered for the patient’s good. In modern day medical practice, physicians may have information about the long-term health consequences of a screening test (or genetic test) on patients who are not having any symptoms and do not know they have a disease. In addition, treatment options have expanded exponentially and different treatments may have different risk-benefit ratios. Experimental treatments may be available with varying toxicities. Given these significant changes in the options available to patients and the litigious environment in which modern medicine is practiced, fully informed consent has become an element of the legal and moral obligations of the physician.

**Patient Factors**

*Is the duty to respect a patient by allowing that patient to make decisions altered by the patient’s inability to make a decision?*

While children are unable to make decisions at younger ages, the fact is that children outgrow their dependent states. The AAP has promoted the concept of pediatric assent in recognition of this developmental trajectory. Pediatricians and parents have fiduciary responsibilities during this developmental trajectory to protect and promote the child’s health-related interests. Patients have cognitive needs to know and understand what is happening to them, and affective or emotional needs to feel known and understood. A parent’s request to shield a patient from specific knowledge is less morally objectionable at young ages. As maturation progresses and a child’s ability to understand information increases, there is an increasing moral obligation to the patient to honor specific requests. This has the potential to place a parent’s concept of what is best for the child in conflict with a physician’s view of what is best. These conflicts challenge a family’s right in a liberal society to raise a child with its own values.

In this case the child is fully participating in her care but does not know the specifics of her illness. She feels cared for and understood by her family, who has answered her questions about her illness in a vague way. There is no conflict about the medical care of the child; however, there is a conflict about what the child should be told about her disease.

**Family Factors**

*What does it mean to respect the family’s values? What harm may come to the child as a result of disrupting a stable system of social support provided by the family? What harm to the therapeutic relationship may result if a physician imposes his or her values on parents?*

Respecting a family’s values means recognizing that parents have the primary role in helping to define what constitutes their child’s well-being and their understanding of the good. It means a physician needs to respect a parent’s interest and freedom to raise a child with the parent’s own values. Parents are responsible for providing all a child’s basic needs and that includes opportunities to assist in the development of the child’s moral person. The needs of all members of a family may influence a health care decision related primarily to one child. A physician who superimposes his or her own values over a family’s has the potential to do harm by destroying a therapeutic relationship and upsetting a stable support structure for the child.

**Disease-Specific Factors**
**Does knowing about the disease positively affect its course and prognosis?**

Stronger arguments for full disclosure of disease status can be made for diseases in which a child’s knowledge of the disease will positively affect its course. Diabetes is an example in which self-care would be impossible if a child did not know about the disease. In the case under discussion, the child knows she is sick and is fully compliant without knowing her diagnosis. This makes the parent argument for less than full disclosure stronger. The fact that she is adopted and knows it is important because in the case of HIV, her adoptive parents are not in the chain of HIV transmission and are not a risk of having their HIV status disclosed. However, this does not lessen their concern about the psychological effect of full disclosure.

**Does knowing the diagnosis and prognosis affect the adjustment process or prognosis? Does knowing the facts of the disease help the patient to plan her life?**

Often a good case can be made for full disclosure of a diagnosis with children because a variety of support groups exist for many conditions and discussions with other families and children with similar illnesses can be therapeutic. It is also possible that children perceive that there is a secret, and keeping the secret in some cases may be a burden to them. Children often wish to protect their parents from pain just as parents wish to protect their children. In this case, there are no disease-specific support groups available for this family and the prognosis for the patient does not influence or change the family’s objective of doing its best to live a “normal” life with a chronic, life-threatening condition.

**Conclusions and Suggestions**

Respect for patients and their families is a cornerstone of the therapeutic relationship, and respect should be maintained even in settings where physicians may disagree with a family’s decision. Parents deserve wide latitude in determining what is best for their child. In conversations in which there is a difference of opinion between the parents and physician, it may be helpful to articulate deeply held assumptions about what having a good life means. Often the differences are rooted in different sets of presuppositions about the nature and meaning of life. When the respective goods are ordered and shared, those participating in discussion often feel heard and understood even if they cannot come to agreement. In the case presented, there is sufficient agreement about the ordering of the goods, and care of the patient was accepted by the primary care physician. In cases in which agreement cannot be found, physicians have the opportunity to refer patients for care to another physician of the family’s choice.

*This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.*

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Session 10. Autonomy, Beneficence, and the Rights of Parents and Children: Exploring the Application of Ethical Principles in Pediatrics

Christy L. Cummings, MD, FAAP, and Mark R. Mercurio, MD, MA, FAAP

Overview
Pediatrics involves the unique physician-parent-patient relationship. Medical decisions are best made with the rights and obligations of each of these individuals kept in mind, as well as an understanding of ethical principles. The following case explores the ethical principles of autonomy and beneficence, the patient’s best interest standard, and the rights of parents, children, and adolescents in medical decision-making. The case is discussed in light of relevant policies and guidelines of the American Academy of Pediatrics (AAP). Participants will review these ethical principles as well as understand a practical approach for applying them to future cases. Participants should be made aware that an approach to ethical problems based on rights and principles may be helpful, but this is not the only available approach, and other approaches may also be valid and prove useful.

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

Case Summary
You are the physician taking care of a 4-year-old girl admitted to the pediatric intensive care unit 3 days ago after prolonged submersion in a neighbor’s pool. She has been on mechanical ventilation since admission and remains critically ill. Per the clinical team, survival is uncertain, with a high likelihood of severe neurologic disability. The parents request continuation of life-sustaining medical treatment, such as mechanical ventilation and artificial nutrition and hydration, and full resuscitation, including chest compressions and epinephrine, in the event of cardiac arrest.

- Who should decide on the medical treatment plan?
- What are the best interests of the child?
- What are the rights of the child?
- What are the rights of the parents?
- What would you do? Would you offer withdrawal of life-sustaining medical treatment? Would it be appropriate to withdraw without parental permission?
Alternate Cases

1. A 14-year-old girl is brought into the office by her mother because of a suspicious-looking mass on her neck. The girl refuses testing of any sort, even venipuncture, but the mother insists that you perform a biopsy right now in the office to determine the cause.

2. The parents of a 27-week gestational age male born earlier this morning via “crash” cesarean delivery have just informed you that they would like to withdraw life-sustaining medical treatment, including mechanical ventilation and intravenous nutrition and hydration, for their child, citing that they don’t want to care for “a handicapped child.”

3. You are the pediatrician taking care of a 3-day-old female in the well-baby nursery. She is ready to be discharged home, but you are concerned about possible congenital heart disease after hearing a harsh murmur on auscultation today. The parents have refused imaging and invasive diagnostic testing to investigate the cause of the murmur, saying she will be fine and will outgrow this murmur like her older brother.

4. An 8-year-old boy and his parents are seeing you in the office for disruptive behavior in the classroom and at home that is concerning for attention–deficit/hyperactivity disorder. Both parents have demanded psychotropic drugs, while the boy is sitting alone on the examination table, refusing to take medication, repeating “I don’t want to take anything.”

Learning Objectives

1. Review and understand the ethical principles of autonomy and beneficence.
2. Understand the patient’s best interest standard.
3. Recognize that parental authority does not equate to parental autonomy.
4. Understand the rights of the child and parents.
5. Differentiate among permission, assent, and consent.
6. Understand how to apply these ethical principles to future cases.

Suggested Reading for Instructor


Further Reading


Hardwig J. *Is There a Duty to Die? And Other Essays in Medical Ethics.* New York, NY: Routledge; 2000


**Case Discussion**

*What are some rights of the child with regard to medical management decisions?*

The child has a right to a life, which includes a right to treatment that has a reasonable chance of resulting in a significant extension of life. She also has a right to mercy, here defined as the right not to be made to experience unnecessary suffering. This would include pain that results from treatment that offers no significant benefit to her. She has a right to justice, here defined as fair and equal medical treatment (Beauchamp and Childress; Cummings and Mercurio). Though not relevant to this case, it should also be noted that a child has a right to be informed and to participate in decision-making as appropriate for age and mental state.

*What are some rights of parents with regard to medical management decisions?*

Parents have a broad but not unlimited right to make decisions on behalf of their children as they see fit. They have a right to guidance and support from the medical team as they make those decisions, and to have explained to them all relevant information so that their decisions are well informed (Beauchamp and Childress; Cummings and Mercurio).

As described previously, when the patient is a newborn, an infant, or a child, parents are generally accorded the right to make medical decisions on the child’s behalf, referred to as parental authority. Contemporary justifications for parental authority have included 1) parents are responsible for bringing up their children, and that responsibility necessarily requires having rights for decision-making, 2) apart from the child, parents will be the ones most likely to have to live with the consequences of any decisions made, 3) parents know the child best, and 4) affection and close family ties makes parents most likely to reach decisions based on the child’s best interest (Forman and Ladd).

Parental authority, though widely accepted, is not absolute. For example, while a competent adult has the right to refuse even lifesaving medical treatment for herself, she is generally not accorded the right to do so for her child. Examples might include requiring chemotherapy for a child with a highly treatable cancer despite parental insistence on herbal or complementary medicine alone, or requiring blood products for a child with hemophilia whose parents identify themselves as Jehovah’s Witnesses. As expressed by the US Supreme Court, “Parents are free to become martyrs themselves. But it does not follow that they are free, in identical circumstances,
to make martyrs of their children before they have reached the age of full and legal discretion when they can make that choice for themselves” (Prince v Massachusetts).

What is autonomy?
The word *autonomy* derives from the Greek autos (self) and nomos (rule). Respect for autonomy, central to adult medical ethics, implies recognizing one’s right to make decisions for oneself and act on these freely (Beauchamp and Childress). This right has been understood in the context of health care to include a right to make decisions based on accurate and complete information. Competent patients are generally accorded a right to autonomy or self-determination. Perhaps the most fundamental component of this right is the right to refuse unwanted therapy. This does not necessarily include a right to demand any therapy.

*Competence* in this context can be defined as having the ability to understand a proposed therapy or procedure, including its risks, benefits, and alternatives, and to be able to arrive at a decision based on consideration of these factors in light of one’s values and life plans (Beauchamp and Childress). An autonomous decision is one made with adequate information and understanding of the implications of various possible outcomes. For any patient not considered competent, a truly autonomous decision is not possible, so a surrogate decision-maker should speak and decide on that patient’s behalf. In the case of young children, parents nearly always fill the role of surrogate decision-maker (Cummings and Mercurio). Adolescents may be competent to make certain medical decisions and are understood to have developing autonomy.

The doctrine of informed consent, which requires that competent patients be given relevant diagnostic and prognostic information and then retain the right to grant or withhold consent for any treatment, is derived from the principle of respect for autonomy.

What is the difference among parental informed consent, permission, and patient assent? Why is this important?
The doctrine of informed consent is limited in pediatrics, in that only patients themselves can actually give informed consent. Parents or other surrogate decision-makers provide *informed permission* for the diagnosis and medical treatment of their children (American Academy of Pediatrics Committee on Bioethics, 1995). The AAP also encourages the concept of *assent*, the developmentally appropriate child’s willingness or preference to participate in a proposed therapy or procedure. The practice of soliciting assent is modeled after obtaining informed consent from competent adults and recognizes the child’s developing ability to participate in the decision-making process. Soliciting assent also indicates an expectation that children will be active participants in their health care. Physicians can foster this practice by

1. Helping the child achieve a developmentally appropriate awareness of the condition
2. Telling the child what to expect with tests and treatment
3. Assessing the child’s understanding of the situation
4. Soliciting an expression of the child’s willingness to accept the proposed care

It may not always be possible to include children in the decision-making process due to age or mental condition, as in this case, but this may be possible and is encouraged in many other situations.
**What is beneficence?**
The principle of *beneficence* underscores the moral obligation to act for the benefit of others (here, patients), including protecting the rights of others, preventing harm to others, and helping those in danger (Beauchamp and Childress). One can see that respect for autonomy and beneficence may at times be in conflict, such as when a competent patient refuses a treatment that would clearly benefit him or her.

**On which principles should surrogate medical decisions be based?**
When deciding on behalf of an incompetent patient, decisions are ideally based on the patient’s previously expressed wishes or what the surrogate decision-maker believes the patient would have wanted, known as *substituted judgment*. This seems consistent with respect for autonomy and applies to most adults and perhaps at least to some extent to many older adolescents. For patients who have never been competent, such as small children, autonomy or previously expressed wishes are not relevant. Here, the *patient’s best interest standard* should be central to the decision. This holds that decisions should be made for a patient based on weighing the relative benefits and burdens to the patient of the treatment under consideration (Beauchamp and Childress; Cummings and Mercurio). It is, then, a standard based largely on the principle of beneficence.

**What would be in this child’s best interests?**
In this case, one could argue that it is in the patient’s best interest to live as long as possible, regardless of prognosis, justifying the use of life-prolonging measures such as mechanical ventilation, artificial hydration and nutrition, and aggressive resuscitation. Such an argument could be based on religious beliefs, but the choice to value life over other considerations need not be made solely on religious grounds. By this reasoning, the benefit of being alive outweighs or trumps the burdens of ongoing intensive care. Others could argue that quality of life may sometimes matter more, and that an artificially prolonged life without meaningful social interaction or the possibility of regaining any meaningful interaction is not in the patient’s best interest. Furthermore, complying with the parents’ requests to prolong life via cardiopulmonary resuscitation (CPR) and mechanical ventilation, for example, could perhaps result in additional harm (burden) to the patient by causing unintentional pain and suffering. By this reasoning, the benefit of being kept alive is outweighed by the burden of possible pain, indignity, or other factors.

In this way, determining the child’s best interest requires a consideration and comparison of all relevant burdens and benefits to the child of the treatment under consideration. Clearly, this will often be a very subjective judgment. Participants should be asked to consider and discuss which of these approaches they feel is preferable.

**If best interest is often a subjective value judgment, whose values should count the most?**
In general, the values of the family should be determinative. Parents should be given wide discretion and are not always required to choose what is (in the opinion of physicians) in the child’s best interest. But if they reach a decision that is *clearly opposed* to the child’s interests, with major consequences, pediatricians should consider overriding their decision, with court assistance if necessary and if time allows (American Academy of Pediatrics Committee on Child Abuse and Neglect and Committee on Bioethics, 2000). For this case, participants should discuss
whether they feel the parents’ decision meets that threshold, thus obligating the physicians to seek to override it.

**What if parents refuse a treatment recommended by the physician?**

The same threshold should be sought. Is their choice merely suboptimal, or is it clearly opposed to the child’s best interests? It may become difficult to determine. A useful guideline for all pediatricians, however, has been provided by the AAP Committee on Bioethics: “All children are entitled to effective medical treatment that is likely to prevent serious harm, or suffering, or death” (American Academy of Pediatrics Committee on Bioethics, 1997). In rare case in which a pediatrician is concerned that a child is being denied this basic right because of parental choice, help from others, such as the hospital ethics committee and (in rare circumstances) the court, should be sought as time allows.

**Is it appropriate to consider the interests of others, such as other family members, when making medical decisions for a child?**

It is widely held that the benefits and burdens to the patient, and not the family, medical team, or society, are the relevant considerations. This is what is meant by patient’s best interest. It has also been suggested, however, that it is reasonable for parents to consider potential benefits and burdens to the entire family in making their decision or for the medical team to consider the interests of society (eg, financial costs) in determining what choices are made available to the patient or family (Hardwig). Participants should discuss whether they prefer the stricter patient’s best interest standard or a broader inclusion of the interests of other people affected by decisions.

**What should be done in this case?**

In a case such as this, the medical team might feel that ongoing intensive measures and CPR would be inappropriate. Would it be ethically permissible to withdraw life-sustaining medical treatment despite parental objection? Would it be permissible to continue treatment as they have requested? These questions should be discussed in the seminar, based on the previously described considerations, and including the following points. However, it is essential at the outset to emphasize the importance of patience and compassion when working with parents who have been so devastated, and how their state of mind could influence their ability to work through the decision-making process.

One could argue that complying with the parents’ requests to attempt to prolong life, via mechanical ventilation, artificial nutrition and hydration, and CPR, for example, could harm the patient by causing additional pain and suffering. Further, doing so would be very unlikely to provide significant benefit to the child if there was an extremely poor prognosis. By this reasoning it could be permissible to withdraw life-sustaining medical treatment and refuse aggressive resuscitative measures despite parental request, while providing adequate comfort measures based on an assessment of the child’s interests. Furthermore, some who feel the benefits and burdens to individuals in addition to the patient should be considered might feel that withholding or withdrawing these treatments would be more consistent with the interests of those from whom resources would be diverted by maintaining the status quo.

The counterargument would be that there may be a chance for survival, and the values of the family may be such that any survival is a worthwhile goal. If informed parents wish to continue life-sustaining treatment, realizing that their child may not regain her former quality of life or be
permanently neurologically devastated, and sufficient pain control is achieved, it would be permissible to continue life-sustaining medical treatment, thus respecting the parents’ right to parental authority. Where there is a chance for long-term survival and pain is adequately controlled (which should most often be attainable), parental preference for ongoing treatment should be respected, even if the medical team feels it to be inadvisable.

The physician’s decision will require consideration of the rights and obligations discussed up to this point and weighing the 2 arguments just presented. Some believe, and it is here suggested, that certain cases are so bleak (some prognoses so poor) that it is inappropriate to offer CPR and is appropriate to otherwise limit life-sustaining treatments. This is particularly true when patients appear to be suffering. In such cases in which options are to be limited over parental objection, physicians should seek input from others such as a second opinion, hospital ethics committee, and legal counsel. Many hospitals also have policies that specifically address such situations. But just as great emphasis should be placed on the values and preferences of the family, great caution is advised whenever considering overriding those preferences. It should be an occurrence of last resort. There may be some cases in which a child’s dying is being significantly prolonged and her suffering thus continues, to benefit others (eg, parents), and this is generally not appropriate. However, one should also consider that parents faced with such devastating information may need some time to understand and accept the situation. During this time it is the responsibility of the clinical team to give the patient adequate pain control and the family the support they need.

Participants should discuss the relative merits of these arguments and whether the severity of the prognosis in this case justifies withholding treatment despite parental request.

**Conclusions and Suggestions**

Decision-making involving the health of children should include the physician, parents, and when possible, developmentally appropriate children. Effective communication among these groups is paramount. While an understanding and application of the principles outlined herein will be essential to decision-making, conflicts and potential conflicts are most often resolved or avoided by open, frequent communication among all those participating in the decision.

*This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.*

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Session 11. Institutional Ethics Committees

Micah Hester, PhD

Overview
Beginning in the 1960s with decisions about who should get kidney dialysis, suggested by courts in the 1970s, required by the Baby Doe regulations in the 1980s, and proliferated in response to Joint Commission accreditation requirements in the 1990s, institutional ethics committees (IECs) are now mainstays of hospitals in the United States. Most have a traditional charge to provide education, policy review, and consultation, but the specific practices of IECs vary among different institutions. It is helpful to understand the form and function of IECs to use them best in practice.

This module will discuss the functions of IECs and the roles they play in health care institutions, as well as their usefulness in patient care and policy development. Participants are encouraged to discuss their knowledge of, experiences with, and reservations about interacting with IECs. Further, they are encouraged to learn more about the specific practices and policies of their own hospital’s IEC.

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

Case Summary
Tommy was 3 years old when he was hit by a car resulting in severe traumatic brain injury (TBI). Two weeks into his pediatric intensive care unit (PICU) stay, Tommy’s parents were presented with the option to forego life-sustaining treatment. After a few days of reflecting and discussing the issue, they determined that stopping the ventilator was best, but by that time there was a new PICU physician who, after review of Tommy’s condition, did not think that forgoing life-sustaining treatment was warranted. With more intensive therapy, Tommy was able to breathe without the ventilator, and he was moved to the rehabilitation unit. Because of his TBI, however, he continued to be fed through a tube. Neurologic scans indicated problems with the basal ganglia, and Tommy’s parents suggested that Tommy’s condition was not in his best interest and asked the palliative care physician about the possibility of stopping feeds. At the same time, physical and occupational therapists working with Tommy, as well as nurses and social workers from the PICU who came to visit him in rehabilitation, believed they saw slight but noticeable improvements in his cognitive status—possible tracking, smiling, and reacting to...
some stimuli. The entire unit, as well as these PICU staff members, is concerned about the ethics of what the parents are suggesting.

- Should a request be made for an IEC consultation?
  - If so, at what point should it be (or have been) made?
  - If so, who should or who can call for the IEC?
  - What role would the IEC play if called in?
- What can you expect from the IEC?
  - How will it function?
  - Does it mediate, facilitate, or recommend?
  - What training is involved?
- Are there good reasons to avoid calling in the IEC?
  - Are committee consultations helpful or harmful?

Alternate Cases
1. Diagnosed with biliary atresia at 3 months, Jamie’s parents reluctantly agree to a Kasai procedure to temporarily mitigate his liver problems. His parents are told that the Kasai procedure may work for as long as 5 years, but eventually Jamie will need a liver transplant. Jamie’s parents, stating that they have seen family members do better than doctors ever thought possible and that they have faith that God is already healing Jamie, are reluctant to pursue transplant. Unfortunately, within a year Jamie’s liver begins to fail, and transplant is medically indicated. The parents, however, refuse to take Jamie to a transplant center. The liver specialist who has just admitted Jamie to the hospital believes that the parents’ decision is unacceptable, and she calls the IEC hoping to convince the committee that the transplant should be pursued over the parents’ objections.

  - What role should the IEC play?
  - Who should be involved in the IEC discussions?
    - Should Jamie’s primary care physician be notified?
    - Should the parents be involved?
    - Should legal counsel be present?

2. Mary Jo, a child who is chronically disabled, has had trouble gaining weight even on full-feeds at home and in the hospital. Her “Is and Os” are often unexplainably negative. Also, her percutaneous endoscopic gastrostomy tube continually has problems, including breaking. The gastroenterologist finds the myriad problems baffling, even disturbing. “Breaks almost never happen,” he notes. He is concerned that Mary Jo’s mom may be interfering with the tube, purposefully causing problems. He wants to put Mary Jo under video surveillance without mom’s knowledge to see if he can catch her “messing with” Mary Jo’s feeds. Policy requires that the IEC review the case before he can proceed.

  - Are you aware of institutional policies that might require IEC involvement?
    - Should policies require IEC involvement?
  - Should the IEC take the lead on developing policies that have ethical content?

Learning Objectives
1. Understand reasons that IECs exist and functions they can play in the institution.
2. Understand the different ways that IECs provide case review and consultations.
3. Recognize the benefits of IEC involvement when challenging ethical issues arise.

**Suggested Reading for Instructor**
[http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/1/205](http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/1/205). Accessed May 13, 2011

[http://cpj.sagepub.com/content/46/9/771.extract](http://cpj.sagepub.com/content/46/9/771.extract). Accessed May 13, 2011


**Further Reading**


[http://jama.ama-assn.org/cgi/content/abstract/290/9/1166](http://jama.ama-assn.org/cgi/content/abstract/290/9/1166). Accessed May 13, 2011

**Case Discussion**
*What do you know about the prognostics of TBIs and the interests or values of the parents and family? In light of that knowledge, is forgoing life-sustaining treatment an option that should be offered at this time?*

It is often said that good ethical reasoning begins with good understanding of the medical facts. The emphasis here, then, should be on beginning with good clinical knowledge in relationship to the determination of what options are materially relevant to consider.

Of course, ethical reasoning also takes a good understanding of personal, social, and institutional factors as well. Be careful not to set up a false dichotomy between medically relevant information and ethically relevant considerations. No medical “fact” is understood in a vacuum; they are interpreted in light of one’s personal, professional, and cultural influences.

*The option for forgoing life-sustaining treatment was, in fact, given to the parents and then later taken off the table. If you disagree with either action, should that trigger a call to the*
IEC? If you agree with either, is this still worth calling the IEC about? Are there any concerns about taking the step to call for IEC involvement?
Explore here why ethics consultations might or might not be triggered. Discuss barriers to or concerns about contacting the IEC. In what ways do personal opinions or institutional pressures act on the decision to call for a consultation?

In this case, the health care workers called for an IEC consultation.

Were they right to call for a consultation?
Should an IEC consultation have been called for? Were these particular health care professionals overstepping their authority in doing so?

It is important to discuss briefly what reactions the group has to how the scenario played out. Moving too quickly to a discussion of the role and functions of the IEC may leave members of the group distracted by their own lingering opinions about the case.

Conclusions and Suggestions

What is an ethics committee?
Most IECs are developed as mechanisms to handle ethically challenging issues in a hospital or other health care institution. The membership of an IEC typically is composed of institutional staff members—physicians, nurses, social workers, chaplains, administrators, and sometimes legal counsel (the latter 3 groups are not always included because of conflict of interest concerns). Many employ community or unaffiliated people as well to serve as a check on institutional bias and provide greater insight. When available, someone educated in philosophical or religious ethics is often included as well.

What functions does an ethics committee serve? What place in your organization does it hold?
Aside from serving the institutional function of satisfying Joint Commission accreditation requirements calling for a mechanism to handle ethical concerns in the institution, IECs traditionally serve 3 functions within the institution.

- Review and develop institutional policies.
- Educate staff in the institution.
- Provide consultations and case reviews.

Not all IECs perform all 3 functions. Some institutions have a separate ethics consultation service, while other IECs may do little to no policy review or other organizational ethics activities—these may be done by other committees or by a compliance or ethics officer in the institution.

Also, it can prove useful to know whether your IEC is a medical staff committee or a committee that reports directly to the board, or if it resides in some other part of the organizational structure. Its place in the organization can affect its functional scope, practices, and authority.

What does an ethics committee consultation look like?
Consultations may occur in 3 general ways.
1. **Singular consultant:** Here an individual (hopefully well trained) is tasked (by the institution or the IEC) with consulting. That person will take calls and respond as needed. This process allows for maximum expediency and flexibility but a minimum of perspective.

2. **Small team consultation:** Some institutions use a small team (typically 3 to 5 persons from the larger IEC) to consult. This process provides a bit less flexibility and expediency than the single consultant model but, in turn, provides more perspectives.

3. **Full committee consultation:** Here at least a quorum of the entire IEC meets to discuss an ongoing case. Needless to say, this is the least expedient and flexible approach, but it maximizes the perspectives brought to bear.

Like many aspect of IEC work, the details of how the IEC functions in a consultation are specific to each institution. In fact, some institutions may use a combination of these consulting models depending on the type and source of the consultation request.

**What does an ethics committee consultation try to accomplish?**

There are different philosophies that IECs live by in relation to consultations. In general, they may try to:

- Facilitate discussion among different and differing parties.
- Elucidate and clarify values-based concerns within a situation.
- Mediate disputes to dissolve or resolve conflicts.
- Analyze ethical concerns in a situation and provide a recommendation.

Obviously, there can be overlap in fulfilling these objectives. It is important to know what your IEC consultation (or your ethics consultation service) attempts to accomplish and with what methods. Further, you may want to make sure that the IEC representatives have an understanding of the unique aspects of pediatric care and decision-making.

While in most cases IECs have no decision-making authority, they may make recommendations addressing their view of the ethically best decisions available. In such cases, patients, families, and physicians are typically not bound to those recommendations, but it should not be ignored that IEC recommendations do carry some amount of moral authority. Also, some institutional policies may give a determinative role in decision-making to IECs for specific situations. For example, a policy on the use of covert video surveillance in cases of suspected patient condition falsification (ie, Munchausen syndrome by proxy) may require that before the surveillance can be implemented, the IEC review and sign off on its use for the case at hand.

**Who may call for a consultation?**

The answer to this question depends entirely on the ethics consultation policy of your institution. However, most institutions allow for consultations to be called by a wide variety of people—not simply attending physicians or unit directors but almost anyone in the institution, including patients and family members (in fact, this breadth is recommended by the American Academy of Pediatrics [AAP] Committee on Bioethics). Again, there may be some limits specific to your institution.

**Do ethics committees really help? If so, how?**
Research indicates that IEC consultations can provide help for institutions, practitioners, patients, and families. For institutions, consultations have been shown to help reduce costs, shorten length of stay, and champion positive professional and organizational values. Practitioners who have triggered ethics consultations indicate satisfaction with help in clarifying unrecognized values at stake, opening lines of communication, and reducing tensions with others. Families report that consultations offer support, provide a forum in which to be heard, and help them better understand the complexities of the medical and ethical situations.

**What more might an ethics committee do?**
In some cases, situations pose problems that set precedence or require wider institutional actions. Institutional ethics committees, then, may attempt to develop or promote system-based protocols or policies to handle these issues. In the case of Tommy, the staff caring for Tommy or the IEC may want to follow up in the coming months with staff debriefings to deal with lingering ethical concerns and moral distress. Furthermore, the IEC may want to work with staff in the PICU to develop protocols to address differences among staff or to better handle handoff issues when new attending physicians take over the ongoing care of a patient.

Finally, IECs may set up forums for education, whether about specific issues in caring for patients or in light of the development of policies with significant ethical content. The point is that while the IEC is most often associated with case reviews and consultations, many IECs play much wider roles in their institutions, and it is helpful to familiarize yourself with the full extent of functions the IEC performs. The AAP Committee on Bioethics has its own list of 6 recommendations addressing IECs that might be helpful to review and implement where appropriate.

*This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.*

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Session 12. Brain Death, Permanent Vegetative State, and Medical Futility

Diane Plantz, MD, and John Lantos, MD, FAAP

Overview
Technology now allows many patients with severe neurologic disorders who in the past would have died to have their lives prolonged. Some such patients are brain-dead; others are in a state of permanent unconsciousness; and still others have severe brain damage but some interaction with their environment. The care of such patients raises controversial questions. Are their lives worth living? At what expense? Should society impose limits on the kind of care that should be offered to patients who have no hope of ever recovering consciousness? When the patients are children, the issues become even more complicated. How much can parents request? Can a physician refuse to provide the treatment if they believe the treatment is medically futile? Who determines if the treatment is futile and by what criteria? Should cost be included when determining if the treatment is appropriate?

This module will help the participants understand the differences among brain death, coma, permanent vegetative state, and minimally conscious state, as well as help them appreciate how one’s determination of futility affects decision-making with regard to treatment options.

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

Case Summary
A 4-year-old boy suffered a traumatic brain injury (TBI) in a motor vehicle accident. Now, 6 months after the accident, he has been diagnosed as being in a permanent vegetative state. After multiple episodes of pneumonia, his lung function has deteriorated to the point of requiring long-term mechanical ventilation. His parents provide the ventilation treatment at home, but he is periodically hospitalized with aspiration pneumonia. The physicians believe that continuing the ventilator is futile.

- Is this treatment futile?
- Who determines whether a treatment is futile?
- Who has the right to decide medical treatment for this child?
Would these answers be different if the child were brain-dead or in a minimally conscious state?

Alternate Cases
1. A 3-month-old has been declared brain-dead. The infant was found apneic and pulseless in his crib and was resuscitated. Since admission to the pediatric intensive care unit, he has not improved. The infant meets all the criteria for the determination of brain death. The parents do not want to withdraw support. Currently he is receiving intravenous nutrition and hydration and ventilatory support via an endotracheal tube. The parents want a feeding tube placed and a tracheostomy for permanent ventilatory support. The physicians believe this treatment is futile and refuse to provide it.

2. A 6-year-old girl is in a minimally conscious state, living in a chronic care facility as a ward of the state. Her brain injury is a result of nonaccidental trauma as an infant. She has been living in this chronic care facility since initial discharge with no familial involvement. Recently she has required multiple hospitalizations for pneumonia. Long-term ventilation is recommended. Her caregivers at the facility state that she interacts with her environment at times. She periodically grunts when she is being weighed, withdraws from painful stimuli, and smiles when caregivers sing to her. How does one determine quality of life and therefore determine whether long-term ventilatory support would be futile in this case?

Learning Objectives
1. Understand the differences among brain death, coma, permanent vegetative state, and minimally conscious state.
2. Recognize different definitions of futility.
3. Understand parental rights to make medical decisions for children and the potential limitations to these rights.

Suggested Reading for Instructor

Further Reading


Case Discussion
In this case, the child is not brain dead. Mechanical ventilation for a patient in persistent vegetative state is not physiologically futile. The ventilator will achieve its intended effect; it will support his respiratory status, decreasing his risk for pneumonia. With regard to qualitative futility, the physicians may feel that this child’s quality of life is poor, based on their own values. The parents, on the other hand, may feel that their child’s quality of life is acceptable. When determining futility based on quality of life one must recognize that their values play a role in this determination. Therefore, if the parents believe the child has an acceptable quality of life, a decision to provide mechanical ventilation for their child must be respected.

In alternative case #1, the child meets the criteria for brain death. In that case, they could legally withdraw the ventilator without the parents’ permission. In some such cases, parents have sought legal protection, through restraining orders or other legal means, and courts have allowed their wishes to continue mechanical ventilation to prevail. Those cases are rare.

The patient in alternative case #2 is awake, alert, and has some interaction with her environment. She does not appear to be in pain. While many people would consider her quality of life miserable, and would withhold or withdraw life-sustaining treatment, others would opt to continue treatment. In such a case, where a patient is neither permanently unconscious nor in intractable pain, either option is permissible.
Conclusions and Suggestions
Caring for individuals with severe neurologic disorders can be very difficult, especially when the question of medical futility arises. It is important to remember the difference between physiologic futility and qualitative futility, with determination of qualitative futility being based on one’s personal values. At this point in our society, when we do not deem something to be medically futile based on financial implications, we need to respect the parents’ determination of what is best for their severely neurologically devastated child.

What are the differences among brain death, coma, permanent vegetative state, and minimally conscious state?

Brain Death
The Presidential Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research established guidelines for the diagnosis of brain death in 1981 (Table 1). There are 2 criteria for the determination of death: the irreversible cessation of circulatory and respiratory functions, or the irreversible cessation of all functions of the entire brain, including the brain stem.

Table 1. Guidelines for the Diagnosis of Brain Death
1. An individual with irreversible cessation of all functions of the entire brain, including the brainstem, is dead.
2. Cessation is recognized when evaluation discloses findings of (a) AND (b)
   a. Cerebral functions are absent
   b. Brainstem functions are absent
3. Irreversibility is recognized when evaluation discloses findings of (a) AND (b) AND (c)
   a. The cause of coma is established and is sufficient to account for the loss of brain functions
   b. The possibility of recovery of any brain functions is excluded
   c. The cessation of all brain functions persists for an appropriate period of observations and/or trial of therapy
4. Complicating conditions confounding the diagnosis of brain death
   a. Drug and metabolic intoxication
   b. Hypothermia
   c. Children (particular caution in applying neurological criteria to determine death in children <5 years old)

In 1987, the American Academy of Pediatrics Task Force for the Determination of Brain Death in Children developed the guidelines for the determination of brain death in children listed in Table 2.

Table 2. Guidelines for the Determination of Brain Death in Children
1. Coma and apnea must coexist.
2. Absence of brainstem function
   a. Pupils unreactive to light (midposition or dilated)
b. Absence of spontaneous eye movement, or in response to oculocephalic and oculovestibular testing
c. Absence of movement of bulbar musculature including facial and oropharyngeal muscles (corneal, gag, cough, sucking, and rooting reflexes)
d. Respiratory movements are absent with patient off the respirator.
e. Apnea testing using “standardized methods” can be performed

3. Absence of hypotension for age or hypothermia
4. Flaccid muscle tone, absence of spontaneous movements (excluding spinal reflexes)
5. Examination consistent with brain death throughout the period of testing and observation
6. Observation and testing according to age
   a. 7 d to 2 mo: two examinations and EEGs separated by 48 h
   b. 2 mo to 1 y: two examinations and EEGs separated by 24 h; repeat examination and EEG are not necessary if concomitant cerebral radionuclide study demonstrates no visualization of cerebral arteries
   c. Older than 1 y: when an irreversible cause exists, laboratory is not required and an observation period of at least 12 h is recommended; A more prolonged period of at least 24 h of observation is recommended if it is difficult to assess the extent and reversibility of brain damage (e.g. following an hypoxic-ischemic event). The observation period may be reduced if the EEG demonstrates electrocerebral silence or the cerebral radionuclide angiographic study does not visualize cerebral arteries

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Coma
Coma is a “state of deep, unarousable, sustained pathologic unconsciousness with the eyes closed which results from dysfunction of the ascending reticular activating system either in the brain stem or both cerebral hemispheres” (Ashwal and Cranford). This state must persist for greater than 1 hour. Patients are unconscious because they lack both wakefulness and awareness (Ashwal).

Permanent Vegetative State
Permanent vegetative state is a condition of “complete unawareness of the self and the environment accompanied by sleep-wake cycles with either complete or partial preservation of hypothalamic and brain stem autonomic functions” (Ashwal). Patients show all the following characteristics as developed by the Multi-Society Task Force on PVS:

- No evidence of awareness of themselves or their environment; they are incapable of interacting with others.
- No evidence of sustained, reproducible, purposeful, or voluntary behavioral responses to visual, auditory, tactile, or noxious stimuli.
- No evidence of language comprehension or expression.
- Intermittent wakefulness manifested by presence of sleep-wake cycles.
- Sufficiently preserved hypothalamic and brain stem autonomic functions to survive if given medical and nursing care.
- Bowel and bladder incontinence.
Variably preserved cranial nerve (papillary, oculocephalic, corneal, vestibule-ocular, gag) and spinal reflexes.

**Minimally Conscious State**
Minimally conscious state is a condition of “severely altered consciousness in which minimal but definite behavioral evidence of self or environmental awareness is demonstrated” (Ashwal and Cranford). Diagnostic criteria from the Aspen Neurobehavioral Work Group (Giacino et al) are as follows:

1. Simple command following.
2. Gestural or verbal “yes/no” responses (regardless of accuracy).
3. Intelligible verbalization.
4. Purposeful behavior including movements or affective behaviors that occur in contingent relation to relevant environmental stimuli and are not due to reflexive activity. Some behaviors include the following:
   a) Appropriate smiling or crying in response to the linguistic or visual content of emotional but not to neutral topics or stimuli.
   b) Vocalization or gestures that occur in direct response to the linguistic content of questions.
   c) Reaching for objects in a way that demonstrates a clear relationship between object location and direction of reach.
   d) Touching or holding objects in a manner that accommodates the size and shape of the object.
   e) Pursuit eye movement or sustained fixation that occurs in direct response to moving or salient stimuli.

**Differentiation Among Brain Death, Coma, Permanent Vegetative State, and Minimally Conscious State**
The patient with brain death will show evidence meeting the diagnostic criteria listed previously demonstrating completely destroyed brain stem. Coma patients lack wakefulness and awareness, while permanent vegetative state will have complete or partial preservation of brain stem and hypothalamic function but will have no awareness of self or environment with periods of wakefulness. Minimally conscious state will have behaviors associated with conscious awareness that may occur inconsistently but are reproducible and sustained to determine their nature.

**Do these categories make up the whole spectrum of severe brain damage?**
No. These categories reflect those individuals with severe neurologic damage. There are many patients who have more awareness and behaviors than individuals in minimally conscious state.

**Is life-sustaining treatment futile for infants or children in any of these categories? What is the definition of futility?**
A strict definition of futility would be the complete absence of any efficacy in reaching any physiologic goal. In clinical medicine, the term is usually used to mean that a treatment or therapy will not improve or benefit the patient in any way. Schneiderman et al defined futile as “any effort to achieve a result that is possible but that reasoning or experience suggest is highly improbable and that cannot be systematically produced.”
Is there a difference between physiologic futility and qualitative futility?
Futility has been expanded to mean many different things to many different people. Diekema states there are 2 different types of futility: strict physiologic futility and qualitative futility. Strict physiologic futility means that an “intervention would not achieve its intended immediate physiologic effect.” The treatment simply would not work. Examples of strict physiologic futility include the use of antibiotics to cure a viral illness or cardiopulmonary resuscitation for a patient who has been pulseless for longer than 1 hour. Qualitative futility “weighs the potential benefit of an intervention with the quality of its effects.” Qualitative futility is controversial because it requires a value judgment about the quality of the effects of treatment. Such a value judgment could be made by physicians, patients, or surrogates for the patient. If these parties agree (as is often the case), they can act on the futility determination. If they do not, one must prevail.

Is cost-effectiveness relevant to determinations of futility?
One should not confuse cost-effectiveness with medical futility. Just because a treatment is not cost-effective, such as long-term ventilation in a patient with neuromuscular disorder, does not mean that it is futile. When physicians use cost-effectiveness as a determinant of the appropriate level of care for patients with serious neurologic impairment, they are incorporating a value judgment to the decision-making, a judgment about quality of life that is usually left to the patient and family.

Are there limits to parents’ rights to make treatment decisions for their children?

In Brain-dead Children
Laws in every state allow the physician to forgo life-sustaining medical treatment in individuals who are determined brain-dead regardless of age. There have been cases in which parents have protested the removal of life-support based on brain death criteria and prevailed. These are rare. In most cases of disagreement, the child’s respiratory and circulatory systems fail before the court decision is made.

In Permanent Vegetative State or Minimally Conscious State
A child who is in permanent vegetative state or minimally conscious state is not dead. Therefore, parents have the right to make health care decisions for this child. A few states allow physicians to override patients or surrogates if the physician determines that further treatment is futile.
Session 13. Critically Ill Newborns

Mark R. Mercurio, MD, MA, FAAP

Overview
The newborn intensive care unit (NICU) is a common setting for difficult ethical challenges, often involving life-and-death decisions. These may include withholding treatment such as resuscitation, mechanical ventilation, or surgery, or withdrawing life-sustaining medical treatment such as mechanical ventilation and artificial nutrition and hydration. Such decisions are frequently faced because of the high morbidity and mortality of some conditions commonly encountered in this setting, such as extreme prematurity, perinatal asphyxia, and major congenital anomalies. Who should decide when a treatment should be withheld or withdrawn? Ideally, decisions are made by the parents, physicians, and nurses working together, but what is to be done when they disagree? On what basis should decisions be made? Ideally, a careful ethical analysis is carried out, based on solid clinical and prognostic data and the values of those involved in making the decision. In reality, data are often very vague and values are often not shared in common, but a decision must nevertheless be reached.

Such critical ethical decisions may be more common in the NICU than in other pediatric settings, but they are certainly not unique to the NICU. Nonetheless, is there something unique about ethical problems encountered with this patient population? For example, is borderline viability based on extreme prematurity a unique situation in pediatrics, or is it analogous to other problems sometimes encountered in the care of older children? Are clinicians more willing to withdraw or withhold life-sustaining treatment for this patient population than for others in pediatrics or adult medicine? If so, is this justified?

In this teaching module participants will examine these questions in the setting of specific case examples. The primary case involves resuscitation of a newborn at borderline gestational age, but the questions and principles identified should be relevant to a wider range of issues in the NICU.

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

Case Summary
A 36-year-old woman who has been pregnant 3 times but has no living children presents to the hospital in active labor and ruptured membranes at 22 weeks and 5 days’ gestation. The fetus is a female singleton, the product of in vitro fertilization. Pregnancy was otherwise unremarkable,
including several normal ultrasounds. Estimated fetal weight is 530 grams. On physical examination the cervix is dilated and the obstetrician believes that delivery will occur within the next several hours. The pediatric team meets with the woman and her husband to share information, answer questions, and discuss the plan.

- What options should be offered to the parents for resuscitation and treatment?
- If informed parents request resuscitation and intensive care but the clinical team feels they are inappropriate, is the team nevertheless obligated to provide it?
- If informed parents decline resuscitation and intensive care measures but the clinical team feels it is inappropriate to withhold those measures, is the team nevertheless obligated to withhold those treatments?
- What ethical principles or approaches can be applied to guide clinicians and parents through the care provided to this child?

Alternate Cases
1. A woman is in labor at 32 weeks with a fetus known to have trisomy 13, including congenital heart disease. This diagnosis carries with it a high probability of death in the first weeks or months of life, and profound cognitive impairment among those who survive longer. In the event of respiratory failure, what options should the parents be offered for resuscitation of the newborn, mechanical ventilation, or cardiac surgery?

2. A child is born at term with hypoplastic left heart syndrome. He is initially stable and placed on a prostaglandin infusion to maintain systemic blood flow. Parents are informed that there is a much greater than 50% chance of survival at 5 years, but this will require at least 3 separate surgical procedures and extensive hospital time. Some neurologic disability, though not likely severe, is also likely should he survive. The cardiology service has recommended that the surgery be performed, but the parents have requested that the prostaglandin infusion be stopped and the child be allowed to die.

3. A full-term baby is delivered by cesarean for severe fetal bradycardia. She requires extensive resuscitation in the delivery room, including intubation, positive-pressure ventilation, chest compressions, and epinephrine. Her Apgar scores are 1, 2, and 4 at 1, 5, and 10 minutes, respectively. The cord pH is 6.70/6.85. Early course in the NICU is notable for severe lung disease, hypotension, disseminated intravascular coagulation, and seizures. At 7 days of age, she is minimally responsive to tactile stimulation, is ventilator dependent but with some spontaneous effort, and has magnetic resonance imaging evidence of severe ischemic changes of the brain. What options should be offered to the parents? What should the clinical team do if the parents insist on maximal efforts but the clinical team feels this would be inappropriate?

Learning Objectives
1. Understand the major components of honest disclosure when presenting a critical decision and options to parents.
2. Understand ethical considerations in withdrawing or withholding therapy from a critically ill newborn.
3. Understand the parents’ right to decide and limitations of that parental right based on the rights of the newborn, including the patient’s best interests.
4. Understand the role of the parents and of the physician in critical decision-making in the NICU.

Suggested Reading for Instructor


Further Reading


Case Discussion
*What should the parents be told by the pediatric team?*
After appropriate introductions, parents should be given the relevant information about likelihood of survival and long-term disability, as well as anticipated clinical course should their daughter survive (eg, duration of NICU stay and common major problems). It is important to be honest with the parents, and with ourselves, about the degree of uncertainty of outcome data. For example, in this case the gestational age is certain because of in vitro fertilization, but often obstetric estimates of gestational age may be 10 to 14 days high or low, which would yield a wide range in the predicted chance of survival. Depending on the certainty of the gestational age,
it may be more appropriate to speak in terms of a range of predicted outcomes rather than a specific number.

Also, the predicted chance of survival may be center-dependent; simply quoting overall survival statistics may be inadequate. For example, some centers may never attempt resuscitation if younger than 23 weeks, tell parents that they have never had a survivor at 22 weeks, and remain unwilling to try on that basis. This reasoning is of course circular, creating a self-fulfilling prophecy, and thus is invalid. The appropriate question to be addressed is, what percentage of newborns in this situation survive when maximum efforts are made? If one does not have those data, it would be best to say so. Survival data from centers more aggressive with a given diagnosis (eg, 22 weeks’ gestation) may be markedly different than from less aggressive centers (Mercurio).

The conversation with parents should be based on our obligation to tell the truth and to provide them, as the surrogate decision-makers for the child, with relevant data so they can make their best decision. This recognizes their rights as parents and the child’s right to have decisions made in good faith on her behalf by appropriate surrogate decision-makers.

**What options should parents be given for resuscitation?**

In general, parents have a right to make the decision on their child’s behalf. If there is no chance of success, however, the physician is not obligated to provide a procedure or to offer it. No newborn should be made to undergo a procedure, particularly an invasive or potentially painful one that offers no chance of benefit. This would include resuscitation, but one needs to be sure that prognostic information is up to date. Some believe there is no chance of survival after birth at 22 weeks, but in fact data have shown that with aggressive treatment, survival is unlikely but nevertheless possible. In Japan, where they are apparently more aggressive in this setting, at least one large series showed survival to discharge for those born at 22 weeks to be greater than 30% (Itabashi et al). This in itself does not prove that resuscitation at 22 weeks should be performed or even offered, only that a decision not to offer resuscitation cannot be justified by impossibility (or futility).

As a reasonable rule of thumb, resuscitation for this (or any) newborn should be offered to the parents unless there is virtually no chance of success or to provide the procedure would clearly be opposed to the child’s best interest (American Academy of Pediatrics Committee on Bioethics); that is, the burdens of the procedure to the child would clearly outweigh the benefits. Burdens taken into account could be short term (eg, pain) or long term (eg, disability). Benefits might include the chance for survival and the potential happiness that life could bring to the child. Of course, this will often be a largely subjective judgment, and the balance of benefit and burden are not always clear—in which case the judgment and values of the parents should usually be determinative. Thus, unless it is clearly opposed to the child’s interest (ie, if there is uncertainty on the part of the clinical team), it should be discussed with the parents. A physician is not morally obligated to do whatever parents ask, but if the physician does refuse a request for any treatment, including resuscitation, there should be a valid moral justification for that refusal. Simply referring to hospital policy or standard of care does not in itself qualify as a valid moral argument. Any standard or policy is only as defensible as the ethical reasoning behind it.
If the physician would recommend against a procedure (eg, resuscitation) but would be willing to provide it if requested by the parents, should the physician mention it if the parents don’t?

Parents should be made aware of their options, whether or not they know enough to ask. They should not have to be savvy enough to ask to be given that right. A counterargument might be that once they are given the option, they might feel obligated to choose aggressive care even if it is not what they truly want. Perhaps this places an impossible burden on parents and potentially a sense of guilt that could last throughout their lives should they choose to forego resuscitation. There is often tension between the physician’s obligation to fully inform parents (and give them maximal latitude in decision-making) and to minimize their suffering. This tension should be discussed in the seminar.

What if the physician feels the procedure (eg, resuscitation) should be performed, but the parents refuse?

Parents should be given wide latitude in making such decisions, and even if the physician believes the procedure in question should be done, an informed parent’s refusal should generally be respected. There will be some threshold, however, beyond which the child has a clear right to the procedure. That threshold should be determined by the child’s prognosis; that is, at some point, the chance of a good outcome is so high that it is clearly in the child’s best interest to undergo the procedure (eg, neonatal resuscitation) and it should be carried out regardless of parental preference. It could be said that at this point the child’s best interests trump or outweigh the parents’ right to decide. Just as there may be a lower threshold of prognosis below which the neonatologist would refuse to attempt resuscitation, there should be an upper threshold above which the physician is obligated to try. In such a case, it would be disingenuous to offer the parents options if there is only one choice the medical team is willing to consider. Participants should discuss how good a prognosis should have to be to make resuscitation obligatory.

Is it appropriate for hospitals to have policies or guidelines addressing which newborns should be resuscitated?

It seems very reasonable for the appropriate clinical group (eg, a hospital’s neonatology section, perhaps with input from others such as the ethics committee) to have discussed and agreed on guidelines as to which patients are candidates for resuscitation and to have shared them with obstetricians working at the facility. This will avoid the problem of changes in plan or options available to parents as responsibility is handed off between neonatologists. It would seem unfair that the parents of a child born on Monday are given a choice that parents of a similar child born on Tuesday are denied just because a different physician is on call (Mercurio).

How should such guidelines be developed?

Guidelines should be based on a good understanding of the relevant data and their weaknesses, as well as sound ethical reasoning. For any group who share a diagnosis in common (eg, extreme prematurity, major congenital anomaly), considerations such as the patient’s best interest, fairness, and transparency are essential. Also, guidelines should avoid grouping together newborns who may have very different prognoses. In the case of extreme prematurity, for example, it has been well demonstrated that there is a wide range of predicted survival within a given gestational age category, depending on other factors such as gender, size, antenatal steroids, and multiple gestation. Data clearly show that a larger 22–week gestational age girl could have a better chance of survival and intact survival than a smaller 23–week gestational age boy (Tyson et al). Thus it makes little sense (and would be unjust) to offer resuscitation to the
23-week boy’s parents but not the 22-week girl’s parents. Policies based on gestational age alone greatly increase the likelihood of such injustice. A similar problem may be found with congenital anomalies, such as severe congenital heart disease, if patients are inappropriately lumped together despite very different prognoses.

Overall it would seem preferable to base resuscitation policies on prognosis, recognizing that the numbers provided in the literature will often be approximations. It also seems reasonable to allow discretion within those guidelines to the physician on the scene. Lastly, it should be noted that national and international organizations (including the American Academy of Pediatrics and the Nuffield Council on Bioethics) have created guidelines, and these may prove helpful. Perhaps it would be ideal if there were, with allowance for physician discretion and exceptions, one policy for all hospitals in a given region or country, thus avoiding the injustice of similar babies in nearby facilities being given very different options. Here again, a defensible policy will be grounded in deliberation based on applying sound ethical principles to available data.

**Should resuscitation be less obligatory for a newborn compared with older children? That is, should parents be given more latitude deciding whether it is done in the case of a newborn compared with an older child with a similar prognosis?**

It is often stated that all children deserve equal consideration when such decisions are made, but in practice physicians might consider resuscitation or other life-saving procedures as more “optional” for a newborn than for an older child with a similar prognosis for survival and disability. While this would be difficult to prove, survey data support this supposition, particularly in the case of premature newborns (Janvier et al). A possible explanation (though not necessarily a moral justification) might be that the newborn has not yet developed interpersonal relationships with parents to the extent that older children, even older infants, have. Participants should discuss whether a different (less obligatory, more permissible) approach to resuscitation should exist for newborns and what possible ethical justifications there would be for it. It is here suggested that unless a valid ethical justification can be identified, different criteria for resuscitation specifically for the case of newborns are not permissible. This same question can be discussed for the example of artificial nutrition and hydration or for surgical intervention.

**If the patient is resuscitated and placed on a mechanical ventilator, is it morally permissible to later withdraw the endotracheal tube or other life-sustaining treatment, thus allowing the baby to die?**

Most ethicists agree that if it was permissible not to place the endotracheal tube, it would be equally permissible to withdraw it. In some situations it might even be preferable from an ethical standpoint because clinicians may have more prognostic information than was available at birth. Thus, parents are often given the option of attempted resuscitation and beginning intensive care, and then deciding whether to continue. Two important caveats should be considered: 1) While it may be equally permissible from an ethical standpoint, it may be psychologically more difficult for parents or staff to withdraw interventions once they have been initiated; and 2) the acceptability of withholding intubation or resuscitation is based on prognosis, and if prognosis changes for the better (e.g. the patient does significantly better than was anticipated), at some point it may no longer be appropriate to withdraw intensive care measures.

**Conclusions and Suggestions:**
Physicians should be familiar with current outcomes data, and the limitations of those data, before making decisions or policies regarding newborn resuscitation. Each facility that provides medical care for critically ill newborns should discuss the data, as well as the relevant ethical and practical considerations, in order to develop a general approach to newborn resuscitation. The primary consideration in developing such a policy should be the patient’s prognosis.

Parents have a right to know all information relevant to major decisions concerning their child, and it is the obligation of the physician to provide that information honestly, even if they do not ask.

After sharing the relevant information, physicians should work with parents to determine a plan for their child. In general, the wishes of parents should prevail, but there will be rare circumstances wherein the parents’ right to decide will be limited by the rights and interests of the child.

This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 14. Maternal-Fetal Conflict

Susan F. Townsend, MD, FAAP

Overview
Pregnancy is a unique circumstance in medical ethics because of the absolute requirement to access the fetus only through intervention on the pregnant woman. Increasingly, as medical advances have offered the promise of therapy to the fetus, fetal interests have been considered separately from maternal interests by clinicians, policy makers, and the bioethics community. This is a somewhat artificial distinction, as usually maternal and fetal interests are aligned, and care of the fetus is intertwined with and dependent on care of the pregnant woman.

When conflict arises between maternal and fetal interests (eg, treatment of cancer during pregnancy that may result in fetal demise), a variety of ethical frameworks may be useful to consider for conflict resolution and decision-making. Helpful theoretical approaches include case-based analysis, the ethics of care, feminist theory, and traditional ethical principlism that uses the framework of autonomy, beneficence and nonmaleficence, and justice. In addition, societal and practitioner values can elevate emotionally laden issues of obstetric conflict and benefit from a comprehensive, thoughtful analysis from a variety of perspectives.

Different theoretical approaches all agree with the importance of promoting the autonomy and bodily integrity of the pregnant woman, ensuring that she has the information to provide a fully informed consent that is consistent with her values regarding pregnancy outcome. In cases in which her decision may harm her fetus, coercion to force treatment is never justified. In extraordinary cases, legal intervention has been attempted. Using the courts to enforce treatment compliance by pregnant women has frequently been unsuccessful or has activated processes that are hasty and incomplete, and such court rulings are frequently overturned on appeal. Evidence shows that continuing a trusting, compassionate, professional relationship with the pregnant woman generally results in greater success in improving maternal and child health. Feminist ethics perspectives can help detect subtle, gender-based biases in clinicians’ approaches to conflict resolution and support collaborative decision-making for the pregnant woman and her health care team.

Participants will evaluate considerations of the pregnant woman’s right to refuse treatment, if the fetus may be harmed by her decision, from a variety of ethical perspectives, including principle-based, feminist theory and case reviews. They will discuss strategies to optimize health outcomes for the pregnant woman and her fetus.

Instructor’s Guide
- Case Summary
- Alternate Cases
- Learning Objectives
Case Summary
Jesse is a 24-year-old who presents in active labor with no prenatal care. The fetus appears to be term, quite large, and at risk for dystocia. Jesse is told that a cesarean birth is the best route of delivery for the fetus’ well-being. She declines the operation and requests a natural childbirth. Although the fetus begins to have heart rate deceleration consistent with fetal distress, Jesse continues to decline the recommended cesarean delivery.

- Does the physician have an ethical obligation to intervene on behalf of the fetus as a patient?
- What are the best interests of the pregnant woman and how are they determined?
- What are the best interests of the fetus and how are they determined?
- What ethical considerations, other than best interests, can inform the decision-making process?
- Can the pregnant woman refuse the recommended treatment, particularly if harm is expected to come to the fetus?

Alternate Cases
1. Katherine is at 24 weeks’ gestation with active labor, vaginal bleeding, and non-reassuring fetal status. Her obstetrician recommends a cesarean delivery to optimize outcome for her and her fetus. She refuses.

   - Should gestational age of the fetus have a bearing on the decision-making process?

2. Sally presents at 18 weeks’ gestation for her first obstetric appointment, and abnormalities on her cervix are noted. A Papanicolaou test shows malignant cells, and she is diagnosed with an advanced stage of locally invasive cervical cancer. The recommended treatment is immediate surgical resection of the cervix and pregnant uterus followed by radiation, and this will result in fetal loss. With immediate treatment, her 5-year survival is estimated at 55% to 65%, and she will no longer be able to become pregnant. Delay in treatment will decrease her chances of survival.

   She asks at what stage in pregnancy the fetus is viable and is told that survival of the fetus generally is not expected until after 24 weeks, with the majority of newborns not having “good” outcomes until after 26 weeks’ gestation, although some premature neonates born as early as 23 weeks can survive with a significant rate of handicap. In any case, delaying her treatment for 5 or 6 weeks to deliver the fetus could lead to extension of the cancer and hasten her death, with a high likelihood of perinatal death or significant handicap to the fetus.

   Sally declines treatment of her cancer at the present time, and states a strong belief that the cancer will not spread and that waiting for treatment to deliver her fetus at 24 weeks’ gestation will result in a healthy baby.
• Should potential harm to the pregnant woman have a bearing on consideration of her refusal of treatment?
• How can this conflict be approached in ways that optimize outcomes for the woman and her fetus?

3. Tess is a 19-year-old who presents for her first obstetric visit early in the first trimester. She is informed about routine screening tests for pregnant women, including blood typing, testing for syphilis, hepatitis, and rubella immunity, to which she consents. HIV testing is not mandatory in her state and is not offered. Over the course of the pregnancy, she confides that her partner has cheated on her many times and they have finally split up. She is offered HIV testing and consents. The test returns positive for HIV at 36 weeks. She is counseled to start antiretroviral therapy and have a cesarean delivery. She refuses, stating she has concerns about toxicity of the medication, is afraid of surgery, and doesn’t believe the test because she has had excellent health throughout the pregnancy. With cesarean delivery and appropriate antiretroviral therapy, risk of transmission of HIV to the newborn is less than 1%. Without such treatment, perinatal transmission may be as high as 25%.

• Can she refuse cesarean delivery to prevent perinatal transmission of HIV?
• Are there additional considerations related to counseling around HIV testing and treatment that go beyond other situations of maternal-fetal conflict?
• What strategies could be used to achieve optimal health outcomes for her and the fetus, given the diagnosis of HIV?

Learning Objectives
1. Understand the unique aspects of pregnancy from an ethical perspective and become familiar with recent considerations of the fetus as a patient.
2. Become acquainted with ethical frameworks other than principle based used in analysis of maternal-fetal conflict, such as feminist ethics, ethics of care, and case-based analysis.
3. Recognize the limitations of applying best interests analysis to the fetus as a distinct patient from the pregnant woman. Be aware of the potential for gender and social bias inherent to attempts for legal remedies that favor the interests of the fetus over those of the pregnant woman.
4. Understand the importance of respect for the autonomy of the pregnant woman in the context of maternal-fetal conflict and informed refusal of intervention.
5. Identify strategies for conflict resolution that maintain a therapeutic physician-patient(s) relationship, including development of hospital guidelines and use of ethics consultation.

Suggested Reading for Instructors

Further Reading


Case Discussion

Who is the patient here, the pregnant woman, the fetus, or both?

Over the past decade, the increasing use of technology to visualize and test the fetus during pregnancy has led physicians and society to consider the fetus as a patient separate from the pregnant woman. This contrasts with earlier societal views of pregnancy not as a medical condition but as an extension of nature, and has led to the view of the fetus as having separate interests to be addressed by the medical team providing care. Language around obstetric
decision-making has reinforced the separate consideration of the fetus from the pregnant woman (eg, fetal distress, fetal interests). Nonetheless, access to the fetus for treatment must occur through the pregnant woman’s body, a unique situation. Consider other situations in which medical intervention to benefit one patient (eg, a child with end-stage renal failure needing a transplant) involves risk to another patient (eg, organ donation) when the 2 patients are not intertwined. Would you consider both individuals to be your patient if you were the transplant surgeon? As a pediatrician, would you expect a parent to donate a kidney to a child under such circumstances?

What are the best interests of the fetus and the pregnant woman? Are there areas where their best interests are congruent in addition to being in conflict?
There are many parts of this case in which the interests of the mother and the fetus are aligned. In general, pregnant women are highly motivated to ensure the health of their fetuses and desire a good pregnancy outcome for themselves and their future children. Maternal psychological well-being is important for fetal and neonatal well-being. Optimal maternal health ensures fetal health. Defining areas in which maternal and fetal interests are aligned is important for maintaining a therapeutic relationship with the pregnant woman. If the patient (pregnant woman) has a strong aversion to operative delivery, it may be for good reason. Explore those reasons to understand and honor the patient’s perspective.

What ethical considerations, other than best interests, can inform the decision-making process?
In many situations of obstetric conflict, the body of evidence supporting the recommended intervention may not be comprehensive or as conclusive as initially presented. The medical evidence supporting any recommendation for route of delivery is often incomplete. In cases in which courts have intervened to order cesarean delivery, for example, the fetus has not infrequently been delivered unharmed by the vaginal route. There is very little evidence that fetal heart rate monitoring improves neonatal outcome but much evidence that it leads to increased cesarean delivery rates. Cesarean deliveries have increased in the United States without comparable improvements in neonatal outcome. Thus, in every case, the evidence for potential harm to the fetus must be carefully and objectively analyzed. What are the outcomes in similar cases in which cesarean delivery is refused? When evidence in support of the treatment recommendation is weak, uncertain, or not available and outcomes vary, there is poor ability to predict individual outcomes. In obstetric conflict about route of delivery this is often the case, and emphasis on the conflict may be disproportionate to the evidence basis. Patient autonomy to accept or refuse treatment recommendations should be respected in all circumstances. In particular, when the evidence for treatment benefit is uncertain, practitioners should minimize the polarization and conflict around a refusal of treatment.

Feminist ethics uses the ideas of feminist theory to evaluate ethical issues from a gender-based perspective. In particular, a feminist ethics analysis will point to distinctions in how women are treated compared with men, rather than using a neutral “human” perspective in decision-making. For example, some hospital policies and state laws exclude pregnant women from participating in health care decisions, such as advanced directives refusing treatment. This implies a lack of competency of pregnant women to participate in health care decisions and contributes to a distorted view of women as decision-makers. Feminist ethics calls attention to such inequities and exclusions and asks whether a moral wrong is perpetrated by gender-biased policies.
Feminist theory can be considered in relation to the question, if the patient were not pregnant and was refusing surgery, would her wishes be respected? Is there a comparable situation in which one would consider forcing a father to undergo treatment to benefit his child, for example?

Other, non–principle-based ethical theories include the ethics of care, which evaluates the moral dimension of relationships with others. Many pregnant women have other children and family obligations that inform their decision-making. Care-based ethics asks, what is the patient’s relationship to the fetus? To her physicians? To her social unit?

Using feminist theory and the ethics of care can reframe the issue in terms of the patient’s values and life experiences, to understand and support her decision or devise additional treatment strategies.

**Can the pregnant woman refuse the recommended treatment, particularly if harm is expected to come to the fetus?**

Yes. However, anticipated harm should neither be exaggerated nor dismissed. Continued conversation with the pregnant woman as labor progresses may lead to changes in her decision. Preserving the physician-patient relationship in a compassionate, professional manner will allow ongoing reevaluation of the decision, depending on whether the fetal status improves or worsens and the mother is able to deliver vaginally or not.

**Should you go to court to force a cesarean delivery?**

Not in these circumstances, and legal intervention should generally be avoided to resolve obstetric conflict. Although individual judges in emergency circumstances have ordered cesarean delivery, on review such decisions have largely been overturned, found to be lacking in due process for the pregnant woman and to exaggerate the medical benefit of intervention. Other consequences of forced intervention or coercion should be considered, in particular as it affects the trust relationship necessary between physician and patient.

**Alternate Case 1**

**Does the gestational age of the fetus have a bearing on decision-making?**

Fetal interests and medical analysis of the benefits and harms of delivery will vary with gestational age. However, there may be less data and even more uncertainty about outcome at extremely early gestations, and this should be acknowledged.

**Alternate Case 2**

Sally presents at 18 weeks’ gestation with invasive cervical carcinoma. Treatment entails a prompt complete hysterectomy, which will end the pregnancy and cause fetal death. Delaying treatment until fetal viability puts her survival at risk and may result in the death of her and her fetus, or survival of a significantly impaired fetus.

**Should potential harm to the pregnant woman have a bearing on consideration of her refusal of treatment?**

Although the context of her decision is different, pregnant women have the same rights to refuse treatment as nonpregnant women. It is important to note (from a feminist ethics perspective) how societal values and perspectives are more sympathetic to this decision when it is undertaken on behalf of the fetus and is viewed as altruistic. This is another area in which feminist ethics and
ethics of care can help address counseling to optimize fetal and maternal outcomes and to support the rights and well-being of the pregnant woman as a full autonomous being.

**Alternate Case 3**

*Are there additional considerations related to counseling around HIV testing and treatment that go beyond other situations of maternal-fetal conflict?*

Communitarian ethics (placing a value on the health of the community that can override autonomy) informs much of the approach to routine prenatal screening with attention to public health concerns, such as limiting the spread of communicable diseases (eg, syphilis). Routine prenatal screening for HIV is recommended by the Centers for Disease Control and Prevention; however, social stigma and the history of HIV, as well as evolving concepts of maternal autonomy, have resulted in varying state laws about prenatal screening for HIV, often described as opt-in or opt-out approaches. Discussions should focus on why HIV testing is considered different from, for example, syphilis testing of pregnant women and newborns.

**Conclusions and Suggestions**

The interests of the fetus are generally aligned with the pregnant woman. When they are not, the fetal best interests should be discussed, but respect for the autonomy of the pregnant woman and her bodily integrity should prevail.

Concerns about potential harm to the fetus related to maternal decisions must be evaluated in the context of the best medical evidence, as well as each woman’s broad social network and her cultural beliefs and values. Medical evidence should be presented in the context of what is known and what is uncertain, and potential options and outcomes will vary with fetal gestation.

Gender bias and discrimination toward women should be avoided, and the circumstance of pregnancy should not be used as a reason to infringe on or limit a competent woman’s rights.

Evidence indicates that providing prenatal care and treatment in a supportive, rather than coercive way is most effective to promote maternal and child health.

Hospital guidelines can be developed to support a framework of shared decision-making in the situation of maternal-fetal conflict and provide guidance for compassionate conflict resolution. At times, an ethics consultation may be helpful to mediate conflict resolution. Intervention by the courts is rarely appropriate or indicated and should be avoided.

*This instructor’s guide was developed by Mary B. Adam, MD, MA, PhD, FAAP; Douglas S. Diekema, MD, MPH, FAAP; Mark R. Mercurio, MD, MA, FAAP; and the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.*

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Session 15. Genetic Testing and Screening of Children

Lainie Friedman Ross, MD, PhD, FAAP

Overview
Every year, approximately 4 million children undergo genetic testing as part of newborn screening. This is the most common form of genetic testing in the entire population. Other children undergo genetic testing as part of a diagnostic workup for clinical problems (from progressive muscle weakness to developmental delays) or as part of research protocols or family linkage analyses. With the completion of the human genome project, there are hopes that genetic medicine will evolve into personalized medicine and become an integral part of medical practice. The expansion of genetic testing and screening in pediatrics raises ethical issues about the limits of parental autonomy, whose consent is needed, and what rights to privacy, if any, do children have with respect to their parents.

Participants will discuss the issue of mandatory consent in newborn screening and whether such a policy can persist in light of expanded screening; the benefits and risks of carrier genetic testing and under what circumstances it should be encouraged, permitted, or discouraged; and the benefits and risks of predictive genetic testing and under what circumstances it should be encouraged, permitted, or discouraged.

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Case Summary
Parents come to see you, their pediatrician, prior to the birth of their first child. They are hoping to have a natural delivery and want to minimize the “medicalization” of their baby’s birth. They ask you about the benefits and risks of refusing newborn screening. They are also concerned that the blood spot may be used for research purposes without their knowledge.

Alternate Case
Shari, a 15-year-old, comes to your office with her mother. Her younger brother, Bob, had an abnormal newborn screen for cystic fibrosis (CF), but a sweat test result was negative, indicating that he does not have CF. Bob was found to have one CF mutation (delta F507, the most common mutation). Both parents were screened and found to have delta F507. Shari is very healthy and tall and her parents and physicians are not concerned that she has CF, but her parents
wants to know if Shari can be tested for being a carrier. Also, her mother, 2 maternal aunts, and maternal grandmother all had breast cancer in their early 30s. They have been tested and found to have BRCA mutation. Shari’s mom wants Shari tested for the BRCA mutation so that if she is a carrier, she will get appropriate screening. There is no breast cancer in her father’s family. Shari is ambivalent about genetic testing.

**Learning Objectives**
1. Be familiar with the history of newborn screening practices and policies.
2. Be aware of the controversies surrounding newborn screening in the United States today.
3. Understand when carrier identification of minors occurs and the risks and benefits of this identification.
4. Be able to discuss under what circumstances carrier identification of minors is or ought to be encouraged, permitted, and discouraged.
5. Understand the risks and benefits of predictive genetic testing for adolescents.
6. Be able to discuss under what circumstances predictive genetic testing of minors is or ought to be encouraged, permitted, and discouraged.

**Suggested Reading for Instructor**
[http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/6/1451](http://aappolicy.aappublications.org/cgi/content/full/pediatrics;107/6/1451). Accessed May 16, 2011


**Further Reading**


[http://jmg.bmj.com/content/31/10/785.citation](http://jmg.bmj.com/content/31/10/785.citation). Accessed May 16, 2011
Case Discussion

What conditions are included in newborn screening?
The first condition included in newborn screening was phenylketonuria (PKU), an autosomal recessive condition that if left untreated, leads to mental retardation. Treatment entails dietary therapy. Screening began in the 1960s with the development by Robert Guthrie of a simple assay that could be performed on blood collected on filter paper. Hypothyroidism (which may or may not have a genetic basis) and galactosemia were added in the 1970s and 1980s. Expansion occurred slowly because each condition required a separate test, and it was expensive. In 1986, a study found that penicillin reduced morbidity in newborns with sickle cell disease, and most states quickly incorporated hemoglobinopathy screening into their newborn screening programs. However, the largest expansion in the number of conditions included in state newborn screening programs has occurred in the past 10 years with the adoption of tandem mass spectrometry (a platform technology) that allows for screening for many conditions with one sample at one time, including conditions for which there are no therapies and conditions about which the natural history is poorly understood. Virtually all of the conditions included in newborn screening are autosomal recessive, meaning that both parents must be carriers to have an affected child.

There is also newborn screening beyond the blood spot. Hearing screening is now universal in the United States and data are being collected to show the benefits of pulse oximetry screening to detect some cardiovascular and pulmonary conditions.

Can parents refuse newborn screening?
In all states except Wyoming and Maryland, newborn screening is mandatory, meaning that it can be done without parental permission, even without parental notification. However, in all states except Nebraska and South Dakota, parents have the right to refuse newborn screening.

How should a pediatrician respond to parental refusal?
The first step is to understand why they are refusing. Parents may refuse because they misunderstand the risk. If a parent says, “But those conditions do not run in our family,” the correct answer is that it is rare for individuals to know that an autosomal recessive condition runs in the family because carriers are asymptomatic and often not identified. Alternatively, a parent may say that they would prefer to wait to see if symptoms develop. These parents must be educated that such an approach may be too late; by the time a child is clinically symptomatic, irreversible changes may have occurred.

Some parents refuse because of religious or cultural beliefs about blood testing; others because of concerns about the medicalization of the birth process. These parents should be counseled that the probability of a missed diagnosis is low, but it can be devastating. In most states, parental refusals are respected on the grounds of parental authority (often referred to in the bioethics literature as parental autonomy); parents have the right and responsibility to make health care decisions for their child, unless their decision is abusive or neglectful. Given the low likelihood of a missed diagnosis (less than 1 in 3,000), the refusal does not qualify as neglectful.
Why is newborn screening mandatory?
Bob Guthrie developed the bacterial inhibition assay screening test and the filter paper that made newborn screening for PKU feasible and acceptable. Three factors coalesced to garner widespread interest and support for a program that promised to be able to screen, diagnose, and prevent at least some causes of intellectual disability. First, President John Kennedy had a special interest in intellectual disabilities partially due to his sister, Rose Marie. A second key factor was the growing strength of the National Association for Retarded Children (NARC), now known as The Arc of the United States, a parent advocacy group that was keen on preventing disabilities. Third was Robert MacCready, the state laboratory director for Massachusetts. MacCready, as chair of the NARC Public Health Service Committee, lobbied for mandatory legislation in Massachusetts because he thought uptake was not fast enough and was instrumental in encouraging Guthrie and NARC to support and advocate for mandatory legislation nationally.

Are there reasons to reconsider the need for parental consent for newborn screening?
The main argument in support of voluntary consent is based on the great deference that our society gives to individual decision-making about health care matters and, in the realm of pediatrics, the deference given to parents about how they raise their children. In 1994, the Institute of Medicine report, Assessing Genetic Risks, supported voluntary consent for newborn screening. In 2001, the American Academy of Pediatrics statement on genetic testing of children also supported voluntary consent.

Three empirical facts support voluntary screening. First, in states where newborn screening is voluntary, the data find high uptake (greater than 99% in Maryland). Even when optional screening is offered, uptake is very high (greater than 98% in Massachusetts when tandem mass spectrometry was offered as a research program).

Second, the expansion of newborn screening to include conditions like sickle cell disease and CF has led to the identification of carriers. Traditionally, the identification of genetic carriers has required strict informed consent in part because of the eugenics movement in the first half of the 20th century, culminating in the extermination of those declared “unfit to breed” in Nazi Germany and numerous sterilization laws in the United States. The early modern genetic counseling programs of the 1970s insisted that genetic testing be voluntary and that genetic counselors provide information in a nondirective fashion to distinguish modern-day genetics from the eugenics movement earlier in the century.

The early history of sickle cell screening actually reaffirms the need for voluntary programs and informed consent. Sickle cell screening began as a population screening program in the early 1970s using a solubility methodology known as Sickledex, which did not distinguish between sickle cell trait (being a heterozygous carrier with minimal health implications) and sickle cell disease. Like the test itself, the screening organizers, physicians, and the general public were confused about the difference between trait and disease. Not surprisingly, then, that the program was a serious failure clinically (because of the clinical limitations of the Sickledex test itself) and sociopolitically (because of the clinical misunderstandings by physicians and the public and the poor psychological and educational preparation of the African American community about the benefits and risks of screening). Despite good intentions, the program led to discrimination in health insurance and employment (including the military) and eventually was considered an attempt at “genocide against those of African ancestry.” The unintended adverse consequences
of sickle cell population screening gives further justification for requiring voluntary and informed consent for wide-scale carrier identification in newborn screening hemoglobinopathy programs.

Third, the widespread adoption of tandem mass spectrometry and identification of conditions for which treatments are not known to be effective represent a paradigm shift in newborn screening. Traditionally, the justification for using the state’s public health powers to mandate screening depended on meeting the Wilson and Jungner criteria, which include such requirements as the condition being an important health problem, the natural history of the condition being well understood, and there being a suitable test acceptable to the population as well as an accepted treatment and an agreed-on policy on whom to treat as patients. The expansion to include conditions identified by tandem mass spectrometry, for which the effectiveness of treatment, need for treatment, or duration of treatment are unknown, represents a shift from a focus on public health emergencies to the provision of a public health service, making the justification for a mandatory program even more tenuous. Proponents of a mandatory program traditionally argued that the benefits of newborn screening for a condition like PKU are so strong that one would not want any parent to refuse, but adoption of tandem mass spectrometry means that this no longer holds for all of the conditions identified.

What is done with newborn blood spots after screening is completed?
Policies and practices vary by state. However, the Guthrie cards have been described as “a national treasure.” The potential use of residual blood spots for research was realized early in the history of newborn screening, and these residual samples have been used over the past 4 decades for de-identified population research on environmental exposures, infectious diseases, and genetics.

Parental concern about the use of residual blood spots for research, however, is growing. In 2009, parents went to court in Minnesota and Texas about the use of these samples for research when they were collected without parental consent. The desire to use the residual blood for research is another argument in favor of seeking parental consent for newborn screening.

Alternate Case
What is Shari’s risk of being a CF carrier?
Both parents are carriers, which means that with any pregnancy, they have a 25% chance of having an affected child, a 50% chance of having a child who is a carrier, and a 25% chance of having a child who is healthy. Given that Shari does not have CF, her risk of being a carrier is 2 in 3.

What are the pros and cons of knowing that one is a carrier for an autosomal condition?
The most common reason for carrier testing is for reproductive planning. Because ideally reproduction only occurs in adulthood, most professional statements discourage carrier testing in childhood. These statements give a variety of reasons for deferring carrier testing until adulthood, including the minor’s right to privacy, the fact that many adults choose not to be tested, and the unknown risks and benefits of screening for genetic information that will not be needed for a long time. Concern has been expressed that carrier identification of minors may lead to labeling and stigmatization; that it may be misunderstood, leading to medical mismanagement; or that it may lead to vulnerable child syndrome and increased anxiety.
The statements seem to ignore that some children will know their carrier status because it was identified as part of newborn screening. Newborn screening programs have been identifying carriers of sickle cell for 20 years in many states and the data do not show that it has been harmful. And now newborn screening programs are identifying carriers of CF, even though there are methodologies for identifying CF in newborn screening programs that would not identify carriers (repeated immunoreactive trypsinogen measurement). Other children know their carrier status because parents had prenatal testing or because they were tested when a sibling was found to be affected. Psychological data about getting this information in childhood are generally reassuring. There is some evidence suggesting that children may be better able to incorporate genetic risk status into their self-identities and self-concepts than adults and some data to support the position that the benefits of certainty outweigh the harms of ambiguity, even when a genetic test result is positive and confirms risk or diagnosis. Another benefit of carrier testing in childhood is that at least some minors will screen negative and they and their parents can be reassured that they are not at risk for having a child with this particular genetic problem. And there are some studies in which adults have stated that they wished they had known at a younger age.

The data to date do not necessarily confirm that the best time for carrier testing is adulthood. First, there are some data to show that there may be health implications of being a carrier; for example, there are data to show that being a sickle cell carrier may place one at greater risk for exertional sickling, and that being a carrier for Duchenne muscular dystrophy increases one’s risk of cardiomyopathy. But even if knowledge about carrier status is mainly focused on reproductive issues, the data are not clear when is the best time to learn this information. In several countries around the world, carrier programs have been developed in high schools to ensure that individuals have this information before marriage and reproduction. There are concerns about the voluntariness of screening programs that take place in the schools. It is also not clear whose consent would be needed in the United States for a minor to participate. One could argue that carrier information is about reproduction and should be covered by specialized consent statutes that allow adolescents to consent for themselves. One could argue on the other hand, however, that such genetic information is more complex and has familial implications, such that parental involvement should be required.

**What role should Shari play in deciding about CF carrier testing?**

In general, the guidelines discourage carrier testing during adolescence even if Shari is eager for this information, unless she needs it for reproductive decision-making. Clearly if such testing is going to be offered to adolescents, the adolescent should have a say in the decision-making given that the information is purely elective. Whether the adolescent should be able to get testing alone is more controversial. Currently, parental permission is needed outside of the reproductive context. However, parental consent should not necessarily be definitive in that the child’s dissent should be heard. What role the adolescent should play may depend on whether there are health risks of being a carrier. Given that we know of no health benefits for CF carrier testing, the child’s dissent should be definitive. It is more complicated if there are health risks associated with the carrier status because there may be more pressure on parents to seek testing and to be able to do so even over the objections of the adolescent to make informed medical decisions.

**What is Shari’s risk of being a BRCA carrier and of developing breast cancer?**
Shari’s mother is known to have a BRCA mutation. BRCA is an autosomal dominant gene. If Shari’s mother is a BRCA carrier, Shari has a 50% chance of inheriting this gene. However, BRCA is not completely penetrant, meaning that even if Shari inherits the gene, her risk of developing breast cancer is between 30% and 85%. Given the high number of relatives with breast cancer, her risk is probably on the higher side. If she does not inherit the gene, her risk of developing breast cancer is similar to the general population (about 1 in 9 women).

What are the risks and benefits of knowing one is a BRCA carrier?
The most common reason for undergoing predictive genetic testing with a positive family history is to clarify one’s risk status. While all women are at risk for breast cancer (1 in 9), those who carry a BRCA mutation are at much higher risk of getting breast cancer and of getting breast cancer at a younger age. All of the professional statements, however, discourage predictive testing for adult-onset diseases in childhood. The arguments are the child’s right to privacy; the child’s right to make this decision as an adult; the unknown effect of identifying carriers when the information is not relevant for years or decades; concerns about self-identity and how others will treat the child; concerns that a child who tests negative may experience survivor guilt. Additional risks of knowing one is a carrier for BRCA include psychosocial stress and anxiety about one’s increased cancer risk. Other risks include concerns about discrimination, particularly for health insurance, although the Genetic Information Nondiscrimination Act of 2008 should reduce this problem. There may, however, be discrimination with life insurance. There is also the concern of social stigmatization.

The benefit of knowing if one is a carrier for BRCA is that there are actions a woman can take to reduce her risk of breast cancer, although none of these actions are needed until adulthood, which is one reason to discourage testing of minors. Recommendations for adult women with BRCA include more frequent mammography screening starting at a younger age. Some women will choose to undergo prophylactic surgery.

Again, the data to date do not necessarily confirm that the best time for predictive genetic testing is young adulthood. To the extent that the data do not show serious harm, it may be morally appropriate to give families greater deference. However, because the information is elective, the adolescent should be part of the decision-making process. If there are no health risks in childhood, the adolescent’s refusal should be respected.

What role should Shari play in deciding about BRCA genetic testing?
In general, the guidelines discourage predictive genetic testing during adolescence, even if Shari is eager for this information. Given that we know of no health benefits for BRCA testing of minors, the child’s dissent should be definitive. Thus, to the extent that the policies may be modified to permit greater family discretion, the adolescent should have a say in the decision-making given that the information is purely elective. Such a practice also acknowledges the adolescent’s emerging right to privacy about health information as well as her right not to know.

Whether the adolescent should be able to get testing alone is more controversial. Consider the case in which there is a positive family history but the parent has not yet undergone genetic testing. A minor’s request for genetic testing may challenge a parent’s right to privacy. To date adolescents have greatest autonomy in health care decisions regarding sexual and reproductive health, not for life planning. Given the complexity of genetic information and the frequency of
misunderstandings about genetic results, a policy of involving parents and children in predictive genetic testing for late-onset conditions is morally justifiable. This is not to deny that parents can obtain this information prenatally, only to argue that the elective nature of the information places some constraints on parental autonomy. Nor should this be understood as a testament in support of wide-scale predictive genetic testing of children. In general, the presumption should be against testing to allow the child to decide whether or not he or she wants this information as an adult. However, if the parent and adolescent want this information, the justification for the state to override family autonomy is weak at best.

Conclusions and Suggestions
Genetic policies developed in the early days of genetic testing treated genetic testing as exceptional. As genetic testing and screening becomes more mainstream, policies will need to be revised to become more consistent with other health care policies. In general, parents have wide discretion in health care decision-making for their children.

Currently, consent is not needed for newborn screening. Given the expansion of newborn screening to include conditions that do not meet the Wilson and Jungner public health screening criteria, this will need to be reconsidered.

Consent for newborn screening must also be reconsidered if we want to use residual blood spots for research purposes.

In general, carrier testing of minors should be discouraged. However, to the extent that carrier status is associated with health risks, carrier testing should be permitted, if not encouraged.

In general, predictive testing of minors for late-onset conditions should be discouraged. However, families and not physicians must decide whether the benefits outweigh the risks. The parents and the maturing adolescent should be involved in deciding whether to undergo predictive testing for adult-onset conditions when no treatment is necessary or feasible during childhood.

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