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

October 2017 Revision

Editors

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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 in 2009. 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. The first edition was published in 2011 with 15 modules under the leadership of Mary B. Adam, MD, MA, PhD, FAAP, Mark Mercurio, MD, MPH, FAAP, and Douglas Diekema MD, MPH, FAAP. This second revision includes updates of all the previously developed modules along with four new modules. 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 also grateful for the organizational and editorial assistance received from Anjie Emanuel, MPH, Gretchen Niemann, MA, and Florence Rivera, MPH. This project would not have moved forward without their hard work.


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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 relevant to the topic. 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 from one module to the next. For example, many of the concepts in Session 3, “Informed Consent and Assent in Pediatrics,” were covered in Session 4, “Minors as Decision-makers.” However, in Session 4, the focus of informed consent is set within 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 performing 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 the 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 5, “Religious, Cultural, and Philosophical Objections to Care,” and Session 13, “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.

These modules and cases presented in them are not intended to direct outcomes in resolving the ethical dilemmas that 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 ethical 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 about the most desirable outcome.

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

Sincerely,

The Editors

Douglas S. Diekema, MD, MPH, FAAP
Steven R. Leuthner, MD, MA, FAAP
Felipe E. Vizcarrondo, MD, MA, FAAP

October 2017
Session 1. Ethics Education and Available Resources

Douglas J. Opel, MD, MPH, FAAP

Overview

Ethics 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 incorporating a patient’s or family’s values into clinical decision-making, medical practice includes a moral component. Ethics education has, therefore, been made a priority in medical training programs. In fact, the Accreditation Council for Graduate Medical Education (ACGME) requires that pediatric residency and fellowship programs address the core competency of professionalism—the demonstration of a commitment to carrying out professional responsibilities and an adherence to ethical principles. As a result, faculty are often called on to teach ethics and professionalism to trainees. Common questions about ethics education include: how should ethics education be approached? What are the goals of ethics education? What ethics resources are available to attending pediatricians to help facilitate and promote ethics education among residents and fellows?

This module highlights the importance of ethics education in pediatric training and identifies the resources needed to become involved in ethics education. It reviews the goals of ethics education and discusses research on the use and impact of ethics curricula. Participants will learn general approaches to ethics curricula for pediatric residents and fellows and describe the current state and current debates in the teaching of ethics to medical trainees.

Instructor’s Guide

▪ Case Summary
▪ Alternative 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 ethics educational resources are available to help develop a curriculum?
- Are there models for effective ethics curricula?
- What should the general goals be for ethics education?
- Will this make a difference? What outcomes have been improved as a consequence of ethics education?

Alternative 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 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. Describe the goals and outcomes of ethics education.
2. Describe the current state of ethics education in pediatric residency training.
3. Identify resources for teaching and assessing ethics and professionalism.
4. Describe two aspects of ethics education that are presently being debated.

Suggested Reading for Instructor


Howard F, McKneally MF, Levin AV. Integrating bioethics into postgraduate medical education: The University of Toronto model. *Acad Med.* 2010;85:1035-1040

Further Reading


**Case Discussion**

**What is the current state of pediatric resident and fellowship education in ethics?**
A few investigators have recently conducted surveys to assess the current state of ethics education in pediatric residency programs. In 2008, Lang and colleagues found that 35% of surveyed pediatric program directors reported that they had no professionalism curriculum, although this fell to 5% in a 2012 follow-up survey. In these and other surveys, most programs report that they teach ethics and professionalism without a structured curriculum. Cook et al found that 48% of programs with a clinical ethics curriculum use an *ad hoc* process for choosing topics, 25% repeat topics annually, and 27% organize topics in a multiyear cycle to parallel training. Most programs (56%) report that they spend 4 to 11 hours per year on ethics teaching, while 34% spend ≥12 hours per year. There are little data on ethics education in pediatric subspecialty fellowship programs, although some formal ethics curricula have been published and there is a general increased recognition of its importance.

**Why is ethics education considered important?**
Every physician-patient encounter has a moral dimension. 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 an ethics curriculum should be. Besides meeting the ACGME core competency requirement in professionalism, what other goals should one consider?**
One important goal of ethics education is to increase awareness of ethical issues encountered in medicine and pediatrics. Another goal is to acquire methods or tools for conducting ethical analysis. These and other goals have been incorporated into publications describing the objectives for medical ethics education, the most recent being the Romanell Report. In this report, the authors propose that the objective for medical ethics education should
be the following: “Upon completion of medical school or a residency training program, learners will, with an appropriate level of proficiency: 1) demonstrate an understanding of the concept of the physician as fiduciary and the historical development of medicine as a profession; 2) recognize ethical issues that may arise in the course of patient care; 3) utilize relevant ethics statements from professional associations to guide clinical ethical judgment and decision-making; 4) think critically and systematically through ethical problems using bioethical principles and other tools of ethical analysis; 5) provide a reasoned account of professionally responsible management of ethical problems and act in accordance with those judgments; and 6) articulate ethical reasoning to others coherently and respectfully.”

If I’m looking to develop an ethics curriculum, it would be nice to have a starting point. What ethics curriculum models are available?
There are only a few 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.7 A more recent published example is the postgraduate medical education ethics curricula from the University of Toronto.8 The American Board of Pediatrics and the Association of Pediatric Program Directors have published a workbook that provides suggested methods for teaching and assessing professionalism among pediatric trainees.9

What are some other available ethics resources to help develop the content of a curriculum?
A recent survey found that few pediatric program directors were aware of available ethics and professionalism resources.10 In addition to this curriculum produced by the American Academy of Pediatrics (AAP) Section on Bioethics, the AAP Committee on Bioethics routinely publishes policy statements on various ethics topics that are published in Pediatrics. There are also articles on core ethics topics published in Pediatrics in Review. The American Board of Pediatrics offers an annotated bibliography of bioethics references that is regularly updated and intended to promote familiarity with bioethics topics and problem solving. This bibliography is available for download (https://www.abp.org/sites/abp/files/pdf/bioethics.pdf). Lastly, there are numerous other Web-based bioethics resources. Recommended links include the following:

- AAP 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 (http://www.bioethics.net/resources/pediatric-ethics-consortium/)
- Hastings Center Bioethics Forum (http://www.thehastingscenter.org/publications-resources/forum/)
- MedEd Portal (https://www.mededportal.org/)

Other useful resources have been compiled elsewhere (eg, Treuman Katz Center for Pediatric Bioethics, Seattle Children’s Hospital (http://www.seattlechildrens.org/research/initiatives/bioethics/education/)).
Does ethics education actually make a difference? What positive outcomes have been associated with 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 lecture series plus case discussions with an ethicist in attendance) involving 85 internal medicine residents and found that residents who received the ethics lecture series plus case discussions with an ethicist were more confident addressing ethical issues and procedures with ethics dimensions. In other studies, investigators have documented an improvement in learner awareness, attitudes, knowledge, decision-making, and moral reasoning with ethics educational interventions.

What are some current debates about how to teach ethics?

There is active debate regarding where to position an ethics and professionalism curriculum within a pediatric residency or fellowship training program. Should it be integrated within the overall pediatric curriculum or kept as a separate curriculum? There are advantages and disadvantages to both. An integrated curriculum emphasizes the importance of ethics and professionalism to all of medical practice, but a downside is that it can become so integrated that it is invisible. A separate curriculum may be more visible but be less feasible because of curriculum crowding.

Another actively debated issue is how to assess a learner’s fulfillment of the professionalism core competency. There is a need for validated assessment tools, and Kesselheim and colleagues have attempted to address this need. However, some argue that it may simply be too difficult to assess certain aspects of professionalism. Consequently, there has been renewed focus on creating objectives that are specific, measurable, action oriented, reasonable, and time bound.

Conclusions and Suggestions

Ethics education is an important part of pediatric residency and fellowship training. There are numerous resources and curricula available to help in the development and augmentation of education in ethics and professionalism.

References


This instructor’s guide is part of a collection edited by Douglas S. Diekema, MD, MPH, FAAP; Steven R. Leuthner, MD, MA FAAP; Felipe E. Vizcarrondo, MD, MA, FAAP on behalf of the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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

Overview

Participants will discuss the application of widely accepted principles of medical ethics in pediatrics, which involves the unique physician-patient-parent 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 cases explore 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. Each 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 to applying them to future cases. Participants should be made aware that an approach to ethical problems based on relevant rights and principles may be helpful, but this is not the only available approach, and other approaches may also be valid and prove useful.

Instructors Guide

▪ Case Summary
▪ Alternative 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. According to the clinical team, survival is uncertain yet possible, but with a high likelihood of neurological disability. The parents request continuation of life-sustaining medical treatment, such as mechanical ventilation and medically administered nutrition and hydration, and extensive resuscitation, including chest compressions and epinephrine, in the event of cardiac arrest.
Who should decide on the medical treatment plan?
What approach best serves the interests of the child?
What are the relevant rights of the child in this setting?
What are the relevant rights of the parent(s)?
What would you do? Would you offer withdrawal of life-sustaining medical treatment? Would it be appropriate to withdraw without parental permission?

Alternative 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, including 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 male infant born earlier this morning at 27 weeks’ gestation via emergency cesarean section have just informed you that they would like to withdraw life-sustaining medical treatment, including mechanical ventilation and intravenous nutrition/hydration, for their child, stating that they do not want to care for “a handicapped child.”

3. You are the pediatrician taking care of a 3-day-old female infant 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 as her older brother did.

4. An 8-year-old boy and his parents are seeing you in the office for disruptive behavior, both 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 their parents.
5. Differentiate between permission, assent, and consent.
6. Understand how to apply these ethical principles to future cases.


Suggested Reading for Instructors


Further Reading


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

Prince v The Commonwealth of Massachusetts, 321 US 158 (1944)


Case Discussion

What are some rights of the child relevant to medical management decisions?
The child has a right to 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. Although not relevant to this case, it should also be noted that a child has a right to be informed and to participate in the decision making as appropriate for age and mental state.
**What are some rights of parents relevant 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.1,2

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.3

Parental authority, although widely accepted, is not absolute. For example, although 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 decline on religious grounds. 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.”4

**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.1 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, or more precisely those with capacity, 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.

*Capacity* in this context can be defined as having the ability to understand a proposed therapy or procedure, to understand its risks, benefits and alternatives, and to be able to then arrive at a decision based on consideration of these factors in light of one’s values and life plans.1 An autonomous decision is one made with adequate information and understanding of the implications of various possible outcomes. For any patient not considered to possess capacity, 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.2
Adolescents may have the capacity to make certain medical decisions and are understood to have developing autonomy.

The doctrine of informed consent, which requires that patients with capacity be given the 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 between 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 diagnostic procedures and medical treatment for their children.5,6 The AAP also endorses the concept of *assent*, the developmentally appropriate child’s willingness or preference to participate in a proposed therapy, procedure, or research. 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; and
4. Soliciting an expression of the child’s willingness to accept the proposed care.5,6

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.1 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.\textsuperscript{1,2} It is, then, a standard based largely on the principle of beneficence.

\textit{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, medically administered nutrition and hydration, and extensive 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 the ongoing intensive care. Others could argue that quality of life may sometimes matter more. An artificially prolonged life with associated burdens of many interventions, yet without meaningful social interaction or the possibility of regaining any meaningful interaction, is not in the patient’s best interest. Further, complying with the parents’ requests to prolong life, via cardiopulmonary resuscitation (CPR), mechanical ventilation or medically administered nutrition and hydration, 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.

\textit{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 the physicians) in the child’s best interest. But, if they reach a decision that is \textit{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.\textsuperscript{7} For this case, participants should discuss whether they feel the parents’ decision meets that threshold, thus obligating the physicians to seek to override it.

\textit{What if parents refuse a treatment recommended by the physician?} 
The same threshold should be sought. Is their choice merely suboptimal, or is it \textit{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.”\textsuperscript{8} In the 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 the 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, the 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. 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, medically administered 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 extensive 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 could be permanently neurologically devastated, and sufficient pain control is achieved, it would be permissible to continue life-sustaining medical treatment, thus respecting the parent’s 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 rare cases might be 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 might 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 give 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 and developmentally appropriate, the children themselves. Effective communication between these groups is paramount. Although 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.

References


2. Cummings CL, Mercurio MR. Ethics for the pediatrician: autonomy, beneficence and rights. Pediatr Review. 2010;31(6);1-4


4. Prince v Massachusetts, 321 US 158 (1944)


Session 3. Informed Consent and Assent in Clinical Pediatrics

Yoram Unguru, MD, MS, MA

Overview

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

Instructors Guide:

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

Case Summary

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

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

Alternative Cases

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

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

Learning Objectives

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


Further Reading


*Cardwell v Bechtol*, 724 S.W. 2d 739 (Tenn 1987)


Diekema D. Adolescent refusal of lifesaving treatment: are we asking the right questions? *Adolesc Med.* 2011;22(2):213-228


**Case Discussion**

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

Assent is an interactive and ongoing process between a child and a clinician (or a researcher) wherein developmentally relevant information is disclosed about a particular intervention. During the assent process, the child is engaged and his or her input is sought. The goal of assent is to protect children’s rights by allowing them to voice their preferences when it is appropriate to do so. The assent requirement, traced to
the concept of respecting children as individuals, calls for the need to recognize and respect the wishes of children as they develop cognitively and mature.\(^2\) Respecting a person means helping him or her to make choices that are as informed as possible. Above all else, assent is about respecting a child’s “developing capacity.”\(^3\) For assent to “work,” the physician must truly know the individual child. This demands an appreciation of the child’s developmental stage and recognition of his or her basic preferences. Parents possess knowledge of their child’s preferences and developmental stage and are ideally situated to assist the physician in acquiring information.

Understanding or capacity is a critical component of assent; a second and equally important facet of assent is the child’s desire to make decisions.\(^4\) A child should be included in medical decisions to the extent of his or her abilities and desire to be involved.\(^5\) Children need to be encouraged by parents and physicians to communicate openly so that they may be active participants in the assent process. Shared decision making empowers children to the extent of their capacity\(^6\) and in doing so, promotes their values, interests, and abilities.\(^7\)

Capacity for decision making is not an all-or-none phenomenon, but rather a process that matures with time and experience. No single child experiences life, health or disease in exactly the same way, and each child’s personal experiences with decision-making is unique. These experiences contribute to the child’s unique capacity for decision-making. Children of varying ages possess varying abilities to synthesize information and to make decisions accordingly. Weithorn and Campbell showed that children 14 years and older appear to be as capable as adults in making informed treatment decisions. Common Law in some states (eg, Tennessee) adopt a similar approach based on the so-called “Rule of Sevens,” by which minors 14 years and older have presumed capacity for making medical decisions (Cardwell v. Bechtol). Hein and colleagues suggested that children as young as 9.6 years may be competent to consent to participation in clinical research.\(^8\) This finding is of particular interest, as most experts agree that assent (and consent) for research participation requires a more sophisticated and nuanced decision-making capacity than assent (consent) for clinical care.\(^9\)

Although at least one study found that children’s age and intelligence were the sole determinative factors influencing ability to provide consent to clinical research (Hein 2015), age alone does not reliably identify a child’s ability to understand. Knowledge, health status, anxiety, experience with decision-making, and each child’s unique cultural, familial, religious background, and values all play a role in children’s understanding of their situation and affect their ability to make decisions. Children who, either because of poor health (often resulting in more experiences and a greater role in decision making) or whose parents have allowed them to make “life decisions,” seem better equipped to appreciate that their choices carry certain consequences and insomuch they may have a greater understanding of what is required to assent to participate in medical (and research) decisions than a healthy child or a child whose parents have insulated them from making decisions.
What are some of the barriers influencing a child’s ability to participate in decisions?
For assent to be valid, it must be voluntary. Children are particularly vulnerable to influences in medical consent/assent situations because of their physical, emotional, and financial dependency on adults\textsuperscript{10} and because of their relative inexperience with healthcare related decisions. Subsequently, rather than act with developing autonomy, minors may regress to dependency on significant others.\textsuperscript{11}

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

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

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

Thus, adolescents often possess the skills to make informed treatment decisions, yet they are neurodevelopmentally constrained and may lack perspective and life experience. As such, they are more likely to act impulsively and to focus on their current situation rather than the future. Accordingly, minors must be guaranteed added protections ensuring their ability to provide voluntary and informed decisions.

Many parents believe that decisions about what to do concerning their ill child’s life is theirs to make, regardless of the child’s awareness or capacity.\textsuperscript{17} Some parents are not aware that it is acceptable to include their children in the decision-making process.\textsuperscript{18}
Thus, it becomes the physician’s responsibility to broach the topic of children participating in decisions about their care. Ideally, physicians need to do this relatively early on in discussions with families and should revisit the point periodically to assure that a child’s increased decision-making parallels their developmental growth.

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

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

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

Methods to assess understanding are underutilized and should be employed when evaluating the veracity of a child’s decision-making prowess. These can include such techniques as the “talk-back” method wherein using her own words, the minor explains the process by which she reached a decision. Alternatively, a brief questionnaire or assessment tool may prove helpful. The ideal evaluation tool should account not only for the child’s rational and cognitive abilities, but also for the influence of socioemotional factors.
How can an appreciation for soliciting a child’s assent help you negotiate with this teenage patient?
The process of obtaining a child’s assent requires several steps. The physician must (1) help the patient achieve awareness of his or her condition; (2) tell the patient what to expect regarding diagnosis and treatment; (3) assess the patient’s understanding; (4) assess factors influencing patient responses (ie, undue pressure); and (5) solicit the patient’s willingness to accept care.

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

How do you balance Josh’s goals with those of his parents and your own?
Children recognize their role in decision making as intertwined with that of their parents and respect their parents’ input. 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. Additionally, shared decision making between children and adults (parents), coined “collaborative paternalism,” has been shown to yield many positive benefits including improved academic performance and less risky behaviors—for example, substance abuse and criminal activities (Partridge).

The American Academy of Pediatrics (AAP) 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” (Committee on Bioethics 1995). The AAP views assent as a process that ideally incorporates joint decision making by all parties. The AAP endorses the view that discussion leads to the development of a meaningful relationship between a child and physician, and it is this aspect of assent that is paramount in the process.

As advocates for children, pediatricians have a responsibility to foster children’s evolving capacities. Accordingly, pediatricians should make every effort to provide parents with the tools to allow their children to think independently. Doing so enables children to make reasoned and valid age-appropriate decisions knowing that they can rely on their parents to support these decisions and to ensure that their parents will (mostly) protect them from the consequences of unwise decisions. Children learn to make good, sound decisions with practice and by relying on those they trust. Parents and children may not be in a position to fully recognize the extent to which their relationship may serve to limit a child’s ability to make free or voluntary decisions. Thus, it is the physician’s responsibility, as the child’s advocate, to serve as a facilitator and to ensure that this process occurs.
**How does assent differ from consent?**

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

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

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

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

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

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

All states also have mature minor doctrines, which allow minors who have been found by the appropriate state body to possess adequate decisional capacity and understanding of their medical condition, the right to consent to treatment without parental permission. This doctrine applies only to specific medical decisions and varies by state in terms of who can make this determination and the age at which it can be made. Age plays a role in mature minor doctrine, with 16 years being the common cutoff, but in some states, minors as young as 14 years can be granted the right to consent to any medical treatment without parental consent. The process by which an adolescent may be recognized as a mature minor varies by state.
Finally, minors who meet criteria for emancipation may consent to all aspects of their care and do not require parental permission. Emancipated minors include children who are either (1) married; (2) active-duty military; or (3) living on their own and managing their own finances.

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

**How can you find a way to enable Josh’s parents to allow him to transition into control of his own health care management?**
As noted by the AAP and other professional medical organizations, parents and providers have a role in helping adolescents’ transition to become autonomous adults capable of making responsible and appropriate medical decisions. Thus, as Josh develops an appreciation of his disease with an understanding of its consequences and as he starts to take ownership of his care (as evidenced by improvement in medical “parameters”) his parents should start to relinquish certain aspects of his care while still remaining involved in an oversight capacity. Decision making involving older children requires the patient’s assent and parental permission.

**How would this situation be different if Josh were 18 instead of 17?**
Were Josh 18, unless he was deemed lacking in capacity, he would be responsible for health care decisions in most states. If he lacked in capacity, then a health care surrogate would be appointed. Ultimately, many 18-year-old adolescents (and young adults) desire parental involvement in matters of health and, as such, seek their parents’ input.

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

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

This strategy results in one of 3 decision-making roles determined by the gravity of the decision to be made and the child’s capacity. Some decisions will be made exclusively by the child with minimal to no parental input, some decisions will place the parents in a more central role while children will be “consulted” for their preferences, and finally, some decisions will be made exclusively by parents and children will be asked only to “ratify” the decision.
For example, (1) a child might have decisional priority for choosing how blood is to be drawn (ie, right or left arm; with or without a local anesthetic); (2) the child could decide at what time of day a medication is taken, but not refuse to take it; and (3) the child could approve of a life-saving intervention, but not refuse it. Giving children the option to decide respects them as people with developing autonomy, it allows them to learn from the decisions they make and to improve on future decisions, and it provides them with a sense of control and “ownership” that comes with making decisions related to one’s health.

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

Conclusions and Suggestions

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

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

References


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Session 4. Minors as Decision-Makers

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

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) teenagers 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 scientific data indicating caution about this arbitrary age cutoff, we generally uphold 18 as the age of majority, if only for legal reasons. Further complexity enters into this because some, although by no means all, minors 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 birthday.

Instructor’s Guide

▪ Case Summary
▪ Alternative Cases
▪ Learning Objectives
▪ Suggested Reading for Instructor
▪ Further Reading
▪ Case Discussion

Case Summary

Jane developed leukemia at 14 years of age, when she presented with fatigue and bruising. Because she fell into a high-risk category, after achieving remission, she began preparation for stem cell transplantation. She received stem cells from an 18-year-old brother. Now, at 16 years of age, she has had multiple complications of her transplant. She has chronic graft-versus-host disease (GVHD) of her intestines, with intermittent moderate-to-severe abdominal pain. She has moderate renal insufficiency, and in the last 6 months, she twice needed hospitalization in the pediatric intensive care unit (PICU) for respiratory failure, once with
pneumonia and once with a somewhat less clear picture, eventually believed to represent lung GVHD. The second of those episodes of respiratory failure required more than 3 weeks of mechanical ventilation. In addition to needing a ventilator, the PICU staff found it difficult to keep Jane comfortable: she experienced opioid-resistant escalating abdominal pain and periods of severe agitation, requiring complex polypharmacy. Despite use of agents that usually produce amnesia, Jane vividly recalled much of her last PICU stay and repeatedly told her family and health care providers how much she hated the experience. During a clinic visit with the stem cell and palliative care teams, Jane announced that she did not ever want intubation and mechanical ventilation again. She acknowledged that she might survive another episode of respiratory failure. However, she knew that the likelihood of eventual recovery of good gastrointestinal and lung function was small (one of her doctors had quoted a figure of less than 15%). She said she had thought carefully about all her options and conferred with her pastor and concluded that, on balance, she wanted comfort care and no more trips to the PICU. 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 have the legal authority to make autonomous health care decisions?
- How should a physician address conflict between the patient’s desired course of medical action and the parents’?

**Alternative Cases**

1. Sandy, a 14-year-old, has received a diagnosis of Hodgkin lymphoma, with disease above and below the diaphragm. The chemotherapy and radiation that constitute standard treatment carry a high likelihood of leaving her sterile. Her oncologist discusses the possibility of removal of one ovary for cryopreservation prior to her anticancer treatment. Although Sandy has completed puberty, she has no sexual experience and has never contemplated having children. Can Sandy make a mature choice to accept or reject the extra surgical procedure and any other associated risks of ovary removal? If not, should her parents have moral authority to decide this for her?

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, has become 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 relinquish the baby 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 potential additional 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.

**Examples from Case Law**


**Learning Objectives**

1. Define the circumstances under which a minor would have the legally authority to make autonomous health care decisions.
2. Discuss how the adolescent and brain development literature influences the approach to minors as medical 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 rationale for court intervention.

**Suggested Reading for Instructor**


**Further Reading**


**Case Discussion**

*What factors should be considered in allowing a minor to refuse potentially life-prolonging medical treatment?*

1. Issues related to basic informed consent
   - 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*?
Do these factors differ for our patient in important ways as compared to a typical 35-year-old making a similar decision?

2. Why is the patient refusing treatment?
   ▪ Have her family and involved clinicians worked to maximize the patient’s quality of life and control of 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 respiratory failure developed again soon, such as attending a special event in another country?

3. Efficacy of treatment
   ▪ What data would we want about the outcomes of another episode of acute respiratory failure? What constitutes treatment success to the medical team? To the patient?
   ▪ What level of efficacy/chance of success, if any, would lead us to attempt to override Jane’s refusal of intubation and mechanical ventilation?
   ▪ Would a 50% chance of 5-year survival suffice to justify trying to override Jane’s decision?
   ▪ Does Jane’s young age in any way alter thinking about the fact that the likelihood of success of treatment for respiratory failure is low? That is—if she survives, she might have a long life ahead of her.

4. Morbidity and mortality of treatment
   ▪ Can we justify a treatment that may prolong Jane’s life but, in her view, do so with an unacceptable quality of life both in the PICU and beyond?

   If the adults responsible for Jane’s care conclude that she does not have the maturity to make a fully autonomous decision against additional invasive mechanical ventilation and PICU care, what measures could one justify to impose such treatment on Jane? 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 actuate 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 for 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 what they can to preserve the integrity of the patient’s involvement and the relationships among the patient, family, and members of the health care team. Turning to the court system in these cases should always be a last resort. Court intervention disrupts the integrity of the physician-family-patient relationship, negatively 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 physically resisted intubation, 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 one or more of the following:

- 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 contrary to the wishes of parents or medical professionals, courts may grant the minor total or partial emancipation (mature minor status) to make decisions. Such judicial actions are based on existing case law, state statutes, or common law practices, and will therefore be determined on a case-by-case basis. Courts often consider the patient’s prior experience with his or her medical condition, intelligence, and general evidence of maturity in making these determinations.

Does the brain development literature suggest that we should not allow adolescents to make medical (or other important) decisions?

Brain development in adolescence can be best described as a period of change and evolution in both brain structure and function that extends well-beyond what we typically consider adolescence. There is considerable evidence to suggest that normal 14-year-olds have reasoning and cognitive abilities that are equivalent to those legally entitled to make their own decisions. However, many researchers also describe questions of judgment as influenced not solely by reasoning skills. Typically, adolescents’ decisions are highly influenced by social and emotional factors. Emerging evidence from neuroscience indicates that areas of the brain that direct emotional regulation, impulse control, and appraisal of risk/reward in relation to logical
reasoning abilities continue to evolve into the middle of the third decade. As a result, researchers suggest that the differences between adolescents and adults are small in situations where emotional arousal and social influence are controlled (in a hypothetical scenario for example). However, when emotional factors and social influences are heightened, the differences between adolescents and adults are far more pronounced.¹

Therefore, although most agree that reason and cognition often mature early in adolescence, this does not necessarily translate into mature decision making. This should not prevent the possibility of medical decision making by minors, but it should help us better understand the nature of how adolescents may approach medical decisions and what influences their determinations.

What do we know about adolescent development that helps address the dilemma Jane and her caregivers face?

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 PICU stays. Some studies² 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, 25 years of age, that does not automatically mean we should prevent decision making much earlier.³ A number of studies suggest that adolescents do, in fact, seek and in some cases defer to parental help with medical decision-making in the face of serious illness. Clinicians should undertake careful individual assessments of cognitive and emotional functioning and family dynamics when considering whether any particular child should be granted decision-making authority.

References


Session 5. 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 necessary 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
- Alternative 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 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?

**Alternative Cases**

1. A 5-year-old child receives a diagnosis of acute lymphocytic leukemia and requires chemotherapy that will necessitate periodic blood transfusions. His parents belong to the Jehovah’s Witness faith and consent to treatment of the child’s cancer but firmly refuse to consent to any blood product transfusions.

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 wonders whether she should involve child protective services or seek a court order to compel treatment. (Should cultural differences be respected in decisions about health care for children? Is this different from a Christian Scientist refusing treatment for meningitis or a Jehovah’s Witness refusing a life-saving blood transfusion?)

**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 do you think is best for the patient?*

This patient has sustained a wound that you would consider dirty and at risk of tetanus. Usually, this would result in a recommendation for administration of 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 should 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 a legally valid consent is considered battery under the law.

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

Although parents are given wide latitude in terms of the decisions they make on behalf of their children, parental authority is not absolute, and when a parent acts contrary to the best interest of a child, the parent’s authority to make decisions can be limited. However, 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 the state child protection agency (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 child to be subjected to by a parent? Does it matter how great the potential harm is?
Harm must be more than trivial. Generally, harm must be serious. The harm in this case is the risk of tetanus, which nearly every reasonable person would consider to be a serious consequence.

Does it matter how likely the harm is?
Risk of harm must be significant, not simply a possibility. It is easier to justify a claim that the risk of refusing tetanus vaccination and immunoglobulin is significant when an unvaccinated child has sustained a deep 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 two 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 the physician demonstrate evidence that it is likely to benefit the child. There is an important difference between proven efficacy (data-based) and convention (“it is the standard of care”) when one is attempting to convince parents to accept an intervention.

The usual ethical concepts of harm, benefit, and best interest 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. Evidence-based standards 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.

The constitutional right to religious freedom does not extend to practices that are likely to harm a child. In *Prince v Williams*, the US Supreme Court stated, “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.”

Although 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 whether 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 recommended medical intervention provide a significantly more favorable benefit/burden profile 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 similar situations involving other parents?
8. Would most people agree that the state intervention was reasonable in order to protect the child?

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.

References


Session 6. Parent-Patient-Pediatrician Relationship: Obligations of Veracity, Fidelity, and Confidentiality

Mary Adam, MD, 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 all parties involved in the medical decision bring essential elements to the doctor-patient relationship. Shared decision making requires a willingness to trust by all parties. Parents need to trust the physicians to have skill and competence, children need to trust their parents to have their best interest 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 must take into consideration the developmental trajectory of the child and the increasing participation of the child in the decision-making process.

The development of a trusting relationship between a pediatrician, parent, and child is at the center of the American Academy of Pediatrics concept 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 situations in which 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, and 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.

How does a physician balance the competing and sometimes conflicting goods of confidentiality, veracity, and fidelity? When is it acceptable for a physician to deny a parent authority over what information to give a child? How do you resolve conflicts between the parent’s values and those of the medical profession? What weight should be given to family specific values and at what developmental stage to the child’s specific values? What are the goals of medicine and are the goals of the child/parent/and physician the same?
Instructor’s Guide

- Case Summary
- Alternative 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. She is HIV positive, she does not know her diagnosis, and the 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, although she wanted the best for her child. The patient was recently in the hospital with respiratory problems and although she improved, she is asking questions.

Alternative Cases

1. A 15-year-old female, the daughter of family friends, is 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 and cold and has some wheezing. Mom is convinced he is worse because dad is a smoker and 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 write to the court to inform them 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. In private, the father tells you that the child was conceived via donor insemination and states he does not want his son to know.
Learning Objectives

1. Discuss the basic of the duty of medical confidentiality, veracity, and fidelity and its application to the patient and family.
2. Address a parent’s right to influence the medical care of his child 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- for example, when a family wants information withheld from an older child or when a child and parents disagree on the course of action that should be taken.
4. Identify strategies for preventing or resolving these conflicts.

Suggested Reading and Resources for Instructor


Further Reading


Answering parents’ questions. *J Clin Ethics* (special section) 2003;14:59-87

Case Discussion

**Analysis of the duties**

In this case, the duties to the parent for confidentiality are in potential conflict with the duty to tell the patient the truth. This highlights a challenge in pediatrics when 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 failure to respect a parent’s understanding of what is in the best interest of their child both have the potential to put the therapeutic relationship at risk.

**Is truth telling a moral imperative or is it a virtue?**

One physician’s personal moral values may cause him to view an element of deception as therapeutic and justified 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 in favor of recognition of the patient’s right of self-determination and full disclosure. The move toward a pediatric patient’s right of self-determination becomes more prominent as adolescence approaches. Most states have legislation to protect adolescent’s 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 affect meaningful relationships with peers. The stigma associated with HIV is so significant, and the prevailing popular belief in the United States is that it is associated with high-risk sexual behavior (homosexual lifestyle and prostitution); the adoptive parents believe that she will suffer from the association, although incorrect in her case. Middle school students as a group are known for their propensity 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 although the daughter knows she is adopted and her mother is dead, the adoptive 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 adoptive parents have tried to portray the biological
mother as a caring woman who wanted what was best for the child, especially after she
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 essential for the patient to
know and what ultimately they tell the patient. In this sense, withholding some
information is common in the practice of medicine. Historically, physicians were
regarded as ministers of hope and comfort to the sick. When diagnostic options were
extremely limited and treatment options relatively nontoxic, doctors often believed 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 to be 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 a patient who is asymptomatic
and does 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 both the legal and
moral obligation of the physician.

**Patient Factors**
*Is the duty to respect a patient by allowing her to make decisions altered by the
patient’s inability to make a decision?*
Although children are unable to make medical decisions at younger ages, the fact is that
children mature, become more independent and able to make choices. The AAP has
promoted the concept of pediatric assent in recognition of this developmental trajectory.
Both pediatricians and parents have fiduciary responsibilities during this developmental
trajectory to protect and promote the child’s health-related interests. Patients have both
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 younger ages. As maturation
progresses and a child’s ability to understand information increases, there is an increasing
moral obligation to the pediatric patient to honor his 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 in the best interest of the child. These conflicts challenge
parents’ rights in a liberal society to raise their child according to their 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 parents, who have 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 values on these 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 parents’ interest and the freedom to raise their child according to their own values. The parents are responsible for providing a child’s basic needs, and that includes opportunities to assist in the development of the child as a moral person. The needs of all members of a family may influence a health care decision that addresses a single child. A physician who superimposes his or her own values over a family’s has the potential to do harm by destroying a doctor-parent-patient relationship and upsetting a stable support system 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 for which self-care would be impossible if a child were unaware of the diagnosis. In the case under discussion, the child knows she is sick and is fully compliant without knowing her diagnosis. This makes the parents’ argument for less-than-full disclosure stronger. The child is adopted; the adoptive parents have no personal risk from revealing the HIV status of the child. 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, because a variety of support groups exist for many conditions and interaction with other families, and children with similar illnesses can be therapeutic. It is also possible that nondisclosure may give the child the idea that the diagnosis is a “secret,” and keeping the secret, in some cases, may be a burden to the child. 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 her does not influence or change the family’s goal of doing their best to live a “normal” life with a chronic, life-threatening condition.
Conclusions and Suggestions

Respect of patients and their families is a cornerstone of the doctor-patient relationship, and respect should be maintained even in situations in which physicians may disagree with a family’s decision. Parents deserve wide latitude in determining what the best is 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 beliefs about what having a good life means. Often, the differences are rooted in different sets of values about the nature and meaning of life. When the respective worldviews are shared, both parties will often feel heard and understood, even if they cannot come into agreement. In the case presented, there was sufficient agreement between the family’s values and the pediatrician’s. In cases in which agreement cannot be found, physicians have the choice to refer patients for care to another physician, with the family’s consent.
Session 7. Ethical Issues in the Care of Adolescents

Margaret R. Moon, MD, MPH, FAAP

Overview

Caring for adolescent patients can be one of the most rewarding experiences in pediatrics. A competent and confident approach to the adolescent patient must include an understanding of the ethics issues that arise in everyday adolescent medicine. Physicians must balance respect for the patient’s developing capacity for decision making with the ongoing need for support and guidance from caring adults. Concerns about confidentiality, management of high-risk behavior, parent/adolescent conflict, and emerging independence are part of the adolescent experience.

This module will work to enhance understanding of the stages of adolescent development and the ethical concerns most salient to each, the ethical and public health approach to limited confidential care for adolescents, and the importance of and limits to parental control over adolescent health care choices. Focus will be on preventive ethics; establishing an approach to adolescent patients that can avoid some of the most frustrating and predictable ethical dilemmas. It will seek to encourage providers to embrace the particular experience of adolescent care with confidence.

Instructor’s Guide

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

Case Summary

Michael is 17-years-old and has been your patient for 7 years. He is generally well and has been a good student and now is a leader on the school soccer team. You are aware that there has been some discord in the family lately, after Michael got a tattoo against his parents’ wishes. Michael is in clinic today for a routine well examination and sports preparticipation physical. He is accompanied by his father, who waits outside while you complete your interview and physical examination. During your examination, Michael says that he does not want you to give his father any information about his health status. Your evaluation reveals moderate blood pressure
elevation and a new genital rash, most consistent with tinea cruris. Michael does reveal that he has initiated sexual activity with his girlfriend, and that they use condoms infrequently. He denies alcohol, tobacco, or drug use. He comments that his parents are overbearing and difficult and that he wants to take more control of his own life. When you leave the room to allow Michael to dress, his father asks you: “How is he – anything I should know?”

1. How should you handle Michael’s request for confidentiality?
2. What if he were 13 instead of 16?
3. What is the basis on which we offer confidential care for adolescents?
4. How can physicians caring for adolescents avoid conflicts around confidentiality?

**Alternative Cases**

1. Shari, 14-years-old, and her mother, Ms Evers, come to the acute care clinic. Shari is healthy, moderately cognitively delayed, and emotionally very young. Chief complaint, per the registration documents, is headaches and cough. As you are entering the examination room, Ms Evers asks to speak with you outside. She explains that Shari is well, no headaches or cough, but that she needs birth control initiated immediately. Ms Evers notices that Shari looks older than her age and she is worried about the neighborhood boys who are “hanging around”. Ms Evers would like you to start an injectable contraceptive. Shari’s behavior has not changed, but Ms Evers became pregnant herself at age 16 and is concerned that Shari will be victimized and become pregnant. Ms Evers is a single mother and cannot afford to raise a grandchild. You speak with Shari alone – she denies any interest in sexual activity and seems embarrassed by the conversation. Based on your conversation, you see that she actually has minimal understanding of reproduction.
   - Is it acceptable for this mother to request contraception despite her daughter’s general lack of interest in sexual activity?
   - How should the provider manage this interaction?

2. Allen is 15-years-old. He has had some difficulty with school avoidance, but never trouble with the law or, to your knowledge, with drugs or alcohol. His parents accompany him to the clinic visit today. During your initial interview, the parents angrily accuse Allen of staying out all night long and using drugs. Allen is quiet and does not respond to his parents. He makes eye contact with you, surreptitiously rolling his eyes. Allen’s parents demand that you test his urine for drugs and alcohol. They threaten to throw him out of the house if the test results are positive.
   - How can the provider manage this situation?
Learning Objectives

1. Develop sensitivity to the stages of adolescence and the ethics issues most common within each age.
2. Understand the reasons adolescents are offered confidential care and the limits to the duty to protect confidentiality.
3. Identify limits to parental authority over the care provided to adolescent patients.
4. Develop strategies to avoid the ethical issues most common in everyday clinical care of adolescents.

Suggested Reading for the Instructor


Jones RK, Purcell A, Singh S, Finer LB. Adolescents' reports of parental knowledge of adolescents' use of sexual health services and their reactions to mandated parental notification for prescription contraception. *JAMA*. 2005;293(3):340–348


Case Discussion

Confidentiality in the care of adolescent patients has both intrinsic and instrumental value. One of the central principles of biomedical ethics is the duty to respect autonomy. Clinicians caring for pediatric and adolescent patients are quick to surmise that the duty to respect autonomy is complicated by the fact that autonomy is a developmental construct. As children develop cognitive and emotional capacities, our autonomy-related duty moves from protecting and promoting the developing autonomy of young children, toward respecting the decisions made by adolescents who have decision-making capacity similar to that of adults. As an intrinsic value in medicine, protection of confidentiality is a commitment to respect autonomy and the dignity of patients.

As an instrumental value, the promise of confidential care increases the likelihood that adolescent patients will seek care and offer frank disclosures of health concerns. Both values are especially important in the care of adolescents, who, from a developmental perspective, are seeking to achieve autonomy from their parents and are learning to make appropriate decisions about a variety of issues, including healthy behaviors and seeking health care.
The challenge in adolescent health care is to balance these intrinsic and instrumental values of confidentiality with the duties to promote adolescents’ well-being and avoid harms. Although adolescents are developmentally programmed to seek independence, families remain, in most situations, their primary source of moral and financial support and protection. The clinician should seek to enrich family connections while encouraging healthy independence.

Clinicians caring for adolescent patients will be more successful in analyzing and managing ethical concerns if they interpret adolescent behavior in terms of the stages of adolescence. Generally, early adolescence includes ages 10-13, middle adolescence ages 14-16, and late adolescence ages 17-21.

The table below diagrams the changes in physical, moral and cognitive dimensions as adolescent development progresses.

<table>
<thead>
<tr>
<th></th>
<th>Early Adolescence</th>
<th>Middle Adolescence</th>
<th>Late Adolescence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>10-13</td>
<td>14-16</td>
<td>17-20 and beyond</td>
</tr>
<tr>
<td><strong>Somatic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Secondary sex characteristics
  Beginning of rapid growth
  Awkward appearance |                   | Height growth peaks
  Body shape and composition change
  Acne and odor
  Menarche/spermare | Physically mature
  Slower growth |
| **Cognitive and moral** | Concrete operations
  Unable to perceive long-term outcomes of current decision making
  Conventional morality | Emergence of abstract thought (formal operations)
  May perceive future implications, but may not apply in decision-making
  Questioning mores | Future-oriented with sense of perspective
  Idealism; absolutism
  Able to think things through independently |
| **Self-concept/identity formation** | Preoccupied with changing body
  Self-consciousness about appearance and attractiveness
  Fantasy and present-oriented | Concern with attractiveness
  Increasing introspection
  "Stereotypical adolescent" | More stable body image
  Attractiveness may still be of concern
  Firmer identity |
| Family | • Increasing need for privacy  
• Increased bid for independence | • Conflicts over control and independence  
• Struggle for acceptance of greater autonomy | • Emotional and physical separation from family  
• Increased autonomy |
|---|---|---|---|
| Peers | • Seeks same-sex peer affiliation to counter instability | • Intense peer group involvement  
• Preoccupation with peer culture  
• Peers provide behavioral example | • Peer group and values recede in importance  
• Intimacy/possible commitment takes precedence |
| Sexual | • Increased interest in sexual anatomy  
• Anxieties and questions about genital changes, size  
• Limited dating and intimacy | • Testing ability to attract partner  
• Initiation of relationships and sexual activity  
• Questions of sexual orientation | • Consolidation of sexual identity  
• Focus on intimacy and formation of stable relationships  
• Planning for future and commitment |


As clinicians analyze ethical concerns arising in the care of adolescents, the particular stage of development of the specific patient is an important piece of the puzzle. Parents locked in combat with a child whose behavior seems extraordinary may be comforted if the behavior is presented in terms of normal development.

**Case 1: Discussion**

Michael is entering the later stage of adolescence, marked by increased autonomy and emotional separation from his family. At this stage, he may have significant capacity for medical decision making but is still financially, legally, and emotionally under the care of his parents.

Laws vary from state to state, but most states offer adolescents confidential care for reproductive health issues, such as treatment of sexually transmitted illnesses and contraception. (See the Guttmacher Institute for up-to-date state laws.) Access to confidential care is not based on an intrinsic value of respect for adolescent decision making, but an instrumental value in promoting the public’s health by removing barriers to reproductive health and sexually transmitted disease treatment for adolescents.

Michael’s visit is not a reproductive health care visit, but a general examination. His request to withhold all information from his father will not have statutory support. It can, however, be interpreted as a positive desire to take charge of his own health, consistent with his developmental stage. If he were an early adolescent, the same behavior might be interpreted as a
fairly hollow bid for independence, more an expression of fantasy than an expression of adult capacity for decision making.

This case highlights the importance of preventive ethics – making sure that all parties know what to expect in terms of confidential care prior to the visit and any sensitive disclosures. Michael should know the limits of his right to confidential care. His father should be informed also. This is an excellent opportunity to honor Michael’s desire to take charge while striving to strengthen his connection to his father’s desire to help Michael thrive. Michael’s history of sexual activity, the provider’s counseling about condom use and tinea cruris can be kept confidential. Michael can be encouraged to report his blood pressure issue and his general good health to his father himself at the end of the visit. Michael and his father should be encouraged to come to shared understanding about general health visits and information sharing.

Conclusions and Suggestions: Case 1
1. Requests for confidential care and increasing participation in health care decisions can be supported as normal development in adolescents. Anticipatory guidance to families and adolescents should include the parameters for confidentiality.
2. Statutory support for access to confidential care for reproductive health is based in a public health concern for limiting transmission of sexually transmitted disease and unwanted pregnancy, not a belief that adolescents should be making independent decisions about sexual and reproductive health.
3. It is important to interpret requests for control over health care decisions and information in light of an individual adolescent’s stage of cognitive and emotional development.

Case 2: Discussion
This case challenges us to interpret parental decision making and consider the nuances of parental authority over an adolescent. If Shari, at the age of 14, were cognitively normal, there would be a strong argument to involve her in any decisions about reproductive health and a very strong argument to refuse to initiate injectable contraception without her knowledge and consent. In this case, however, the focus is on the child’s best interests and balancing risks and benefits of contraception in a child whose physical development has outpaced her delayed cognitive development.

Parents are charged with protecting their children’s interests and are generally offered fairly wide leeway in making health care decisions for children. Parents are usually best placed to make choices for children because they are emotionally invested in their children and have the most intimate knowledge of their children’s lives. Challenges to parental authority are most commonly based on concerns for the best interest of the child. In adolescent care, challenges to parental authority can also be based on a duty to respect the developing autonomy of the adolescent.

In this case, Shari is at risk because her physical development and her cognitive development are not synchronized. Because of her cognitive impairment, they may never be. Her mother’s concern for Shari’s wellbeing seems realistic. At the same time, it is not clear whether Shari’s
mother is responding to an actual threat or to her own traumatic childhood. Management of this case requires an assessment of the potential benefits and risks of injectable contraception for this particular child. Benefits and risks to the family matter as well; the risk of an unwanted pregnancy in a child who is not capable of caring for offspring must be considered. Additionally, a discussion of other means to protect this child from unwanted sexual contact, and a richer understanding of the mother’s concerns and anxieties is necessary. The primary care provider’s input should be sought; he or she may have a better understanding of Shari’s actual cognitive capacity related to reproductive health. Finally, no matter what decision is made, appropriate care includes working to educate Shari about sexual behavior and self-protection, including appropriate contraception.

Conclusions and Suggestions: Case 2

1. Parents are, presumptively, the best decision makers for adolescents who do not have capacity to make decisions. The limits of parental authority are set by concerns for the best interests (or at least “good enough” interests) of the child.
2. Even if an adolescent patient cannot participate as a decision maker, efforts must be made to educate her and allow her to assent to care.

Case 3: Discussion

This case puts us in the middle of an angry confrontation between parents and an adolescent child. The challenge is to manage the confrontation appropriately while maintaining a therapeutic alliance with both patient and parents. The demand for drug testing, either surreptitious or not, is fairly common in adolescent care. Parents have legitimate and evidence-based reasons to fear early involvement with drugs and alcohol. Even in the absence of actual substance use, adolescent behavior is often inscrutable to parents, and drug use may arise as the best explanation for inexplicable changes in behavior.

Management of conflict between parents and an adolescent patient requires careful diplomacy and negotiation. Respect for parents, who are challenged to protect adolescent children during their exploration and risk taking phases of development, is paramount. At the same time, respect for the adolescent patient must be demonstrated. Failure on either count risks the therapeutic alliance and minimizes the likelihood of a successful encounter.

Conclusions and Suggestions: Case 3

After a careful presentation of some parameters for discussion, parents and adolescent can be interviewed together and then separately. The confidential nature of the adolescent interview should be presented to both patient and parents, with a clear statement as to the limits of confidentiality. Parents generally accept the need for confidential interviews, but if resistance emerges, a direct explanation of the importance of the routine confidential interview for purposes of safety and appropriate medical care is usually effective. Ongoing parental resistance to a confidential interview should be concerning.
Although the specific treatment plans will depend on the information obtained in the interviews, the goal for both is to establish a calm and organized plan for communication and strategies for management of challenging behavior. Family counseling options should be included. Spot urine drug testing is usually of limited value. It is often best to redirect the demand for immediate testing in favor of a more sustained approach to evaluation and management of substance use concerns.
Session 8. Availability and Use of Pediatric Enhancements

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

Overview

The advent of pediatric enhancements has introduced options and challenges, and the conversation must include unambiguous verbal parameters. Perhaps the most helpful and yet critical 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 result in a thoughtful—and perhaps even sympathetic—response from the parent and the pediatrician. 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 a 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
- Alternative 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, had been 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 the medication had helped her to concentrate better in gymnastics; in addition, she noticed that her study time had become 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 former patient legitimately expects a repeat of the prior situation—is there an obligation to protect the child from intervention?
- Does this constitute a violation of the principle of justice?

**Alternative Cases**

1. The parents of a short 12-year-old boy seek your endorsement of growth hormone treatment for their son. They are convinced that 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 situations with marginal medical indication.
   - 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, he 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. Ought the pediatrician necessarily acquiesce to this request?
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


Yates FD. Ethics for the pediatrician: the persuasion of enhancements in pediatrics.
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; to assist in the process of healing and recuperation back to normalcy; and in the case of lost capacity as a result of illness, disease, or injury, to assist in restoring as much of normal function and ability as possible. To this end, we may consider such items as eyewear, dentures, prostheses, and even hairpieces as therapeutic. 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 ordinary 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 ordinary 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 a pediatrician’s goals is to provide a consistent level of care to all his or her patients. We recognize that from time to time, certain patients will require extraordinary care (ie, additional 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 busy pediatrician. The actual conflict 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 be aware of 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 interest 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 from the child for the actions to be performed. On occasion, these situations become highly charged, and it may be appropriate and necessary to seek an externally appointed child advocate in consultation. Legal recourse should always be one of the last options.

In agreeing to provide treatment, is it possible that the physician has become complicit and is violating the principles of justice?
Cheshire 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 them. Commutative justice suggests that there should be fairness in competition. Enhancements augmenting our patients’ abilities may well place others at a 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, procedural treatments, and qualified professionals to distribute and monitor. 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, supplements, etc, any more than it applies to the use of private tutoring. A primary care physician presented with 2 patients in similar circumstances, but one less affluent than the other, could provide a specific enhancement to one and not the other because of the family’s personal finances. It is, therefore, possible that the pediatrician may become complicit with violation of the principles of justice without intending to do so.

How does the issue of informed consent affect the use of enhancements?
Informed consent requires that the patient comply with 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
often there will be a financial cost at some level (most often to the patient and family) and 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 of the covenantal agreement with the patient, the pediatrician’s primary allegiance is to the child and family. Nonetheless, this allegiance must be balanced with the responsibility to society, and the physician ought to be cognizant of future availability of resources.

**Under what circumstances can the physician refuse to provide the requested enhancement?**
The physician has the endorsement of the AAP in refusing to participate in many of these treatment requests for enhancement. 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 conscience issues also often come to bear, and the experienced physician may well feel uncomfortable in participating 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 our patients and the society in which we live and work. If the use of enhancements is promoted—and perhaps even encouraged—in nontherapeutic situations, the physician would be treating what was once recognized as part of the human condition, thereby obscuring the goals of medicine, jeopardizing the safety of his or her patients, and devaluing the child’s future personal accomplishments.

*This instructor’s guide is part of a collection edited by Douglas S. Diekema, MD, MPH, FAAP; Steven R. Leuthner, MD, MA FAAP; Felipe E. Vizcarrondo, MD, MA, FAAP on behalf of the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.*

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Session 9. Infectious Diseases

Emily Obringer, MD, FAAP and Lainie Friedman Ross, MD, PhD, FAAP

Overview

Infectious diseases present unique ethical dilemmas in which a child may be both a patient and a vector for disease. As such, patient-level decisions may have broader implications for public health. Physicians must strive to work with families to ensure the best interest of the child is being met while also considering the health of the community.

Two common issues related to the ethics of pediatric infectious diseases are vaccine refusal and antibiotic demand. Vaccine refusal stems from a variety of reasons, but in most cases, the parents believe that they are acting in the child’s best interest. Vaccine refusal should lead to a thorough parent-physician discussion of the risks and benefits of immunization for the child as well as the risks and benefits in the context of the family and larger community. Antibiotic demand also typically arises from a parent’s desire to promote the child’s well-being. Nonetheless, physicians are professionally obligated to refrain from providing antibiotics when they are not clinically indicated. Not only does this promote the medical best interest of the child, but in the case of antibiotics, it may also curb the development and spread of multi-drug-resistant organisms (MDROs) in the population.

In any clinical situation, parents and physicians generally both seek the best interest of the child/patient. When differences of opinion occur, physicians should remember that their first obligation is to the child. Tensions may arise for the physician when dealing with patients with infectious diseases, because the risk to others and to public health must also be considered.

Instructor’s Guide

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

A 12-month-old boy presents for a well-child visit with his mother. He is a new patient and you review with the mother the vaccines that are recommended at this visit. The mother agrees to all vaccines, except the measles-mumps-rubella (MMR) vaccine, citing the low incidence of measles in her community. She has also heard rumors that the MMR vaccine causes autism. The boy is an only child who does not attend child care. The family has no plans to travel or to receive foreign visitors.

After a thorough discussion, the mother agrees to give the MMR vaccine at 4 years of age, prior to school entry.

- Why do parents refuse vaccines? Should refusals be permitted?
- Why are parents more likely to refuse the MMR vaccine?
- What is the difference between refusal and delay?
- What if this child’s community were in the middle of a measles outbreak?
- What is your duty as a physician to public health?
- Under what circumstances, if any, should you discharge the patient from your practice?

Alternative Case

1. A 6-year-old girl presents with cough, rhinorrhea, and a sore throat. The child has no underlying medical problems, and the physical examination is only notable for a mildly erythematous throat with no exudates. A few small posterior cervical lymph nodes, but no anterior cervical lymph nodes, are palpable. You suspect a viral etiology and recommend supportive care. The mother demands treatment for a bacterial pharyngitis. You agree to do a rapid strep test, the result of which is negative. The mother still demands antibiotics, stating that her child has had multiple episodes like this in the past and she only gets better once antibiotics are prescribed.

- What is the current state of antibiotic prescribing practices in the United States?
- What is your duty as a physician to antibiotic stewardship?
- How are the 2 cases similar?

Learning Objectives

1. Understand the limits of parental autonomy in the context of vaccine refusal and antibiotic demand.
2. Examine the tension between the physician’s obligations to individual patients and to the community.
3. Recognize the duty of the physician to public health and stewardship.
Suggested Reading for Instructor


American Academy of Pediatrics, Committee on Practice and Ambulatory Medicine, Committee on Infectious Diseases, Committee on State Government Affairs, Council on School Health, Section on Administration and Practice Management. Medical versus nonmedical immunization exemptions for child care and school attendance. *Pediatrics*. 2016;138(3):e20162145

Further Reading


The President’s Council of Advisors on Science and Technology. Report to the President on Combating Antibiotic Resistance. September 2014. Available at: [https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf](https://www.whitehouse.gov/sites/default/files/microsites/ostp/PCAST/pcast_carb_report_sept2014.pdf)

Case Discussion

Why do parents refuse vaccines?

Parents refuse vaccines for a variety of reasons, and it is important for the pediatrician to assess what those reasons are. Some parents refuse on religious or philosophical grounds, while others believe the risks of vaccination outweigh the benefits.1,2 Because parents’ choices may be based
on misinformation, pediatricians have a responsibility to provide accurate, evidence-based information on the topic.

**Should parents be allowed to refuse vaccines?**

Parents have a duty to promote the well-being of their child. This responsibility includes maximizing benefit while minimizing harm. Parents are free to choose how and when medical care is provided to their child, unless there is significant, imminent risk of substantial harm.\(^1\) To determine whether significant risk exists, one must consider the likelihood of contracting the disease if unimmunized, which depends on the communicability of the disease and the prevalence of the disease in the community. Additionally, one should consider the potential harm to the patient if he or she were to become infected.

Measles is a highly contagious infection that can result in debilitating and potentially fatal complications.\(^3\) However, the acute risk of infection to the unvaccinated healthy child in a well-immunized community is relatively low, and in a well-resourced country like the United States, many of the risks from the disease can be mitigated most (but not all) of the time. As such, outside of a major epidemic, a parent’s decision in the United States to refuse measles vaccination (or to delay it) may not be the best decision but fails to reach a threshold level of abuse or neglect. In this case, the parents should be allowed to exercise their right to make medical decisions for their child.

**Why are parents who are compliant with other vaccine recommendations more likely to refuse the MMR vaccine?**

In 1998, British physician Andrew Wakefield published a study in *The Lancet* that suggested there was a link between the MMR vaccine and the development of autism. Although the study was later retracted by the journal, and Wakefield was eventually barred from practicing medicine in the United Kingdom after findings of ethical misconduct in research related to the study, the influence of the study on public opinion persists. Several large multimillion dollar studies provide further evidence to refute Wakefield’s claim,\(^4,5\) and yet the association continues to be promoted by some parent groups and celebrities.\(^6\)

**What is the difference between vaccine refusal and delay?**

Vaccine refusal is the decision by a parent not to give a child a particular vaccine or not to vaccinate at all, whereas delay is the decision to give permission but only at an age later than that recommended by professional bodies like the Advisory Committee of Immunization Practices of the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP). Parents may choose to delay vaccines on the basis of misinformation, as noted in the case of MMR vaccination and autism, or the mistaken belief that it reduces the potential rare risks of vaccination. The latter is a misunderstanding of vaccine science, the timing of which is based on a balance between risk of disease and likelihood of developing immunity.

Immunizations are given in infancy for certain diseases, such as pertussis, *Haemophilus influenzae* type b (Hib), and pneumococcal disease, because infants are at risk for these infections and are able to mount an effective immune response to these particular vaccines. Delaying vaccines like Hib until after 1 year of age fails to protect the child from the risk of infection at a time when he or she is most vulnerable. Vaccines for other diseases, such as measles and varicella, must be delayed until at least 1 year of age, because even though younger infants are at risk, they do not develop effective immunity. Vaccine delay after a child is able to
mount an effective immune response is inadvisable, because it unnecessarily exposes the child to the risk of infection.

The risk to the child of vaccine delay is increased if the child is cared for in a group setting like child care, where there may be other children who have not been vaccinated because of age, medical contraindications, or parental refusal. Even in the child who does not attend group child care, vaccine delay is problematic, because the child may still go to a playground or amusement park where infected individuals may be present. The unvaccinated child who becomes infected also poses a risk to other children, because he or she may unknowingly be contagious before symptoms appear. In addition, vaccines are studied for safety and efficacy based on a vaccine schedule. Efficacy and safety in vaccinating “off schedule” is untested.

What if this child’s community were in the middle of a measles outbreak?
The role of community is important when considering the risk of vaccine refusal to the individual. In an area with low MMR vaccination rates or an active measles outbreak, compared with a well-vaccinated community without active disease, the risk to an unimmunized child of contracting measles is considerably higher. This risk must be taken into account when deciding whether a parent’s refusal to vaccinate is in the best interest of the child.

What is your duty as a physician to public health?
First and foremost, a physician’s duty is to the patient. However, as a member of the larger community, the physician also has an obligation to public health. Fortunately, a decision made in the best interest of the patient is often also in the best interest of public health. For example, ensuring that patients are immunized not only decreases the risk of disease to that individual but also creates herd immunity for those patients who are too young or who have medical contraindications to vaccination.

Respect for patient (parent) autonomy is challenged when others are placed at substantial risk of serious harm because of the actions of the individual. Although refusal of routine vaccinations does not typically meet this harm standard, an individual’s right to refuse may be restricted in epidemic situations or in the case of diseases with severe morbidity and mortality (such as smallpox) when an effective vaccine exists. The physician, in collaboration with the parents, has a duty to weigh the risks and benefits of decisions that may affect both the individual and his/her community.

Furthermore, parents who refuse to vaccinate their children often do so with the knowledge that there is a low incidence of disease in their community—made possible by vaccinated individuals. These so-called “free-riders” are benefiting from a public health landscape to which they did not contribute. Highlighting this fact to the parents and urging them to consider their obligation to their community is an important function that physicians can perform in promoting public health.

Under what circumstances, if any, should you discharge the patient from your practice?
In general, physicians are discouraged from discharging patients from their practice. Respect for the parental right to make decisions that the parent views as in the best interest of their child is an important element of the physician-family relationship. Although the physician may not agree with the parent, building a trusting relationship with the parents is essential to ensure the child has access to good medical care.
In limited situations in which the physician feels strongly that trust cannot be established with the parents, then the physician is not obligated to continue the relationship. However, the physician must ensure that the patient is transitioned to another appropriate care provider.

Assuming that the physician does not dismiss a family for refusal to vaccinate, and remembering his or her duty to other patients, the physician should establish infection-prevention strategies within the clinic to protect patients from spread of disease. In addition, the physician should continue to promote vaccination. The AAP has recently published a statement that discusses strategies to overcome parental hesitancy of vaccines.

What is the current state of antibiotic prescribing practices in the United States?
Arguably, the discovery of penicillin, and the subsequent antibiotic development boon, was one of the most health-promoting innovations of the last century, next to vaccines and clean water. However, a recent study showed that more than 30% of all outpatient antibiotics are inappropriately prescribed. The National Action Plan for Combating Antibiotic-Resistant Bacteria highlights the importance of reducing inappropriate antibiotic use as a key strategy in reducing MDROs. Physicians are strongly encouraged to consider their own prescribing practices and their impact on public health.

What is your duty as a physician to antibiotic stewardship?
The physician’s first duty is to the patient. Antibiotics significantly reduce morbidity and mortality and, when used appropriately, are in the best interest of the patient. But antibiotics, like all medical treatments, also have risks. Physicians should be aware of the potential adverse effects and consider these in the decision to prescribe antibiotics.

In addition to potential adverse effects to the individual patient, the development of antibiotic resistance is a serious emerging concern. Through antibiotic stewardship, the physician plays a critical role in preventing and slowing the spread of MDROs. Physicians are encouraged to use the narrowest spectrum and shortest duration of antibiotic that is appropriate for a given diagnosis.

Finally, physicians have an obligation to refrain from providing nonbeneficial interventions. Parental demand for antibiotics is a common occurrence in pediatrics and physicians should be firm in their resolve to prescribe antibiotics only when clinically indicated. Nonetheless, physicians should be ready to engage in open communication with parents about their clinical decisions in a professional and compassionate manner.

How are the 2 cases similar?
Vaccine refusal and antibiotic demand are common causes of tension that can occur when parental decisions differ from physician recommendations. Physicians must build a respectful relationship with families while ensuring the medical well-being of the child. These 2 scenarios also exemplify the conflict that physicians experience, because they not only have obligations to individual patients and their families, but they also have duties to the community. With the development of MDROs and the resurgence of vaccine-preventable diseases, public health needs to be better integrated into clinical practice.
Conclusions and Suggestions

Pediatric infectious diseases pose unique ethical dilemmas that often involve the physician and his or her relationship with the patient, the parents, and the community. The physician’s primary duty is to the patient. Respect for parental autonomy in making decisions may be limited both by challenges to the child’s medical best interest and also by threats to public health.

References


Session 10. 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, the tort mechanism, which steers individuals and institutions into adversarial roles where the end process may be a litigated trial before a jury of peers, is recognized by all close observers as an imperfect means of addressing a social problem. 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 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 inclined most in the medical profession to a reluctant posture regarding disclosure of clinical errors. This formally normative pattern of behavior has 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
- Alternative 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?

Alternative 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 CT scan of the head. 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 bedsheets. 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?

3. A 12-year-old was transferred to your ICU after 3 days of care in a community hospital ICU, where his condition had progressively worsened. On admission an hour ago, he was in uncompensated septic shock, and he has just died. In quickly reviewing his records from the referring hospital, you see that his admission radiograph of the kidneys, ureters, and bladder from 3 days ago had obvious free intraperitoneal air, likely indicating an intestinal perforation. There is no indication in the records that this finding was noted or recognized. You are about to meet his parents. What should you say to them about why he died?
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


Bell SK, Mann KJ, Truog R, Lantos JD. Should we tell parents when we've made an error? *Pediatrics.* 2015;135(1):159-163

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 although 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 completely 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, although 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 114.¹

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.²

**Even if overall malpractice claims and costs increase, 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.

References


This instructor’s guide is part of a collection edited by Douglas S. Diekema, MD, MPH, FAAP; Steven R. Leuthner, MD, MA FAAP; Felipe E. Vizcarrondo, MD, MA, FAAP on behalf of the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Session 11. Iatrogenesis: Exploring Ethical Obligations

Tomas Silber, MD, FAAP

Overview

Iatrogenesis is defined as any adverse condition in a patient that is the result of a treatment error by a physician, health care professional, or member of the medical team. These events contribute significantly to patient morbidity and mortality.\textsuperscript{1-3} Iatrogenic events are preventable. Harm can also come to patients 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. Many errors of omission or commission are institutional or system failures, such as insufficient enforcement of standards for hand washing resulting in inappropriately high rates of health care-associated infections.

This module will explore the individual and systems ethical responsibilities in the disclosure of iatrogenic events. Participants will discuss professional integrity, “duty to warn,” and transparency. They will examine the moral and legal implications of the response to iatrogenesis. Participants will also review their response to colleagues involved in iatrogenesis. Finally, they will examine the role of apology after iatrogenesis has been disclosed.

Participants may confidentially identify types/episodes of iatrogenesis and reflect on how they relate to their practice of medicine. Within this context other complementary ethical issues may arise: respect for people, professional integrity, fiduciary duties, truth telling, accountability, etc.

Instructors Guide:

- Case Summary
- Alternative Cases
- Learning Objectives
- Suggested Reading for Instructor
- Further Reading
- Case Discussion
- Conclusions and Suggestions
Case Summary
A 7-year-old African American 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 “last hope” research protocol with a new investigational drug for AML. A thorough process of informed consent and assent was followed.

Unfortunately, during the first 3 days of chemotherapy treatment, he had significant side effects, including high fever and neuropsychiatric symptoms. The mother became very alarmed and insisted that something was wrong. On day 4, the principal investigator was informed that the entire study drug had been administered, which did not match the protocol instructions. Subsequent investigation revealed that the pharmacy had received a new batch of the drug with the same appearance as the old lower-dose batch. A labeling error of the new medication occurred. The new batch was labeled as with the lower dose. The excessive dose resulted in severe neurotoxic and nephrotoxic administration. The end result was that all further experimental therapy had to be discontinued. Thus, the child lost his last-chance treatment. He died a few weeks later in another hospital.

Commentary: This young child and his distraught parents had negotiated their way through the vicissitudes of daunting AML treatments, including bone marrow transplant (BMT), only to see their last hope for recovery dashed by this iatrogenic event.

How can the treating clinician best deal with this painful situation?

- Is there an ethical duty to disclose?
- Is there a legal one?
- Do they differ?

Alternative Cases

1. A 14-year-old Hispanic girl was hospitalized because of headaches and fever. She had an unremarkable neurologic examination. A CT brain scan was read as compatible with cysticercosis, and her spinal tap showed a low blood glucose, mild pleocytosis, and negative cultures. Chest radiography was normal, and tuberculosis (TB) test result was negative. An infectious disease specialist and a neurologist were consulted. Treatment for cysticercosis was begun. A few days later, the patient’s headaches got worse and she developed nystagmus and high fever and was noticed to have third nerve palsy with diplopia. She subsequently had a seizure and was transferred to the critical care unit, where she became comatose and died. That same day, a CSF culture report came back positive for Mycobacterium, later identified as Mycobacterium bovis. Posthumously, it was discovered that she had consumed unpasteurized milk in Mexico.
Commentary: Although in the first case, death was attributable to an error of commission (overdose), in alternative case A, there was a diagnostic error and the patient died because of an omission—not having been provided drug therapy against TB meningitis.

- Is there an ethical duty to disclose?
- Is there a legal one?
- Do they differ?

2. It is New Year’s Eve. A 4-year-old child arrives in the emergency department with abdominal pain. A diagnosis of acute appendicitis is made. The on-call attending surgeon arrives. He confirms the diagnosis and indicates immediate surgery. As he is scrubbing and getting ready, the nurse on the case notices that the attending surgeon is agitated and has alcohol on his breath. She now has to decide whether (and how) she will stop the attending surgeon from operating.

Commentary: Alternative case B is the most urgent. In this scenario, the potential for harm is enormous, as the surgeon’s skill will most likely be blunted by his alcohol intoxication. Moreover, the situation is complicated by the power differential between the surgeon and the nurse. To complicate matters, there is a history of friendly relationships and camaraderie among the surgical team that will clearly be disrupted by addressing the surgeon’s drinking and placing a hold on surgery. Alternative case B illustrates yet another obligation, that of being our “brother’s keeper”; to protect the public from those we are concerned may harm them.

- Is there an ethical duty to warn?
- Is there a legal one?
- Do they differ?

*All the cases described have happened. Gender, age, and ethnicity of the patients have been altered to avoid identification.*

Learning Objectives

1. Identify the ethical issues involved in the disclosure of iatrogenesis, give examples.
2. Understand systemic and individual responsibilities for iatrogenesis.
3. Discuss fiduciary relationship, professional integrity, “duty to warn,” transparency.
4. Recognize the need for apology and repair.
5. Examine the relationship between ethical obligations and legal requirements.
6. Consider the need for assistance and solidarity with the professional involved in iatrogenesis.

Suggested Reading for Instructor

Further Reading


Case Discussion

As these cases indicate, physicians and other health care professionals work in settings where patients could be harmed. Below are questions about the clinician’s ethical responsibility.

Is there a 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 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 (doctors, attorneys, police, financial advisors, etc.). Hence, the ethical concept of a fiduciary relationship, one in which the interest of the patient or client be considered above that of the professional. The fiduciary obligation of the medical professional is based on the privilege of being granted permission to become intimately involved in the life of others as part of a curing and healing enterprise. Thus, from the perspective of professionalism, clinicians are expected to do their utmost to prevent errors, alert systems to actual or potential iatrogenesis, and disclose errors when they occur.

On the basis of truth telling, trust, and the special nature of the doctor-patient relationship, a patient’s right to know about iatrogenic events trumps the doctor’s self-interest and any desire for discretion and privacy. This position has its grounding in the basic principles of autonomy and respect for people. The application of these principles is essential: all people are entitled to be informed about important events that can directly affect them.

What can we learn from the cases described?
Iatrogenesis is often related to systemic issues—for example, in our main case, insufficient staffing of the research pharmacy led to lack of double checking of the medications prepared. In alternative case A, proper use of consultants, participation of the more senior attending physicians in the case conferences was noted; nevertheless, the dimension of personal responsibility cannot be overlooked, as is seen in alternative case B.
In alternative case B, the individual’s professionalism is still the cornerstone of correct behavior, and health care systems are in place to ensure that professionalism is flourishing. Hence, there is a clear duty to warn when a member of the health care team is impaired (potential for iatrogenesis). Health care systems need to address this through a system of preceptors, supervisors and administrators with authority to intervene. In the unprofessional behavior described in alternative case B, it was good to know that the surgical nurse did her duty and the child was operated on by another surgeon. Prevention of iatrogenesis is an obligation that extends to everybody, from those in a supervisory role to those in subordinate roles.

**What is the legal approach to iatrogenesis?**
The legal/risk management approach to iatrogenesis exists in parallel to ethical considerations. It takes into account that such an event may lead to a malpractice suit. Indeed, in the mind of many professionals, it is best to “not make waves,” meaning not mentioning the event, not documenting or releasing the details, in short not “making it worse” by disclosing it to those affected. This approach is not advised.

Although this module does not pretend to give legal advice, it endorses the current state of the art in risk management, which favors clear documentation, transparency, and completion of incident reports. Although it is certainly important to avoid finger pointing, a description to the patient (and/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 error. Most malpractice cases have more to do with gaps in communication and adversarial relationships, with perceived secrecy and defensiveness, than with the actual medical events involved.

**Does the legal approach differ from the moral approach to iatrogenesis?**
There is agreement between the ethical and the legal approach to iatrogenesis. Both need to address the professional’s obligation toward the patient and to the institution in which the episode occurred. Both need to be considered in the search for a resolution. In the end, the old dictum should always prevail: good medicine makes good ethics and good ethics makes for the best possible legal outcome.

**How can individual accountability and system responsibility be adequately addressed?**
Even when there are individual errors, iatrogenesis is often related to systemic issues—for example, insufficient staffing of the research pharmacy (main case). Iatrogenesis may include lax supervision of professionals, especially when a history of intoxication or substance abuse is known or suspected (alternative case B). Constructive approaches to iatrogenic events must consider the possibility that training has been insufficient or that supervision and instructions have been neglected and/or not strictly enforced.

Nevertheless, the dimension of personal responsibility cannot be overlooked. Personal contributions to errors must be considered in the context of the systemic deficiencies that might facilitate them. This “no blame” paradigm has been questioned in a patient safety improvement article that proposes the adoption of explicit punitive approaches to poorly performing physicians. 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.\textsuperscript{5}

**What are the ethics of apology and repair after iatrogenesis?**
Clinicians involved in iatrogenesis need to explain to the patient and family, in understandable language, what happened, or if not clear, what will be done to understand what happened. Moreover, physicians should also express their heartfelt regrets and apologize for the error incurred. Physicians, preferably senior members of the health care team, need to inform patients and families how the adverse event will be remedied, and specifically what can be done to help the patient, especially when permanent harm has occurred.

Patients that have been harmed deserve an apology.\textsuperscript{6-8} For such an apology to be ethically significant, it needs to:
1. Be clear about its content, recognizing what went wrong and how it happened.
2. Express the heartfelt sorrow that it caused in all involved and the regrets that followed
3. Include any amends or repair that can be offered, making sure the patient does not experience abandonment of care.

The main case of the adolescent with AML can illustrate 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 had caused the confusion, where it had occurred, when it was identified, and the corrective steps undertaken. The oncologist met with the parents, and she could not help but tearing up as she disclosed the event. Her tears spoke more eloquently than any words could 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 lecture devoted to the topic of “Safety and Prevention of Iatrogenesis.”

In alternative case A, the attending physician talked to the family, recognized and described the treatment team’s error in accepting the diagnosis of cysticercosis, which had not been sufficiently challenged. All were misled by the unusual characteristics of the case, such as the negative TB test result and normal chest radiograph. The family was subsequently met by the division director, who spent time with them listening to their tragedy. Everybody on the team expressed their sorrow, gave condolences, and continued seeing the family while they were awaiting the brain death criteria. Testing the family for TB was undertaken and another little girl (a cousin) received a diagnosis of bovine TB and was treated successfully. This never became a legal case.

Finally, one should remain in contact with the patients and their families. Frequently after the adverse event the doctor patient/family relationship is terminated. This is usually due to professional embarrassment, fear, sometimes even misguided legal advice. 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 that on top of experiencing the
consequences of an error they do not feel alone and abandoned. In many cases, the involved doctor’s show of kindness to the unfortunate victim and the family may be of great help towards the emotional healing of the distraught professional himself. When the treating pediatrician can express a heartfelt regret, apologize and especially add what can be done to help, it makes a difference.

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

The events described in the main case and alternative case, in which the patients had a fatal outcome resulted in enormous emotional pain to the clinicians involved. This emotional pain may manifest in the form of torturing guilt, insomnia, anxiety, depression, and self-doubt. The remorse and regret a clinician feels may become overwhelming. On occasion, errors have led to a painful self-imposed end of a professional career. This is a time for support and solidarity with our afflicted colleagues, who have been rightly referred to as “the second victim.” They should not be avoided; kind understanding and support can indeed accompany the necessary corrective measures.

**Conclusions and Suggestions**

If one accepts that iatrogenesis is often the result of deficiencies in the system, there is an ethical obligation to identify and correct those deficiencies that contribute to error. This can be accomplished through debriefing, morbidity and mortality conferences, and performance improvement reviews. Iatrogenesis affects each individual in the system, requiring personal reflection and commitment. Reviewing and documenting, communicating well with all those involved, and maintaining the integrity to disclose medical errors and the moral courage to prevent potential iatrogenesis (duty to warn) are all part of the medical professional’s ethical obligations. Iatrogenesis must be openly addressed and the documentation must be transparent and followed by disclosure, apology, and amends.

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Session 12. Critically Ill Newborns

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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 on what basis should decisions be made? And what is to be done when they disagree? A careful ethical analysis should be carried out, based on solid clinical and prognostic data and the values of those involved in making the decision. In reality, however, data are often 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 infant born at borderline gestational age, but the questions and principles identified are relevant to a wider range of issues in the NICU.

Instructor’s Guide

- Case Summary
- Alternative Cases
- Learning Objectives
- Suggested Reading for Instructor
- Further Reading
- Case Discussion
- Conclusions and Suggestions
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 with 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 g. 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 decisions regarding the care provided to this child?

Alternative Cases

1. A woman is in labor at 32 weeks’ gestation 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, should the parents be offered resuscitation? Mechanical ventilation? Should cardiac surgery be made available for this child if requested by parents?

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 roughly a 75% chance of survival at 5 years, but this will require at least 3 separate surgical procedures and extensive hospital time. Some neurologic disability, although probably not severe, is likely should he survive, and there is a small chance of significant neurologic disability. In addition, should he survive, there is a possibility that he might require a heart transplant later in life. 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. How should the clinical team proceed? Are they obligated to withdraw support as requested by parents, even if they disagree with the parents, and believe surgery is the appropriate course of action?

3. A full-term baby is delivered by cesarean section 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 and a markedly abnormal EEG consistent with hypoxic-ischemic encephalopathy. What options should be offered to the parents? What should the clinical team do if the parents insist on maximal efforts but the team feels this would be inappropriate?

Learning Objectives

1. Understand the major components of honest disclosure when presenting options to parents.
2. Understand ethical considerations in withdrawing or withholding a specific therapy from a critically ill newborn infant.
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 roles of the parents and of the physician in critical decision making in the NICU.

Suggested Reading for Instructor


Further Reading

Beauchamp TL, Childress JF. Principles of Biomedical Ethics. 7th ed. 2013:101-141


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 (e.g., 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. Although it is important to be honest with parents with regard to the precision (or lack thereof) of the data used to present likelihood of survival and disability, one must also be cautious not to overemphasize one end or the other of the range of predicted outcomes in order to “sell” the parents on a decision one way or the other.

The predicted chance of survival may also be center dependent; simply quoting center-specific survival statistics may be inadequate. For example, some centers may never attempt resuscitation earlier 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 circular, creating a self-fulfilling prophecy, and thus is invalid. The appropriate question to be addressed is, what percentage of newborn infants 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 (e.g., 22 weeks’ gestation) are significantly different than from less aggressive centers.1
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 infant should be made to undergo a procedure, particularly an invasive or potentially painful one that offers no chance of benefit. This would include attempted 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’ gestation, but in fact, data have shown that with aggressive treatment, survival is unlikely but nevertheless possible. This possibility, in itself, does not prove that resuscitation at 22 weeks’ gestation should be performed or even offered, only that a decision not to offer resuscitation cannot be justified by impossibility (or physiologic futility).

As a reasonable rule of thumb, resuscitation for this (or any) newborn infant should be offered to the parents unless there is virtually no chance of success or if providing 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, there is virtually no chance of survival), resuscitation should be discussed with the parents. At present, the recommendation of the American Academy of Pediatrics, based on this approach and the currently available data, is that resuscitation should generally be considered and discussed (although not necessarily recommended) with parents of infants born at 22 weeks’ gestation.2,3,4

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 do not?**

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. Respect for autonomy is a core principle of modern biomedical ethics (as are beneficence, nonmaleficence, and justice), but this can come into conflict with paternalistic tendencies from medical professionals who desire to limit information sharing, perhaps at least in part in an effort to reduce this potential parental suffering.\textsuperscript{7} These tensions should be discussed in the seminar.

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

Parents should be given a great deal of discretion in making such decisions, and even if the physician believes the procedure in question should be performed, 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 with the procedure 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 attempts at resuscitation obligatory.

**Is it appropriate for hospitals to have policies or guidelines addressing which newborn infants 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 at the facility. The existence of such guidelines 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 2009). Additionally, hospital-wide policies encourage consistent communication from both the obstetrician and neonatologist to families about their available options.

**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 newborn infants 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 for a given gestational age, depending on other factors such as gender, size, antenatal steroids, and multiple gestation.\textsuperscript{6,7} Data clearly show that a larger girl born at 22 weeks’ gestational could have a better chance of survival, and intact survival, than a smaller boy born at 23 weeks’ gestation.\textsuperscript{8} 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 considered 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. National and international organizations (including the American Academy of Pediatrics and the Nuffield Council on Bioethics) have created guidelines that 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. This could avoid the injustice of offering parents of similar babies in nearby facilities very different options. Here again, a defensible policy would be grounded in deliberation based on applying sound ethical principles to available data.

Should resuscitation be less obligatory for a newborn infant compared with older children? Should parents be given more latitude in deciding whether resuscitation is performed in the case of a newborn infant, 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 infant than for an older child with a similar prognosis for survival and disability. Although this would be difficult to prove, survey data support this supposition, particularly in the case of premature newborn infants. A possible explanation (although not necessarily a moral justification) for this differential treatment by medical providers might be that the newborn infant 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 newborn infants and what possible ethical justifications there would be for that difference. It is here suggested that unless a valid ethical justification can be identified, different criteria for resuscitation specifically for the case of newborn infants should not be 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?

Many ethicists have suggested that if it was permissible not to place the endotracheal tube, it would be equally permissible to withdraw it (ie, withdrawing life-sustaining support is morally equivalent to withholding that support). In some situations, withdrawing might even be preferable to withholding 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) although 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 (eg, 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 newborn infants should discuss the data, as well as the relevant ethical and practical considerations, 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 parents do not think to 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 best interests of the child.

References


7. National Institute of Child Health and Human Development Neonatal Research Network (NRN). Extremely Preterm Birth Outcome Data. Available at:
Session 13. Maternal-Fetal Conflict

Susan F. Townsend, MD, FAAP

Overview

Pregnancy is unique in medical ethics because of the absolute requirement to access the fetus only through intervention on or treatment to the pregnant woman. Increasingly, as medical advances offer the promise of therapy to the fetus, fetal interests have been considered separately from maternal interests by clinicians, policy makers, and the bioethics community. Despite this distinction in interests, maternal and fetal interests usually 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, maternal refusal of treatment that may benefit the fetus), then a variety of ethical frameworks can support clinical decision making, in addition to principle-based approaches. Helpful tools include feminist theory, case-based analysis, and the ethics of care, along with principles of autonomy, beneficence/nonmaleficence, and justice. The concern for maternal-fetal conflict is often emotionally laden and can benefit from a thoughtful analysis that includes a variety of perspectives.

Ultimately, moral theory instructs the health care provider to accept the pregnant woman’s informed consent or refusal of treatment, according respect to her autonomy and bodily integrity, as well as her values regarding pregnancy outcome. In cases in which a woman’s decision may harm her fetus, coercion to force treatment is never ethically justified. In extraordinary cases, legal interventions have been attempted. Using courts to enforce treatment compliance by pregnant women has been unsuccessful, or has activated processes that are hasty and incomplete, with some court rulings overturned on appeal. Evidence shows that continuing a trusting, compassionate, professional relationship with the pregnant woman generally results in greater improvement of maternal and child health. Exploring of provider values may detect subtle, gender-based biases in the clinicians’ approaches to conflict resolution, and support collaborative decision-making for the pregnant woman and her healthcare team, with respect for maternal autonomy the core ethical principle.

This module will explore considerations of the pregnant woman’s right to refuse recommended treatment or testing, if the fetus may be harmed by her decision. Participants will learn the ethical underpinnings of approaches to maternal refusal of treatment, discuss whether there are limits to a pregnant woman’s autonomy, and become
familiar with strategies for conflict resolution to optimize health outcomes for both the pregnant woman and her fetus.

**MATERNAL-FETAL CONFLICT**

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*Communication to resolve conflict in the setting of maintaining a therapeutic relationship with the pregnant woman is recommended. Coerced treatment is not ethically defensible. Respect for the patient’s autonomy is central.*

**Instructor’s Guide**

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- Alternative Cases
- Learning Objectives
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Case Summary

Jesse is a 24-year-old primigravida woman (G1 P0) who presents at term to the hospital in active labor having received care at home with a local midwife for a planned home birth. Her midwife sent her to the hospital because the fetus seemed quite large and she was concerned for dystocia. Jesse is told that a cesarean section is the best route of delivery for the fetus’ well-being. She declines the operation and requests a natural childbirth. The fetus begins to have heart rate abnormalities, suggesting a nonreassuring status. Jesse continues to decline the recommended cesarean section.

- Can the pregnant woman refuse the recommended treatment (a cesarean section)?
- If so, can you perform the treatment (a cesarean section) without her consent?
- Are there limits to her ability to refuse treatment (autonomy)?
- Would your considerations be different if the fetus was extremely premature versus full term or had anomalies? If so, why?
- How should you ethically proceed to optimize both the pregnant woman’s and the future child’s health outcomes?

Alternative Cases

1. Lila presents at full term in labor, with no previous prenatal care. She reports using heroin just prior to admission, and also smokes marijuana and tobacco daily. She is asked to consent to urine toxicology screening and refuses. When the membranes rupture, there is some meconium staining noted in the amniotic fluid. After several hours of labor, she delivers a 2.5-kg male infant who is vigorous at birth and goes to the well-baby nursery. The pediatrician asks for Lila’s permission to perform a urine toxicology and meconium drug screen on the infant, per hospital policy. Lila refuses to consent to these screens. She plans to breastfeed her son. Consider the questions above in terms of refusing testing that would lead to treatment.

Learning Objectives

1. Understand the central tenet of respect for the autonomy of the pregnant woman in the context of medical decision making.
2. Recognize that maternal and fetal interests are intertwined, and the fetus should not be considered separate from the pregnant woman as a patient.
3. Be aware of the evidence and uncertainty around some recommended treatments and 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. Identify strategies for conflict resolution that maintain a therapeutic doctor-patient relationship and have been shown to improve pregnancy outcomes.
Suggested Reading for Instructor

http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Ethics/Refusal-of-Medically-Recommended-Treatment-During-Pregnancy (accessed August 1, 2016)


Further Reading


Kremer ME, Arora KS. Clinical, ethical, and legal considerations in pregnant women with opioid abuse. Obstet Gynecol. 2015;126(3):474-478


Case Discussion

Who is the patient here: the pregnant woman, the fetus, or both?
Increasing use of technology to evaluate the fetus during pregnancy has led physicians and society to consider the fetus as a patient separate from the pregnant woman. This has led to the view of the fetus as having separate interests to be addressed by the medical team providing care. Language around obstetrical decision making has reinforced the
separate consideration of the fetus from the pregnant woman (such as “fetal distress” or “fetal interests”). Nonetheless, access to the fetus for treatment must occur through the pregnant woman’s body, a unique situation. Consider other situations where 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 hope/expect or mandate a parent to donate a kidney to a child under such circumstances?

**Are there limits to when a pregnant woman can refuse medically recommended treatment?**

The American College of Obstetricians and Gynecologists (ACOG) Committee on Ethics states in Committee Opinion No. 664 that “Pregnancy is not an exception to the principle that a decisionally capable patient has the right to refuse treatment, even treatment needed to maintain life.” Therefore, respect for autonomy compels us to honor the patient’s decision. If a pregnant woman lacks decisional capacity (eg, is in a coma), then a surrogate should be consulted, ideally making decisions based on her previously expressed wishes.

**What is an ethical framework to address the complexities of refusing treatment during pregnancy?**

It is important to recognize a pregnant woman’s freedom to make decisions and not be coerced into treatment. Coercion is never ethically defensible, and the pregnant woman has a fundamental right to control over her body. According to ACOG, the provider has an ethical obligation to respect the patient’s (pregnant woman’s) informed decisions, even if there is a beneficence-based motivation toward the fetus of a woman who presents for care. That said, it is important to recognize that most pregnant women do want to help their fetus, and the maternal fetal relationship is not typically adversarial. Although coercion is unacceptable, discussion and perhaps persuasion with compassion and clarity about goals and fears, to ensure the mother appropriately understands the risks and benefits for herself and her fetus with and without the recommended treatment, best serves her autonomy and the fetal interests.

**Should we use the legal system to obtain court-ordered interventions?**

In many situations of obstetric conflict, such as refusal of a cesarean section, 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 section, for example, the fetus in a third of cases has been delivered vaginally and unharmed. 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. Therefore, it is important to know the objective evidence. Legal or court-ordered interventions against a pregnant woman with decisional capacity are controversial at best and widely demonstrate socioeconomic and racial disparities as well. In addition, in cases in which chronic medical conditions during pregnancy, such us substance use disorders, are criminalized, pregnant women may not seek care, resulting in worse pregnancy outcomes. Coerced interventions including using courts to order treatment should be discouraged and avoided.
**Is there an evidence-based approach to conflict resolution when pregnant women refuse medically recommended treatment?**

Maintaining a therapeutic relationship with your patient is generally recommended to defuse tension and support additional informed medical decision making. Demonstrating respect for patient autonomy and bodily integrity, conveying empathy, and seeking to understand the patient’s values and perspective can help address concerns and potentially allow progress towards conflict resolution. In situations such as drug abuse or HIV therapy refusal, it is important to appreciate that medical therapy offered is important for the woman’s health, and not just based on fetal rights. Open discussion and perhaps persuasion with the woman about this might be of benefit. At the same time, many women do want to do what is best for their fetus, and perhaps this could be useful to address.

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

Yes. However, projected 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.

**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 fewer data and even more uncertainty regarding outcome at extremely early gestations, and this should be acknowledged.

**Are there additional considerations related to counseling around HIV testing and treatment than in 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 newborn infants. Again, legal remedies and coercive strategies may lead to families to avoid other medically recommended treatments and worsen long-term outcomes.

**Does substance use testing of pregnant women improve neonatal outcomes?**

In general, narcotic use in pregnancy affects the fetus and places the newborn infant at risk for neonatal abstinence syndrome (NAS). The risk for NAS appears to be unrelated to dose/exposure. Narcotic use in pregnancy is an increasing national concern, and maternal use is an opportunity to provide treatment to pregnant women. Therefore, universal screening in pregnancy is recommended. Treating NAS in the newborn infant is based on observing for symptoms of central nervous system and sympathetic nervous system
activation. Arguably, the maternal history alone can support monitoring the newborn for NAS symptoms, and treatment is based on symptom detection. At present, long-term effects of in utero narcotic exposure (alone) on children are minimal or unknown. Forced testing may have significant social, criminal, or other legal consequences for women. It is important for providers to disclose any testing to a pregnant woman and to be aware of hospital and community policies and laws related to substance use.

Conclusions and Suggestions

Remember that the interests of the pregnant woman are generally aligned with those of her fetus. When they are not, there is an ethical motivation to consider fetal interests, but an ethical obligation to respect the autonomy of the pregnant woman in refusing medically recommended treatments or testing.

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 objectively, detailing what is known and what is uncertain. Potential options and outcomes may 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 shows that providing prenatal care and treatment in a supportive rather than coercive way is the most effective way to promote both 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 consult may be helpful to mediate conflict resolution. Intervention by the courts is rarely appropriate or indicated and should be avoided.

This instructor’s guide is part of a collection edited by Douglas S. Diekema, MD, MPH, FAAP; Steven R. Leuthner, MD, MA FAAP; Felipe E. Vizcarrondo, MD, MA, FAAP on behalf of the American Academy of Pediatrics Committee on Bioethics and Section on Bioethics.

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Section 14: Genetic and Genomic Testing and Screening of Children

Lainie Friedman Ross, MD, PhD, FAAP

Overview

Every year, approximately 4 million children in the United States undergo genetic testing as part of newborn screening (NBS). This is the most common form of genetic testing performed. Other children undergo genetic testing as part of a diagnostic workup for clinical problems (from progressive muscle weakness to developmental delays), to help determine proper dosing of medications (pharmacogenetics), or as part of research protocols. With the completion of the human genome project, there are hopes that genetic variation will be integrated into clinical medicine (personalized medicine). This will be simplified as sequencing of the entire genome (genomic sequencing) or at least the proteins (exome sequencing) becomes cheaper and quicker. The expansion of genetic and genomic testing and screening in pediatrics raises ethical issues regarding the limits of state authority, the limits of parental autonomy, and what rights to privacy, if any, do children have with respect to their parents.

This module will explore the ethical issues that arise regarding whether and when to perform genetic and genomic testing and screening of children. Participants will become aware of the history of NBS and why screening can be performed without parental permission. Participants will examine the benefits and risks of carrier genetic testing of minors and consider under what circumstances it should be encouraged, permitted, or discouraged. They will also evaluate the benefits and risks of predictive genetic testing of children for adult-onset disorders and consider under what circumstances it should be encouraged, permitted, or discouraged. Finally, the participants will examine the benefits and risks of disclosing secondary findings from whole genome/whole exome sequencing and consider under what circumstances it should be encouraged, permitted, or discouraged.

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Case Summary

Shari, a 15-year-old, comes to your office with her mother. Her infant brother, Bob, had an abnormal newborn screen for cystic fibrosis (CF), but a sweat test was negative, indicating that he does not have cystic fibrosis. Bob was found to have one CF mutation (delta F507, the most common mutation). Shari’s parents were initially angry because they were not aware that newborn screening was being performed. After doing some research, they agreed to carrier screening themselves, and both were found to carry the delta F 507 mutation. Shari is very healthy and tall, and her parents and physicians are not concerned that she has CF, but they want to know if Shari can be tested to determine her carrier status. Shari’s mother as well as Shari’s maternal grandmother and 2 maternal aunts all had breast cancer in their early 30s. They have been tested and found to have a 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 Shari’s paternal family. Shari’s father asks whether it would be cheaper in the long-run to just sequence Shari’s entire exome (or genome) so that they will know all of Shari’s health and reproductive risks. Shari is ambivalent about genetic or genomic testing.

- Why do parents not know that their child had newborn screening performed?
- How should pediatricians respond to a refusal of newborn screening?
- What is the likelihood that an individual is a carrier?
- What are the pros and cons of knowing one’s carrier status?
- What are the pros and cons of knowing one’s risk for adult-onset conditions that run in your family?
- What are the pros and cons of knowing one’s risk for adult-onset conditions that do not run in your family?
- Is sequencing ready for use in the general pediatric population?
- What are the pros and cons of screening for the ACMG 56 whenever sequencing is performed?

Alternative Case

Mr and Mrs Jones are expecting their first child. During their prenatal visit, you explain that their child will have a heel prick for newborn screening. Mrs. Jones would like to refuse the test to avoid a blood draw because they have no family history of childhood-onset metabolic or genetic conditions. When they realize how many conditions are being evaluated, Mr. Jones asks whether it would make more sense to just do whole genome or whole exome sequencing to know about all possible health risks.

Learning Objectives

2. Understand when carrier identification of minors occurs and the risks and benefits of this identification.
3. Be able to discuss under what circumstances carrier identification of minors is/ought to be encouraged, permitted and discouraged.

4. Understand the risks and benefits of predictive genetic testing for adolescents.
   - Be able to discuss under what circumstances predictive genetic testing of minors is/ought to be encouraged, permitted and discouraged.
   - Develop some familiarity with the debate regarding the disclosure of secondary findings that are identified in pediatric exome or genomic sequencing.

**Suggested Readings for Instructor**


**Further Readings**


Mardis ER. The $1,000 genome, the $100,000 analysis? *Genome Med.* 2010;2(11):84


Case Discussion

Why were Shari’s parents not aware that newborn screening was performed on their son Bob?
In the early 1960s, Dr Robert Guthrie developed a simple bacterial inhibition assay to measure phenylalanine in blood collected on filter paper to screen for phenylketonuria (PKU). PKU is an autosomal recessive metabolic condition which, if left untreated, can lead to intellectual disabilities. 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 F. Kennedy had a special interest in intellectual disabilities, in part because his sister Rose Marie was affected. A second key factor was the growing strength of the National Association for Retarded Citizens (NARC), now known as the ARC, a parent advocacy group that was keen on preventing disabilities. The third key factor was Robert MacCready, the state laboratory director for Massachusetts. MacCready, as chair of NARC’s Public Health Service Committee, lobbied for mandatory legislation in Massachusetts because he thought uptake was not fast enough, and he was instrumental in encouraging Guthrie and NARC to support and advocate for mandatory legislation nationally. Guthrie and his supporters were successful, and today, in the United States, newborn screening is mandatory, meaning that it can be performed without parental permission, even without parental notification. However, in all states except Nebraska and South Dakota, parents have the right to refuse newborn screening.

What conditions are included in newborn screening?
Initially, expansion was slow because each condition required a separate screening test. However, the development of tandem mass spectrometry (MS/MS) in the 1990s, a platform technology that allows for screening for many conditions simultaneously with one sample, led to a rapid expansion in the early 2000s. Virtually all of the conditions included in NBS are autosomal recessive, meaning that both parents must be carriers to have an affected child. One exception is hypothyroidism, which is often not genetic. Severe combined immunodeficiency syndrome (SCID) is the first X-linked recessive condition to be added, and some states have also started to screen for X-linked adrenoleukodystrophy.

There is also newborn screening beyond the blood spot. Hearing screening is now universal in the United States, as is pulse oximetry screening to detect some cardiovascular and pulmonary conditions.

How should a pediatrician respond to a parental refusal of newborn screening?
The first step is to understand why parents 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 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 1/3000), the refusal does not qualify as neglectful.

**What is Shari’s risk of being a CF carrier?**
The risk of being a carrier for many disorders varies depending on one’s ancestry or ethnicity. In the Caucasian population, approximately 1 in 30 individuals are CF carriers. It is much less common in other ethnic groups. Because both of Shari’s parents are carriers, it 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 2/3.

**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. The statements give a variety of reasons for deferring carrier testing until adulthood, including (1) the minor’s right to privacy; (2) the fact that many adults choose not to be tested; and (3) the unknown risks and benefits of screening for genetic information that will not be needed for a long period of time. Concern has been expressed that carrier identification of minors may lead to labelling 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 already do learn their carrier status in childhood. Sometimes this is known because it was identified as part of NBS. In many states, newborn infants who are carriers of sickle cell (known as sickle cell trait [SCT]) have been identified through NBS programs for almost 25 years, and the data do not show that this knowledge has been harmful. NBS programs are also identifying newborn infants who are carriers of CF, even though there are methodologies for CF screening that would not identify carriers. Other children know their carrier status because parents had prenatal testing performed, or because they were tested when a sibling was found to be affected. The psychological data about getting this information in childhood is 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 do 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 reproductive risk themselves.

Although being a carrier usually has no health implications, this is not always the case. For example, those with SCT are at increased risk of exertional heat illness (and the National Collegiate Athletic Association [NCAA] now requires screening of all college athletes for SCT). In general, though, carrier status is only identified for reproductive purposes, and the data are not clear about when it is the best time to learn this information. In some studies, some adults have stated that they wished they had known at a younger age. 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 regarding the voluntary nature 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 in a high school carrier screening program. One could argue that carrier information is about reproduction and should be covered by specialized consent statutes, which would allow adolescents to consent for themselves. On the other hand, one could argue that genetic information is complex and has familial implications, such that parental involvement should be required.

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

In 2013, the American Academy of Pediatrics (AAP) and the American College of Medical Genetics and Genomics (ACMG) published a joint policy statement and technical report on genetic testing of children. In those publications, the AAP/ACMG position was to discourage carrier testing of adolescents unless it was clinically relevant. The American Society of Human Genetics (ASHG) came to the same conclusion in 2015.

**What is Shari’s risk of being a BRCA carrier and of developing breast cancer?**

The risk of being a carrier for many disorders varies depending on one’s ancestry or ethnicity. But in Shari’s case, her mother is known to have a BRCA mutation. Because BRCA is an autosomal dominant gene, 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 not 100%, but rather falls between 30% and 85%. Given the high number of relatives with breast cancer, her risk of breast cancer if she were to have the mutation is 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. Although 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 genetic testing for adult-onset diseases in childhood. The arguments are (1) the child’s right to privacy; (2) the child’s right to make this decision as an adult; (3) the unknown impact of identifying carriers when the information is not relevant for years or decades; (4) concerns about self-identity and how others will treat the child; and (5) 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 Non-Discrimination Act (GINA) of 2008 should reduce this problem. There may, however, be discrimination regarding life insurance. There is also the concern of social stigmatization.

The benefit of knowing whether one is a carrier for BRCA is that there are actions a woman can take to reduce her risk of breast cancer. But there are no treatments or preventions that are recommended to begin in childhood, which is why testing minors is discouraged. Recommendations for adult women with BRCA include more frequent mammography screening starting at a younger age. Women may also choose to undergo prophylactic surgery.
**What role should Shari play in deciding about BRCA genetic testing?**

Again, both the joint statements by the AAP/ACMG and the recommendations of the ASHG are to discourage predictive genetic testing during adolescence even if Shari is eager for this information. Given that there are no clinical preventive measures or treatments that should change if one knows a person’s BRCA status during childhood, the child’s dissent should be definitive. This acknowledges the adolescent’s emerging right to privacy about health information as well as her right not to know.

The data, however, do not necessarily confirm that the best time for predictive genetic testing is young adulthood. Rather, there may be circumstances in which predictive testing of adolescents is appropriate. If the family provides strong arguments why waiting would be harmful and both the parent(s) and adolescent want this information, they should receive appropriate genetic counseling. If the adolescent is assessed as being mature, is able to give rational reasons for wanting to be tested now, is able to give convincing arguments why waiting would be harmful, and has the support of his or her parent(s), then the justification for the state to override family autonomy is weak. This is not an endorsement of routine testing of adolescents for adult-onset conditions. 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. But if one is contemplating testing a minor for an adult-onset condition, the decision should be done during later adolescence when the minor can meaningfully participate and make his or her own benefit: risk evaluation. If there are no health risks in childhood, the adolescent’s refusal should be respected. Ambivalence should be interpreted as a refusal.

Whether the adolescent should be able to get predictive testing for adult-onset conditions without involving his or her parent(s) 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 and outside of the reproductive context, it is not clear that there are compelling arguments to justify this.

**Is the use of sequencing technologies ready for routine use?**

Sequencing technologies have been under development since the early days of the Human Genome Project. Current screening usually focuses on whole exome sequencing, which targets the protein coding regions (< 2% of the genome) to reduce time and cost. Whole genome sequencing is more comprehensive and allows one to interrogate single-nucleotide variants (SNVs) and copy number variants (CNVs)—either of which may be clinically relevant in diagnostic dilemmas. Next generation sequencing uses a variety of sequencing methodologies that sequence DNA and RNA much more quickly and cheaply than the previously used Sanger sequencing. Although some sequencing has been quoted at costing less than $1000 per sample, Mardis argues that this ignores many of the other costs associated with interpretation of the results and counselling. Currently, sequencing is not a first-line diagnostic methodology.

**Should adult-onset conditions identified secondarily with sequencing be disclosed to parents and children?**

Although sequencing is not being used as a first-line diagnostic tool, it is being used in some settings for diagnosis with increasing success. In March 2013, the ACMG independently
published a statement in which it argued in favor of intentionally seeking out 56 genetic mutations known to be highly penetrant (at least in high-risk populations) whenever sequencing was performed, regardless of whether the patient or physician requested it, and even if they asked not to be informed. Although the ACMG refers to this as opportunistic screening, critics have labeled it a mandatory hunt. After significant professional and public debate, the ACMG continues to recommend interrogating all samples for these 56 genetic mutations, but they do acknowledge the right of patients and surrogates to refuse such information.

Whether returning secondary findings that identify mutations for adult-onset conditions should even be offered when the sample comes from a child remains controversial. The benefits of learning this information when sequencing is performed on a child is that it may warn a family about a health risk previously not seen or at least not recognized within a family. That is, it may benefit either the child, the parent, or both. Proponents support the additional screening because the sample is already being analyzed, although laboratorians object on the grounds that screening for the ACMG 56 requires additional interrogation, and it is not clear who will pay for this. The AAP/ACMG joint statements as well as the more recent ASHG statement all argue against identifying adult-onset conditions in childhood. Although the statements permit exceptions because family anxiety, for example, this is not relevant in unsuspecting (low-risk) families. Rather, such identification and disclosure ignores the child’s right not to know and the child’s right to privacy of health information from his or her own parents.

Identifying and disclosing risks of adult-onset conditions that are secondarily identified from sequencing is different than testing Shari for BRCA when she is known to come from a high-risk family in which the gene is highly penetrant (which may not be the case when BRCA is found in the low-risk population). Second, Shari has some lived experience with breast cancer and genetic screening, which can help inform her decision. Third, Shari may be experiencing anxiety from the uncertainty with which she lives, which is not the case for adolescents in the low-risk population who may be unaware of such risks.

**Conclusions and Suggestions**

In general, parents have wide discretion in health care decision making for their children. But there are limits, particularly when the health implications are not relevant to the child during childhood.

In general, carrier testing of minors should be discouraged.

In general, predictive testing of minors for late-onset conditions should be discouraged. However, in extenuating circumstances, when the family believes that not testing is causing serious psychological harm, testing may be permissible.

Sequencing is not ready for use in healthy children. It is increasingly being used as a second-or third-tier test for children with diagnostic dilemmas. When performed on pediatric samples, there should be limited return of secondary findings for conditions that do not present in childhood or are only relevant for reproductive purposes.
Session 15. Brain Death, Permanent Vegetative State, and Medical Futility

Ásdís Finnsdóttir Wagner, DO; Julio Quezada, 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 he or she believes the treatment is medically futile? Who determines whether the treatment is futile and by what criteria? Should cost be included when determining whether the treatment is appropriate?

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

Instructor’s Guide

- Case Summary
- Alternative 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?

**Alternative 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

**What are the differences between 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 brainstem.

**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, and these were later revised and updated in 2011. Table 2 shows the Guidelines for Determination of Brain Death in Children.

**Table 2. Guidelines for the Determination of Brain Death in Children**

Reversible conditions or conditions that can interfere with the neurologic examination must be excluded prior to brain death testing.

1. Coma: Patient must exhibit complete loss of consciousness, vocalization, and volitional activity.
2. Loss of all brain stem reflexes, including:
   a. Midposition or fully dilated pupils that do not respond to light.
   b. Absence of movement of bulbar musculature including facial and oropharyngeal muscles.
   c. Absent gag, cough, sucking, and rooting reflex.
   d. Absent corneal reflexes.
   e. Absent oculovestibular reflexes.
3. Apnea: The patient must have complete absence of documented respiratory effort (if feasible) by formal apnea testing demonstrating a PaCO$_2$ $\geq$ 60 mm Hg and $\geq$ 20 mm Hg increase above baseline.
4. Flaccid tone and absence of spontaneous or induced movements, excluding spinal cord events such as reflex withdrawal or spinal myoclonus.

The initial examination should occur at least 24 hours after the brain injury was sustained or cardiopulmonary resuscitation took place. Two clinical examinations must be performed by 2 different physicians, and both tests should include the apnea testing. An ancillary test (ie, electroencephalogram or cerebral blood flow study) is not necessary unless the apnea test cannot safely be performed on the initial test. An observation period of 24 hours for term newborn infants (37 weeks’ gestation to 30 days) or 12 hours for older infants and children (31 days to 18 years) should be present between examinations, however, this can be shortened in both age groups if ancillary testing confirms initial examination (Nakagawa).

**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.”¹ This state must persist for greater than 1 hour. Patients are unconscious because they lack both wakefulness and awareness.³

**Vegetative State**
A patient that is in a vegetative state can exhibit wakefulness but is unaware of herself or her environment.² This condition is further divided into persistent vegetative state if the condition lasts for more than 1 month or as permanent vegetative state if it lasts more than 3 months after a nontraumatic brain injury or 12 months after a traumatic brain injury. Permanent vegetative state is described as state 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.”³ 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.”¹ Diagnostic criteria from the Aspen Neurobehavioral Work Group⁴ 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.

Figure 1. Differentiation Among Brain Death, Coma, Permanent Vegetative State, and Minimally Conscious State

Figure adapted from: Laureys S, Owen AM, Schiff ND. Brain function in coma, vegetative state, and related disorders. Lancet Neurol. 2004;3(9):537-546
The patient with brain death will show evidence meeting the diagnostic criteria listed previously demonstrating completely destroyed brain stem. Normal consciousness has maximal arousal and awareness while minimal arousal and awareness are seen with coma, sleep, and anesthesia.

Patients in a vegetative state will have complete or partial preservation of brain stem and hypothalamic function but will have no awareness of self or the environment with periods of wakefulness. The minimally conscious state is used to categorize those patients who are not in a vegetative state and have behaviors associated with conscious awareness but are unable to communicate consistently because of fluctuating awareness. The term “locked-in syndrome” was introduced by Plum and Posner to describe the quadriplegia and anarthria resulting from the disruption of corticospinal and corticobulbar pathways, respectively. In this state, the patient is unable to move or talk but has intact arousal and awareness.²

**Do these categories make up the whole spectrum of severe brain damage?**
No. These categories reflect 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 on the basis of 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.

How do these concepts apply to the cases?
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 believe 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, even if it is not the medical recommendation, 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. Although 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 in which 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.
References


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Session 16. Training Issues for Residents and Students, Part I: Ethical and Professional Conflicts in the Context of Valued Learning Opportunities

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Overview

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

Professional development in the course of postgraduate medical and surgical training has been provided in the context of progressive independence. Expansion of trainees’ knowledge and skills requires this independence, which, when supervised appropriately, is believed to foster the greatest degree of gains in clinical skills and knowledge. In recent years, supervisory requirements and duty hours restrictions evolved from efforts to ensure that the primacy of patient welfare, principally patient safety, was not sacrificed in the course of valued learning opportunities for trainees afforded by this progressive independence.

In this teaching module, we will 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.

Instructor’s Guide

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

Case Summary

A 7-year-old 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 child becomes hypoxic. As a junior trainee, you suspect VP shunt malfunction; your attending physician agrees. The computed tomography (CT) technicians want the patient there now. You would like to
accompany the child in the event that emergency 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 who fell and suffered a laceration on the 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 the child’s parent that the cut will need sutures, the parent asks who is going to do it and expresses the desire that the child not “be used as a guinea pig.”
   - What do you tell the parent?
   - Do you need to let the parent 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 you had not been asked, would it have been your responsibility to inform the parent of your lack of experience?
   - 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 with acute lymphocytic leukemia in relapse is transferred to the pediatric intensive care unit with septic shock. During the child’s month-long hospitalization, you develop a strong bond with the child and the family. The child is likely dying. You would like to stay after your shift has ended to learn from the attending physician, whose compassionate patient care you admire, ways to be present with the family and things to say during this tragic, 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?
   - Would the considerations differ 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 the trainee's 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 the patient’s 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. Discuss whether questions of fairness might lead to additional obligations to families who come from backgrounds that make it difficult for them to understand the competence of trainees or to challenge the involvement of a trainee in their care.
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**


Carrese JA, McDonald EL, Moon M, Taylor HA, Khaira K, Catherine Beach M, Hughes MT. Everyday ethics in internal medicine resident clinic: an opportunity to teach. Med Educ. 2011;45(7):712-721


Case Discussion

Case 1

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. The means by which attending physicians and other supervisors take these considerations into account occur in the context of a variety of supervisory styles and involvement in the care provided. These, in turn, are typically based on direct observation of the trainee, the supervisor’s underlying degree of comfort permitting independent learning, and other factors.8,9,11,14

Should you be allowed to participate in a procedure that may be beyond your level of competence?
Trainees should not plan to 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 assessed by the appropriate supervisor 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. This trainee’s personal goals for learning should not influence the trainee’s self-assessment of preparedness and suitability to accompany this patient alone to CT scan, because the patient’s safety and welfare are of prime importance. At the core of professionalism is the obligation to place the patient’s well being ahead of needs and interests of the health care provider.3

Case 2

What do you tell the parent?
Honesty about proposed treatments is mandatory. Professionals need to be aware that many individuals from populations that have traditionally been underserved by the health care system or experienced oppression by society in general, 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. Medical students ought to introduce themselves as student members of the team.

**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 authority, should be offered reasonable alternatives to that system of care.

**What is the best compromise concerning training needs and the rights of parents or other family caregivers to expect that their children will receive optimal care?**
You should assure the parent that the procedure will be performed under the guidance of an experienced physician and follow through with the promised plan. When parents demand a procedure be performed by the most expert person, the resident trainee could respond: “I will have my attending supervisor here with me for the procedure” or “I understand your concerns and I will bring my attending physician to discuss this personally with you.” 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 or the child's family. Likewise, this child and family have 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 to undertake procedures beyond their scope of competence. 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.

In some instances, displaying to supervisors what could be construed as a lack of self-confidence or, in some instances, even asking for help, could be the basis for less favorable summative evaluation despite the reality these behaviors might represent the most reflective, respectful and beneficent stance by the trainee. The impression that an enthusiastic posture might make initially if you in fact lack the appropriate experience to
perform the procedure could quickly turn negative once the attending learns more about your preparedness.

Case 3
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 these duties could 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 making an exception to working hour limits because of the importance of the benefits that may result.

Should you ask permission first?
Absolutely. The Accreditation Council on Graduate Medical Education common program requirements recognize that residents may wish to remain beyond the scheduled shift in order to participate in unusual learning opportunities or out of “humanistic attention to the needs of a patient or family.” In these instances, the resident is expected to hand over all other patient care responsibilities, document the reasons for staying beyond duty hours, and submit that documentation to the program director.

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 physician 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. Attending physicians who violate rules by requesting a trainee to stay past duty hours compromise their status as positive role models.

Would the considerations differ 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 the trainee’s 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 unusual and valued care. If a trainee stayed past duty hours merely to observe, but not participate actively in, an uncommon operation or other technical
procedure, 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. These opportunities arise ideally in well-supervised
settings in which the provision of progressive independence is individualized to each
trainee’s needs and abilities. 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.

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Directors. Teaching and Assessing Professionalism: A Program Director’s Guide.
Accessed March 7, 2017

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to teach. Med Educ. 2011;45(7):712-721


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Session 17. Training Issues for Residents and Students, Part II: Ethical and Professional Conflicts that May Arise When Trainees Question What They are Told To Do

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Overview

As outlined by the American Board of Pediatrics, the American Academy of Pediatrics, and others, 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. Trainees need to learn how to identify and address common ethical dilemmas faced in their role as learners with relatively limited knowledge, experience, and judgment compared with their supervisors and superiors. Ethical duties to patients lead to professional obligations that may demand interpersonal negotiation between members of the care team, conversations that may be difficult.

In this teaching module, we will focus on ways that the current hierarchical model of training can foster challenging disagreements between team members at different levels of training and experience regarding important medical care decisions. The trainees’ duty to deliver the best possible care to patients creates an obligation to address these disagreements, an undertaking not without risk.

Instructor’s Guide

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

Case Summary

A 3-month-old is hospitalized early in your night on call with wheezing following 2 days of rhinorrhea and cough, a day of fever to 101°F, and a report from the emergency
department that the infant is in respiratory distress. The birth and past medical history are unremarkable. On examination, the infant is well-appearing, crying but consolable, and wheezing, but not in respiratory distress. Testing of a nasal swab for common respiratory viral pathogens will not be performed until the next morning. Your senior resident tells you that the infant needs a full sepsis work-up, including lumbar puncture, but you disagree. You believe that the diagnostic tests are not indicated and will cause harm, in the form of pain, for the infant.

Alternative Case

A 4-year-old is admitted with a 2-day history of vomiting, diarrhea, fever, and mid-abdominal pain. Laboratory tests and abdominal ultrasonography are normal in the emergency department, where the child is hydrated intravenously. During rounds with the attending physician, you mention your concern regarding the abdominal pain, but the attending physician reassures you that it is attributable to abdominal cramps and wants no further imaging performed. You run into a friend, a pediatric surgical fellow, and ask your friend’s advice (without first consulting the child’s attending physician). After reviewing the history and examining the patient, your friend recommends a CT scan to rule out appendicitis. When you approach the parents for consent to perform the CT scan, they decline to agree to the test unless it is first approved by the child’s attending physician.

▪ Do you need to follow the instructions of your supervisors in these cases?
▪ What are the best actions to take in situations in which you have a dispute with a supervisor about treatment?
▪ Are you taking risks by challenging the authority of your supervisors?
▪ Are there times when it is not appropriate for a junior trainee to challenge the directions of a supervisor?

Learning Objectives

1. Reconcile obligations to pursue the best interests of the patient with awareness that limitations in experience and education may restrict a trainee’s capacity for sound clinical reasoning.
2. Be prepared to address disagreements with team members at more advanced levels of training and experience regarding important medical care decisions, even if doing so carries a risk to the junior trainee of appearing to challenge authority.
3. Appreciate the potential for misunderstanding or misattribution of supervisors’ and trainees’ clinical reasoning and the factors that influence it.
4. Understand the role and obligations of mediators and other supervisory professionals to help resolve such disagreements.

Suggested Readings for Instructor

General materials on professionalism are listed as the first 3 references,¹⁻³ in the final
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 2009,4 Brody and Doukas 2014,3 Carrese et al 2011,5 McDougal and Sokol 2008,6 and Moon et al 2009.7


Case Discussion

**Do you need to follow the instructions of your supervisor in these cases?**

The relationship between a supervisor and junior trainee in the health care setting is one in which the trainee is both dependent on the supervisor for care oversight and education and obligated to deliver the best possible care to patients who are the joint responsibility of all involved. The expectation that a junior trainee follow instructions of a supervisor can come into conflict with duties of beneficence (and nonmaleficence) if the trainee experiences a supervisor’s directive as an order to do something potentially harmful. This is one of many sources of moral distress cited by health professionals, particularly nurses, who work in what have traditionally been considered to be subordinate roles.

The more urgent or emergent the clinical situation, the less time there is for a trainee to question the directive of the supervisor. The more crucial the diagnostic or therapeutic conflict between supervisor and trainee to the well-being of the patient, the more important it is to take steps outlined below.

**What are the best actions to take in situations in which you have a dispute with a supervisor about treatment?**

The best course of action is for you to ask for explanation. It is possible that your understanding of your supervisor’s clinical reasoning, or of the factors influencing it, is mistaken or incomplete. In order that your reasons for challenging their authority not be misunderstood or misinterpreted, you must strive to express your perspectives as clearly and respectfully as possible. This is more challenging in times of heightened stress caused by a large workload, concern for sick patients, and moral distress created by the expectation that you deliver care or render treatments that you believe may not be in the patient’s interests. If work within the clinical team is not experienced as taking place in a “psychologically safe environment,”10p842 trainees may feel inhibited asking questions or expressing differing viewpoints to their superiors.

In many situations, engaging the supervisor in dialogue will largely resolve the conflict over appropriate patient management. All care teams need to have access to an outside party who can help mediate disagreements about care. This may be another senior
resident, a chief resident, another inpatient attending physician, or the chief of service. The duties of such mediators are to listen carefully to all considerations and be guided by the best interests of the patient.

**Are you taking risks by challenging the authority of your supervisors?**

Challenging the authority of your supervisors can put you and your patients at risk. By virtue of their greater degree of experience and training, your supervisors may have taken additional considerations into account or been in similar clinical situations that put them in a good position to make what may be the most sound diagnostic and therapeutic decisions. At the same time, they may not have access to or appreciate all the information that you know by virtue of your close, current work “at the bedside” with the patient and family. Although engaging supervisors in respectful discussion about disagreements is an advanced professional skill worth fostering, you also run the risk of being viewed in an unfavorable light, depending on the dynamics of the process.

Training programs are intimate social groups in which the reputations or perceived attributes of particular members endure. These can form the basis of preconceived notions about how safe it is to disagree with a supervisor that influence a trainee’s comfort level in presenting differences of opinion. This may have a strong effect, together with other characteristics of their relationship, on help-seeking behavior by the trainee.¹⁰

**Are there times when it is not appropriate for a junior trainee to challenge the directions of a supervisor?**

There are times, such as life-threatening emergencies demanding patient resuscitation, when the importance of maintaining a smoothly running, hierarchical team is critical to ensuring the best chance of favorable patient outcomes. In these instances, responsibilities for directing care tend to be shifted to the highest-level professionals available, and all impediments to carrying out treatment must be minimized. Even during patient resuscitation, however, any participating team member who feels that an error is being made, or is about to be made, should not remain silent.¹⁵

In the cases presented, critical illness or insufficient time are not significant barriers to engaging your supervisor in discussion about alternative proposals for management. The second case scenario suggests the potential for harm resulting from delayed diagnosis of a condition, such as appendicitis, which could call for surgical intervention. The greater the likelihood that following instructions from your resident or attending may lead to harm to your patients, the more incumbent it is on you to argue for your own preferences in planning and delivering treatment. At the same time, trainees need to be aware that their own preferred diagnostic or therapeutic suggestions may add unnecessary risks of harm (eg, radiation from an abdominal CT scan) and expense.

**What should the resident do in these specific situations?**

Interns face difficult decisions when supervising physicians disagree with their inclinations. Interns should not act contrary to the orders of supervisors, who likely have greater experience and knowledge. Nor should they “go around their back,” as this
violates the integrity of decision-making on behalf of the patient and the safeguards inherent to clinical supervision of trainees.

In the first case, the intern should discuss foregoing the lumbar puncture directly with the senior resident. A senior mediator, such as the admitting resident, chief resident, or attending physician, may be able to help them reach agreement. Potential mediators may not be impartial. In the end, if everyone is advising the intern that the lumbar puncture should be performed, then the intern should perform the procedure. If the intern still feels a conflict of conscience over this order, the intern may object to the assignment and ask that duty for the patient be transferred to a colleague. As in other clinical situations in which the trainee objects to administering care on moral grounds, responsibility for care remains with the trainee until reassignment of care duties can be accomplished.16

In the second case, the intern should not arrange for the CT scan unless it has been authorized by the attending physician. Regarding the solicitation of other opinions, there is disagreement about the appropriateness of obtaining a curbside consult without the attending’s prior knowledge. Some may perceive it as disrespectful, and indeed the most courteous approach would be to first ask the attending if pediatric surgical consultation is acceptable. If the intern has serious concerns about the plan and has reason to believe the attending may not be receptive to obtaining consultation, it is appropriate for the intern to seek the opinion of a senior physician mediator. The intern’s ability to solicit other opinions when unsure about the plan is both essential to clinical education and a crucial safeguard to patient care.

If the child’s condition worsens or the suspicion for acute abdomen grows, the intern can appeal to the attending physician or other senior mediators in the hospital to assist in communicating these concerns. Regardless of whether the CT scan is performed, the team will need to continue performing serial examinations on the child for signs of appendicitis, intussusception, or other abdominal emergency.

Conclusions and Suggestions

Disagreements with supervisors about important medical care decisions obligate trainees to question directives issued by those overseeing care. Following directions that may be harmful challenges fundamental ethical commitments to patient care and causes moral distress in trainees and fellow health professionals. Physicians are guided by duties of beneficence (and nonmaleficence) and to act virtuously on behalf of their patients: in the words of Brody and Doukas, “doing the right thing (whatever puts the patient’s interests first and foremost) in the right way and with the right attitude.”3p985

Trainees should act in ways that help the care team function smoothly and maintain favorable professional reputations for themselves. As such, they are obligated to develop the capacity to engage supervisors in respectful discussions regarding disagreements about care when potential for harm to the patient exists. Trainees can model this practice after colleagues and others whom they observe doing it well, similar to ways they learn to refine other communication skills. They need to reconcile their obligations to pursue the
best interests of the patient and prevent avoidable harm while not acting or appearing to act in an insubordinate fashion. Senior physicians need to direct care in approachable and nonthreatening ways that foster dialogue and discussion about the best care possible for patients.

References


Session 18. Conflict of Interest

David Y. Harari, MD, MSB and Robert C. Macauley, MD, FAAP, FAAHPM

Overview

Conflicts of interest arise when financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. Conflicts of interest can surface at both an individual and institutional level, and are recognized in various disciplines such as law, medicine, journalism, academia, business, and government. In medicine, however, conflicts of interest can be particularly troubling, as they may have a direct effect on the health and well-being of patients.

In the past decade, thanks in large part to media coverage and investigative reporting, physician and researcher collaboration with the pharmaceutical and biotechnology industries has become one of the most well-known areas associated with significant potential for conflicts of interest. Real concern exists regarding physicians, researchers, and medical institutions who stand to gain financially from the development and use of industry-promoted medications and medical devices. In fact, a major study (Campbell et al, 2007) found that more than 90% of physicians have some sort of relationship with the pharmaceutical industry. Such conflicts may cloud professional judgment and jeopardize the integrity of scientific research, the quality of patient care, and the public’s overall trust in medicine. Fortunately, increased awareness has also led to a dramatic increase in federal, state, and institutional oversight of the interactions between physicians/researchers and the pharmaceutical industry in recent years.

This module will review the key ethical concepts and issues related to conflict of interest by way of specific case scenarios. It will also address ways for preventing and avoiding problematic situations whereby physicians may be faced with compromising their professional and moral responsibilities.

Instructor’s Guide

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

Dr Liu is a pediatrician at the academic hospital’s outpatient pediatrics clinic. Recently, 2 representatives from RD Pharma, a pharmaceutical company that develops and markets asthma medications for children, arrived at the office and asked if they can provide a catered lunch next week for the entire office staff. They also asked Dr Liu if he would be willing to speak at an upcoming medical conference sponsored by the pharmaceutical company. Before they depart, the representatives leave dozens of samples for a new asthma medication on the front office desk.

- Is it appropriate for Dr Liu to accept a “free lunch” from the pharmaceutical representatives? Does it make a difference whether or not he personally attends the lunch?
- Should Dr Liu offer the free samples of the inhalers to patients? Does it make a difference if patients who cannot otherwise afford the medication can benefit from the samples?
- Is it problematic for Dr Liu to accept a speaking engagement at a medical conference sponsored by the pharmaceutical company? Does it make a difference whether or not the company pays for his travel and accommodations?

Alternative Cases

1. Dr Smith is a physician researcher at a medical university. For the past 5 years, she has been investigating a new drug that targets a specific gene mutation implicated in the development of cystic fibrosis (CF). Although housed within the medical school, Dr Smith’s laboratory receives considerable funding from CFx, a local pharmaceutical company that concentrates on novel treatments for CF. Several members from the laboratory and university happen to own some stock in CF. The university has entered into an agreement in which it is entitled to 10% of royalties from any future sales if the drug is manufactured. CFx has recently asked Dr Smith and her laboratory to enter into a nondisclosure agreement, whereby the company would be able to protect its proprietary interests and review any research manuscripts prior to submission for publication. As a new trial is commencing, Dr Smith is looking into how to best recruit patients for the study.

- What types of conflicts of interest can you identify in this case?
- What are the implications of the nondisclosure agreement for academic freedom?
- Does it matter that Dr Smith and/or her staff have equity in the company?
- Would it make a difference if someone else (without any financial stake in CFx) was responsible for clinical trial recruitment?
- What is expected of Dr Smith and her colleagues in terms of disclosing any financial relationship they have with CFx when presenting at conferences, publishing papers, etc?
2. Dr Hernandez is a pediatrician with a busy outpatient practice. Recently, he received a letter from a contract research organization mentioning a current client company that has a new attention-deficit/hyperactivity disorder (ADHD) drug in phase III randomized controlled trials and is looking for physicians who can recruit patients to participate in a 2-year trial. They ask Dr Hernandez whether he would be willing to recruit up to 20 patients, and they offer him $2000 for each patient he enrolls in the study. All medical care received by participants in the study would be paid for by the pharmaceutical company. Dr Hernandez is puzzled as to what he should do. He believes there is a role for this new and promising ADHD medication in his practice, but wonders about the specifics of this agreement.

- Does it make a difference that Dr Hernandez has no financial interest in the company?
- Is it appropriate to recruit patients for whom he thinks the drug can be helpful with the knowledge that he receives a capitation fee per patient he enrolls?
- Should there be a distinction between using the $2000 for personal uses versus investing this money in the group practice (buying medical equipment, hiring more staff, etc)?
- Is there a role for accepting this agreement based on the premise that he might be actually better equipped at handling any conflicts of interest than the next physician to be approached by the company?
- Under what conditions, if at all, should Dr Hernandez agree to be a clinician-researcher for the pharmaceutical company testing its new ADHD drug?

Learning Objectives

1. Define conflict of interest in the context of health care.
2. Highlight the importance of identifying conflicts of interest.
3. Define and describe specific types and levels of conflicts of interest.
4. Articulate the underlying ethical principles associated with conflicts of interest.
5. Discuss strategies for managing and reducing conflicts of interest.

Suggested Reading for Instructor


Institute of Medicine, Committee on Conflict of Interest in Medical Research, Education, and Practice. Conflict of Interest in Medical Research, Education, and Practice. Lo B, Field MJ, eds.

Further Reading


Wazana A. Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA*. 2000;283(3):373-380

Case Discussion

What exactly is a conflict of interest?
Simply put, a conflict of interest is any situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. The Institute of Medicine defines conflict of interest as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.” Primary interests include “promoting and protecting the integrity of research, the welfare of patients, and the quality of medical education,” and secondary interests include “not only financial gain, but also the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues.”

What types of conflicts of interests are identified in this case?
There are several tangible, financial conflicts of interest depicted in this case. The pharmaceutical reps are offering numerous items of monetary value, including lunch, medication samples, travel/accommodation expenses, and possible speaking honoraria. There is also potentially a less tangible conflict of interest in the form of prestige or name recognition associated with speaking at a medical conference.

Why do conflicts of interest in health care matter?
Scientific research and clinical care demand integrity, objectivity, and public trust. Researchers and clinicians with secondary interests (ie, financial gain, professional promotion), however, may be unduly influenced and biased in their professional assessments of and interactions with patients. Although physicians may not think they are personally influenced by external factors, research has shown that physicians are in fact more prone to act differently (ie, change their prescribing patterns) in situations of competing interests. One large study, for example, found that physicians who occasionally accepted industry-sponsored meals were 2 to 3 times more likely to ask that the sponsor’s drug be placed on a hospital’s formulary. The study further found that physicians who accepted a free trip to a drug-company-sponsored conference were also more likely to write prescriptions of the sponsoring company’s drugs. Overall, physicians who interact more frequently with the pharmaceutical industry are more likely to prescribe higher cost drugs and less likely to recommend generics or over-the-counter medications.

Should medical centers permit open access to industry representatives?
Although the pharmaceutical and medical device industries are critical to scientific discovery and the delivery of patient care, industry representatives were historically permitted unrestricted access to academic medical centers, community hospitals, and private physician offices. It is not uncommon for such representatives to provide meals and various monetary gifts (ranging in value from pens to event tickets) in the hopes of influencing provider behavior. It has been estimated that the pharmaceutical industry spends around $15,000 per physician in direct marketing. In working to create an environment based purely on evidence-based care and free of undue influence or bias, however, more and more academic medical centers across the country have instituted policies either banning, limiting, or regulating industry
access to physicians, residents, and students. It is often best to consult with your specific institution’s policies governing if and what type of industry access is permitted.

Is it appropriate for physicians to accept and dispense free samples?
“Free” samples account for more than 60% of the $29 billion spent each year by the pharmaceutical industry to promote its products (Institute of Medicine). Several studies have shown that physicians given “free” samples to dispense to their patients are more likely to then write prescriptions for what are often more expensive – although not necessarily more effective – drugs compared with physicians without access to free samples. It is critical that prescribing physicians rely on evidence-based medicine and safe practice rather than on what is simply available and “free.” At the same time, it is important to take into account any financial hardships of patients who may not otherwise be able to afford certain medications. It is also important to distinguish between what may be time-limited vs ongoing receipt of such samples. Physicians employed by a practice or institution should always refer to their institutional policy before deciding whether to accept and dispense “free” samples.

What about accepting other gifts?
Gifts may include items as small as pens and pads and as large as vacations and meals at luxury venues. Per the American Medical Association, “No gifts should be accepted if there are strings attached. For example, physicians should not accept gifts if they are given in relation to the physician’s prescribing practices.” In accordance with the Physician Payment Sunshine Act, adopted in 2010 and implemented in 2014 as part of the Affordable Care Act, medical device and pharmaceutical companies are now required to report all payments and gifts (in excess of $10) given to physicians and teaching hospitals. These data are also publicly available on a searchable federal database. Many academic medical centers now have policies that either limit or ban the acceptance of gifts of monetary value. It is the responsibility of each physician to comply with their institution’s most updated policy and always keep in mind the mandate of the American College of Physicians “to assess any potential relationship with industry to assure that it enhances patient care and medical knowledge and does not compromise clinical judgment.”

Additionally, although some physicians may be comfortable in accepting gifts of modest value in certain settings, it is nevertheless prudent to be mindful of the perception of conflict of interest this may entail.

What if a physician is invited to speak at an industry-sponsored medical conference?
Expert physicians play a vital role in contributing to the education of their peers and the general public. Payments for speakers and faculty at certain accredited continuing medical education (CME) events, however, may be exempt from mandatory reporting under the Sunshine Act. It is, therefore, important for speakers to explicitly disclose any financial ties they may have with a company before presenting the relevant data. It is also not uncommon for industry-sponsored events to control the content of educational modules or provide invited lecturers with prescribed presentations or slides. Physicians presenting at such events ought to carefully review the prepared materials beforehand and modify them accordingly to ensure utmost objectivity. At the very least, physician presenters must disclose the source and authorship of any materials to the audience.
What other types of conflict of interest might physicians confront in the clinical setting?
In the current health care landscape, it is routinely becoming more common—in large part because of changing payment structures—for physicians to own or have some form of business arrangements with outpatient diagnostic or treatment centers and/or specialty hospitals to which they refer patients (e.g., a gastroenterologist who owns an outpatient endoscopy center, a radiologist who partners with an imaging suite). This sort of partnership constitutes a potential conflict of interest. The secondary interest of physician owners (i.e., increased income from increased referrals) certainly has the potential to interfere with what ought to be the primary interest of physicians (i.e., patient welfare). Given the allure of increased profitability, patients may inadvertently be subject to unnecessary or extraneous procedures. Such concerns about physician self-referral have led to federal regulations (“Stark Laws”), which prohibit physicians from referring Medicare or Medicaid patients to entities for “designated health services” if the physicians or their immediate family members have ownership, investment interests, or compensation arrangements with the entities. In 2008, the Centers for Medicare and Medicaid Services issued a new rule, which requires physicians to disclose to patients any ownership of or investment in hospitals they may have. As with all potential conflicts of interest, full disclosure to all parties involved is always warranted.

Conclusions and Suggestions
Conflict of interest is a very real and serious issue in health care. These conflicts can sometimes be subtle and affect even the most vigilant and well-intentioned physician. Every doctor in training should, therefore, be proactive in identifying potential sources of conflict interest and become adept in reducing or at least managing actual conflicts. Conflicts of interest overwhelmingly surface at the interplay between physicians and the health care industries. Although such collaboration cannot always be avoided—and may, in fact, be appropriate in particular settings—best practice always calls for clearly disclosing any possible conflicts of interest (financial and otherwise) to all parties involved. It is also essential that the clinician be aware that these relationships have the potential to alter their prescribing behavior in ways that may not be apparent to them. Resident physicians should consult with their institution’s particular policies regarding what constitutes, and how best to manage, conflicts of interest.

References

1. Institute of Medicine, Committee on Conflict of Interest in Medical Research, Education, and Practice. Conflict of Interest in Medical Research, Education, and Practice. Lo B, Field MJ, eds.

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Session 19. Post-Trial Obligations in International Health Research Ethics

Seema K. Shah, JD

Overview

International health research raises many controversial ethical issues, including concerns about fairness, exploitation of subjects or communities, and a lack of clarity over what researchers owe subjects who may have limited access to health care and a lower standard of care. These questions arise with special urgency at the end of a research study given that research funding is typically time-limited, but health care needs may persist long after studies are completed.

This module will explore the ethical issues arising in international health research, focusing on the obligations that arise post-trial. Participants will become aware of what international ethical and policy guidance and laws require of researchers, and the controversy and lack of consensus over what researchers might owe subjects at the end of a research study. Participants will understand what ethical principles do and do not apply to post-trial obligations of researchers. They will also explore questions about trade-offs and how researchers might balance different ethical obligations against each other when resources are limited.

Instructor’s Guide

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

Case Summary

A researcher plans a trial studying how to prevent vertical transmission of HIV from HIV-positive mothers to their infants during labor and delivery. This trial will be conducted in low-income countries. The study provides antiretroviral therapy (ART) as prophylaxis to the mother during pregnancy and labor and to the child for the duration of breastfeeding. After the infant is delivered, the study stops providing ART to mothers and refers them to the national programs for HIV treatment. The low-income countries where the study is
being conducted only have resources to provide ART to women whose CD4+ T-lymphocyte counts are below 350; other women will have to wait for their health to decline before they will become eligible for treatment.

- What do international ethical, policy and legal standards require of researchers and sponsors in this case?
- Is it ethical for researchers and sponsors to stop providing ART at delivery?
- If not, what should researchers and sponsors do instead?
- What ethical principles support (or do not support) obligations for researchers in advance?
- How should researchers and sponsors balance post-trial care against other competing benefits they could provide, such as providing care for babies born preterm, providing care for others in the community, or conducting other research in the future?

Alternate Cases

1. In a rural community in Venezuela where villagers have extraordinarily high rates of being afflicted with Huntington disease (HD), an American researcher conducted a landmark genetic study nearly 3 decades ago. This study identified the gene that causes HD; there is now a genetic test that can be conducted to determine whether an individual is afflicted with HD. HD is an adult-onset disease that is uniformly fatal. Those who are afflicted have a 50% chance of passing on the gene to their offspring. There is no cure for HD. Today, the villagers in this community do not have access to the genetic test, but the researcher has provided other types of care and improved infrastructure at a local clinic. The researcher is concerned that providing the test without providing access to genetic counseling would lead people to make poor decisions or have information they cannot process appropriately. There are only a handful of genetic counselors in Venezuela, all of whom are in Caracas, which is several hours away from the village. What should the researcher do or have done?

2. Researchers are conducting a phase III trial of third-line ART for people who have developed resistance to first- and second-line therapy. The trial is being conducted in low-income countries where the drugs are not yet approved. Researchers anticipate that it will take anywhere from 2 to 5 years after the trial is complete for national approvals to be granted. In the meantime, there is no way for trial participants to access third-line therapy, and no alternative treatment that will work for them aside for supportive care and treatment for opportunistic infections. What do researchers owe the participants of this trial?
Learning Objectives

1. Understand the controversy over post-trial obligations in international research ethics.
2. Understand the ethical bases for post-trial obligations and the resulting limitations.
3. Understand the competing obligations for researchers studying international health.

Suggested Reading for Instructor

Weijer C, Leblanc GJ. The balm of Gilead: is the provision of treatment to those who seroconvert in HIV prevention trials a matter of moral obligation or moral negotiation? J Law Med Ethics. 2006;34(4):793-808


Further Reading


Merritt M, Grady C. Reciprocity and post-trial access for participants in antiretroviral therapy trials. AIDS. 2006;20(14):1791-1794

Case Discussion

What does international ethical and policy guidance and laws require of researchers in this case?
There is very limited international consensus on this issue. The World Medical
Association’s Declaration of Helsinki (2013 version) requires that: “In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial.” Guidance from the National Institutes of Health (NIH) on posttrial access to antiretroviral therapy indicates that, “[f]or antiretroviral treatment trials conducted in developing countries, the NIH expects investigators/contractors to address the provision of antiretroviral treatment to trial participants after their completion of the trial,” but also indicates that NIH funds cannot be used to provide treatment post-trial.

The Council for International Organizations of Medical Sciences has new guidance (as of 2016) that requires the following: “Especially in the context of clinical trials, researchers and sponsors must make adequate provisions for addressing participants’ health needs during research and, if necessary, for the transition of participants to care when the research is concluded. The obligation to care for participants’ health needs is influenced, among other things, by the extent to which participants need assistance and established effective care is available locally.” Some countries, like Brazil, require that study drugs be provided post-trial, but do not specify who has the duty to provide them—the Brazilian government, researchers, or pharmaceutical companies? Notably, however, many countries lack laws on this issue, and some ethicists argue that post-trial access is not obligatory.1

At a minimum, among the countries and documents that address post-trial access, it appears that there is agreement that researchers should address the participants’ post-trial needs in the protocol and informed consent.2,3 This suggests that the plan to transition participants to the national program appears to be at least sufficient. However, expecting women to transition successfully days after giving birth seems unrealistic. A reasonable transition plan might include the provision of treatment through the study for a few weeks or months after birth. Some might argue that the researchers should do more, particularly for the women who will not qualify for treatment through the national program, but it is not clear how the researchers would pay for this. Moreover, once treatment is provided, the women may not ever become eligible for treatment through the national program, because their CD4+ T- lymphocyte counts will remain stable, which means that the researchers would have to enter into a lifelong commitment.

What ethical principles support (or do not support) obligations for researchers and sponsors after trials conclude?

The ethical principles of nonmaleficence and beneficence may support post-trial obligations, particularly if stopping care temporarily causes harm to the former participant. Participants might be harmed if stopping therapy after a trial causes resistance to ART or sends message that treatment adherence is not important. Although it is generally agreed that researchers have obligations of beneficence that may include participants, it is worth noting that these obligations could be fulfilled in multiple ways (eg, payment, provision of other kinds of ancillary care, provision of care to members of the community, improving health care infrastructure in the community).
The ethical principle of reciprocity—the idea that someone who has received a benefit from someone else owes something in return—likely does not support post-trial obligations. This principle is intended to ensure that if participants give something to researchers, they receive something in return. What counts as a fair reciprocal arrangement may also vary on the basis of cultural context. However, these participants have already received substantial benefits during the trial, and this benefit may be sufficient to satisfy the principle of reciprocity.\(^4\)

**How might researchers and sponsors plan to address post-trial obligations in advance?**
As alluded to previously, many guidance documents counsel researchers and sponsors to make anticipatory plans with local governments, international aid organizations, and other stakeholders to ensure that participants continue to receive care they need. Unfortunately, grant funding rarely extends after a trial is over or to cover treatment that is unrelated to/not necessary for the conduct of research. It may make sense for researchers to plan for a reasonable transition to another source of care, and what counts as reasonable is an open question. One study has found that some researchers engage in short-term provision of ART or other care to facilitate a successful transition post-trial.\(^3\)

**How should researchers and sponsors balance post-trial care against other competing obligations to research participants, or against their obligation to conduct other research in the future?**
To the extent that researchers are obligated to provide post-trial access to prevent harm from the research itself, there may not be other competing obligations. To the extent that researchers are obligated to provide post-trial access through the principle of beneficence, there are other benefits they could provide to their participants, such as by providing care for infants born preterm or if complications occur that are not related to the trial. However, as researchers, they are first and foremost trained and obligated to conduct research. One way to resolve this potential conflict of duties is for researchers to determine what resources they can spare without compromising their primary duties of conducting research, and plan in advance the best way to allocate these resources amongst these competing options to do the most good.

**Conclusions and Suggestions**
It is important to emphasize to students that although their instincts may suggest that researchers should do as much good for these participants as possible, there are many competing ways to do good, and researchers have primary obligations to conduct research. Additionally, this case is a useful way to point out that ethical and legal guidance is often a starting point for discussion, and does not often clearly resolve complex ethical issues. Finally, the idea of achieving a successful transition post-trial is intuitively attractive and supported by recent guidance, but is still undertheorized in terms of the ethical principles that support it and may be best justified when failing to assist individuals in a post-trial transition may cause them to be harmed.
References


4. Merritt M, Grady C. Reciprocity and post-trial access for participants in antiretroviral therapy trials. AIDS. 2006;20(14):1791-1794
Session 20. Institutional Pediatric Ethics Committees

D. Micah Hester, PhD

Overview

Over the past several decades, the landscape of ethics practice in hospitals has evolved significantly in response to increasingly complex ethical questions and the changing influences of judicial and accrediting bodies. Institutional Ethics Committees (IECs), now commonplace in hospitals across the United States, help navigate these challenges by providing education, policy review/development, and consultation, though specific practices vary among institutions. As such, it is helpful to understand the form and function of IECs and how they may operate to meet the needs of the hospital.

This material will discuss the functions of IECs, the roles they play in health care institutions, and their usefulness in patient care and policy implementation. 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.

Instructors Guide:

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

Case Summary

Tommy was a 3-year-old when he was hit by a car, resulting in severe traumatic brain injury (TBI). Two weeks into his stay in the pediatric intensive care unit (PICU), Tommy’s parents were presented with the option of forgoing life-sustaining treatments (FLST). After a few days of reflecting and discussing the issue, they had determined that stopping the ventilator was best, but by that time there was a new ICU physician who, after review of Tommy’s condition, did not think that FLST was warranted. With more intensive therapy, Tommy was able to breathe without the vent, 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, asking the palliative care physician about the possibility of stopping feeds. At the same time, the physical and occupational therapists working with Tommy, as well as nurses and social workers from the PICU who came to visit him in the rehabilitation unit, believed they saw slight but noticeable improvements in his cognitive status—possibly tracking, smiling, reacting to some stimuli. The entire unit, including these PICU staff members, is concerned about the ethics of what the parents are suggesting.

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

**Alternative Cases**

1. Diagnosed with biliary atresia at 3 months, Jamie’s parents reluctantly agree to a Kasai procedure to mitigate temporarily 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 both 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. Given the high efficacy of transplant procedures in young children, the liver specialist who has just admitted Jamie to the hospital believes that the parents’ decision is unacceptable, and she calls the ethics committee hoping to convince the committee that the transplant should be pursued over the parents’ objections.

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

2. Mary Jo is a chronically disabled child who has had trouble gaining weight even on full-feeds—both home and in the hospital. Her “I’s and O’s” are often unexplainably negative. Also, her 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 mom tampering with Mary Jo’s feeds. Policy requires that the ethics committee review the case before he can proceed.

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

**Learning Objectives**

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

**Suggested Reading for Instructor**


Case Discussion

What do you know about the prognostics of TBIs and the interests/values of the parents/family, and in light of that knowledge, is the option of FLST one that should be offered at this time?

It is often said that careful ethical reasoning relies on a strong understanding of the situation at hand—that is, good ethics begin with good facts. The emphasis here, then, should be on beginning with good clinical knowledge in relationship to the determining what options are materially relevant to consider.

Of course, ethical reasoning cannot be predicated on medical facts alone. A robust understanding of personal, social, and institutional factors are fundamental as well. In fact, the personal and social are not simply fundamental to ethics, but to medicine itself. No medical “fact” can be understood in a vacuum; they are interpreted in light of one’s personal, professional, and cultural influences.

After a few days of reflecting and discussing the issue, Tommy’s parents had 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 FLST was warranted.

The option for FLST 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 ethics committee? If you agree with either, is this still worth calling the ethics committee about? Are there any concerns about taking the step to call for ethics committee involvement?

Many ethically charged situations do not result in a call for an ethical consultation. Explore here why ethics consults might or might not be triggered. Discuss barriers to or concern about contacting the ethics committee. In what ways do personal opinions or institutional pressures influence the decision to call or not call for a consult.

With more intensive therapy, Tommy was able to breathe without the vent, 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, the physical and occupational therapists working with Tommy, as well as nurses and social workers from the PICU who came to visit him in the rehabilitation unit, believed they saw slight but noticeable improvements in his cognitive status—possibly tracking, smiling, reacting to some stimuli. These health care workers call for an ethics committee consult.
Were they right to call for a consult?
Most hospitals’ policies allow anyone related to the case to call for an ethics consultations. Should an ethics committee consult have been called? Were these particular health care providers overstepping their authority in doing so?

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

Discussion about Ethics Committees

What is an ethics committee?
Most institutional ethics committees are developed as mechanisms to handle ethically challenging issues in a hospital or other health care institution. The committee is tasked with addressing clinically relevant ethical issues (research ethics is typically handled by an institutional review board), be they bedside situations or policy concerns. The membership of an ethics committee is often composed of institutional staff members—physicians, nurses, social workers, even chaplains, administrators, and sometimes legal counsel (these last 3 groups are not always included because of conflict of interest concerns). Many use community/unaffiliated people as well to serve as a check on institutional bias and provide greater insight. When available, someone educated in philosophical and/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 The Joint Commission’s (accreditation) requirements calling for a mechanism to handle ethical concerns in the institution, ethics committees traditionally serve 3 functions within the institution:

- Review and/or develop institutional policies
- Educate staff in the institution
- Provide consults/case reviews

Not all committees perform all 3 functions, as some institutions have a separate ethics consultation service, and some ethics committees may do little to no policy review and other “organizational” ethics activities—these may be performed by other committees or by a compliance/ethics officer in the institution.

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

What does an ethics committee consult look like?
Consults may occur in 3 general ways:

1. Singular consultant—an individual (hopefully well trained) is tasked (either by the institution or the committee) with consulting. That person would take the call and
respond as needed. This process allows for maximum expediency and flexibility but provides a smaller range of perspective and knowledge.

2. Small team consult – some institutions use a small team (typically 3-5 people from the larger ethics committee) to consult. This process provides a bit less flexibility and expediency than the single consultant model but in turn provides a greater variety of perspectives and a larger knowledge base.

3. Full committee consult – at least a quorum of the entire committee meets to discuss an ongoing case. Needless to say, this is the least expedient and flexible approach, but it maximizes the number of perspectives (see the description of the committee makeup above) and broadens the knowledge base.

Like many aspects of ethics committee work, the details of how the committee functions in a consult are specific to each institution. In fact, some institutions may use a combination of the consulting models listed above depending on the type and source of the consult request.

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

There are different “philosophies” that ethics committees live by in relation to consults. 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

The actions required to fulfill these objectives are not necessarily unique to each objective, but the primary outcomes of a consultation will be driven by one or more of these objectives. Thus, it is important to know what your ethics committee’s consult (or your ethics consult service) attempts to accomplish and with what methods. Further, especially in hospitals that treat both adults and children, you may want to make sure that the committee representatives have an understanding of the unique aspects of pediatric care and decision making.

Although in almost all cases, ethics committees have no decision making authority, a consultation often results in a recommendation regarding the committee’s view of the ethically best decisions or approaches available. In such cases, patients/families and physicians are typically not bound to those recommendations, but they should be aware that committee recommendations do carry some amount of “moral authority.” Also, some institutional policies may give a determinative role in decision making to ethics committees for specific situations. For example, a policy on the use of covert patient monitoring (ie, hidden video surveillance) in cases of suspect patient condition falsification (ie, Munchhausen syndrome by proxy) may require that before monitoring can be implemented the ethics committee review and approve its use for the case at hand.

**Who may call for a consult?**

The answer to this question depends entirely on the ethics consult policy of your institution. However, most institutions allow for consults to be called by a wide variety of people—not simply attending physicians or unit directors, but most anyone in the institution who have some
involvement with the situation, including patients and family members (in fact, this breadth is recommended by the AAP Committee on Bioethics). Again, there may be some limits specific to your institution.

Do ethics committees really help? If so, how?
Limited research indicates that ethics committee consults can provide help for institutions, practitioners, and patients/families. For institutions, consults 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 consults 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 precedent or require wider institutional actions. Ethics committee, 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 ethics committee may want to follow up in the coming months with staff debriefings to deal with lingering ethical concerns and “moral distress.” Furthermore, the ethics committee may want to work with staff in the PICU to develop protocols to address differences among staff or to handle better “hand-off” issues when new attending physicians take over the ongoing care of a patient.

Conclusions and Suggestions
Finally, ethics committees may organize 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 although the ethics committee is most often associated with case reviews/consults, many committees play much wider roles in their institutions, and it is helpful to familiarize yourself with the full extent of functions the committee performs. Also, the AAP Committee on Bioethics\(^1\) has its own list of 6 recommendations regarding IECs that might be helpful to review and implement where appropriate.

Reference