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FROM THE EDITOR
Competent and Compassionate Care for the Sickest of Children

In this issue of *Virtual Mentor*, we explore the world of pediatric critical care and emergency medicine. Medical emergencies are high-stress, fast-paced situations in which life-or-death decisions are routinely made. When these situations involve children, a number of factors amplify the ethical challenges that physicians may encounter.

Decision making in pediatrics is strikingly different than it is in adult medicine. In a pediatric intensive care unit or emergency department, parents often bear the burden of making medical decisions for their children because they are considered the natural guardians of their children's best interests. This month's case commentaries examine circumstances in which that presumed decision making role is impeded. Edwin Forman, MD, and Rosalind Ladd, PhD, explain "slow codes," when physicians attempt to bypass parental decision making, often with good intentions, and apply their own decisions to a child's end-of-life care. Philip J Rettig, MD, evaluates a situation in which a minor patient refuses a needed exam and no parent is present to aid in decision making. Jalayne J. Arias, JD, MA, and Kathryn L. Weise, MD, MA, discuss a complex case of nonaccidental trauma in which parents are suspected of putting their own interest ahead of their child's.

Decision making for critically ill pediatric patients can also be complicated by the differing levels of development and autonomy among those under the age of legal majority. In the health law section, Valarie Blake, JD, MA, reviews several landmark court cases in which gravely ill teenagers sought to refuse potentially life-saving treatment. In the medicine and society section, Margaret Moon, MD, MPH, discusses the historical and social progression that has led to the manner in which our society designates the services, including emergency care, to which adolescents may consent without parental supervision. This month's excerpt of the AMA *Code of Medical Ethics* gives guidance on how physicians should proceed when adolescents request such care.

The ethics of research and training in the pediatric critical care setting are uniquely challenging. Critically ill children require complex interventions that should be performed by skilled practitioners, which means balancing the training of new intensivists with the risk to the present patients. In the medical education section, Traci A. Wolbrink, MD, MPH, and Jeffrey P. Burns, MD, MPH, identify the ethical concerns inherent in teaching trainees to perform procedures on critically ill children and offer emerging solutions to some of these dilemmas.

Likewise, research involving children is needed to advance medical knowledge, but the informed consent process can be hard on parents who might feel coerced into participation because they fear for the lives of their children. In the first of our policy

articles, Tracy Koogler, MD, reviews the legal and ethical framework for research involving critically ill children.

Born of a need for postoperative care following the advent of new surgical techniques, the pediatric intensive care unit functions largely thanks to innovations such as mechanical ventilation, extracorporeal membrane oxygenation, and renal replacement therapy. Many of the newest technologies are employed in particular clinical situations without formal FDA approval, since pediatric interventions are often slower to be approved than those for adults. While these technologies often improve outcomes for the sickest of children, they also frequently pose new ethical challenges for physicians. In the state of the art and science article, Naomi T. Laventhal, MD, MA, John D.E. Barks, MD, and Scott Kim, MD, PhD, discuss off-label use of therapeutic hypothermia for preterm infants with hypoxic-ischemic encephalopathy.

Finally, pediatric critical care and emergency medicine are environments in which tragedies occur with unfortunate frequency. The child's pain and suffering, the parents' distress, and the pressures on the medical team combine to make caring for children in life-threatening situations intensely difficult. With these emotions come efforts to ease the suffering of our patients, but such efforts are often accompanied by ethical challenges that are well known to all providers who have participated in end-of-life care. In our second policy article, Armand H. Matheny Antommaria, MD, PhD, and Brent Kaziny, MD, explain ethical dilemmas that arise in disaster preparation and potential methods for allocating limited resources when the number of affected children exceeds the capacity to provide aid. In the journal discussion section, Wynne Morrison, MD, MBE, clarifies opposing views expressed in the recent debate in the critical care literature about the provision of general anesthesia before extubation when a patient is not expected to survive.

Although a single journal issue is only able to scratch the surface of the myriad ethical dilemmas relating to care of the sickest children, readers will find articles that illustrate the broad variety of concerns that can and do occur in pediatric critical care and emergency medicine. We are lucky to have contributions from a distinguished group of authors who have shared excellent insights. Although even the most expert opinions often differ when it comes to ethical dilemmas, it is clear in this collection that the common thread among the authors is a desire to provide the most compassionate care possible to the sick children who are their patients. I am hopeful that readers will remain ever mindful of this unifying goal as they read these articles and apply their lessons to the care of their own patients in the future.

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ETHICS CASES
Why Not a Slow Code?
Commentary by Edwin N. Forman, MD, and Rosalind E. Ladd, PhD

Dr. Holbert, a senior neonatologist, was called to attend a patient he knew very well, Mrs. Gage, during the birth of her first child. She was at the hospital with her husband and about to deliver the child, who had been prenatally diagnosed with a number of severe deformities, including a congenital diaphragmatic hernia and severe cardiac anomalies. Dr. Holbert had had a number of frank conversations with Mrs. Gage and her husband and informed them that their child's anomalies were very severe and possibly life threatening. Despite this, she and her husband uniformly insisted that a full and aggressive resuscitation be undertaken. At the end of their most recent discussion, Mrs. Gage agreed to let the team make their initial assessment at the time of delivery and discuss with her and her husband how to proceed at that time. Dr. Holbert felt this was a reasonable plan.

With his resuscitation team in place, Dr. Holbert received the newborn baby boy, who had a weak pulse and was making labored respiratory efforts. Upon reaching the infant warmer to assess the child, Dr. Holbert realized that the anomalies were more severe than initially expected, and, though they might be able to keep him alive temporarily on maximal support, he would most likely never leave the ICU. When Dr. Holbert reported to Mr. and Mrs. Gage on their son's condition and his prognosis, they said, "We want you to do everything. Please don't let our son die."

Trying to balance the good of the child and the emotional needs of the parents, Dr. Holbert turned to his team and quietly instructed them to undertake a "slow code."

Commentary
Many medical students, residents, and other medical staff learn the elements of a slow code early in their clinical years. It seems to be part of the wisdom that some experienced physicians pass on, following a long history known among the medical profession but not generally known to the public.

The intentions behind a call for a slow code are good. Primarily, it is a way to spare parents the full, painful acknowledgement of the extent of their child's deficits and the likelihood of his extremely poor quality of life or death. More importantly, it shields parents from having to make the painful decision to let their child die by choosing not to resuscitate or to stop treatment. It also protects the infant from the rigors of aggressive treatment that is likely to be unsuccessful.

It must be acknowledged that calling a slow code also spares the physician the helpless feeling of doing nothing, having to face parents with empty hands. He or she may also have a lurking fear of parents' anger at the physician's failure or malpractice charges if the infant dies with no medical interventions.

However good the intentions, though, calling a slow code raises significant ethical questions about deceit, paternalism, patient-doctor relationships, and teaching good communication skills.

What Is a Slow Code?

A full code or code blue involves calling a rapid response team and initiating appropriate treatment as quickly and effectively as possible with the goal of reversing an adverse event, returning patients to the status they had before the event that triggered the full code and restoring as high a level of functioning as possible. It is an emergency intervention with high priority, and speed is often critically important. A full code, properly executed, is often life-saving.

A slow code, by contrast, involves initiating some resuscitative measures but carrying them out slowly or omitting the most aggressive. Interventions in a slow code are limited in number, duration, intensity, or all three; for example, giving gentle chest compressions that do not crack the ribs. "Slow" also refers to the reduced alacrity with which staff responds to the call. The implicit hope is that the patient will die of his condition before they arrive.

In a recent article, John Lantos and William Meadow, both experienced and respected neonatologists who are well published in medical ethics, propose the use of a slow code as a legitimate response to situations like Dr. Holbert's [1]. They define a slow code as a short-term trial of some intervention and emphasize that it is mainly a symbolic gesture, not expected to be effective but to give the appearance of doing something effective. Their article defends the use of slow codes.

Ethical Issues

Deceit. A slow code gives the appearance that something is being done that is expected to be effective, and the physician gives the appearance of believing that it will most likely be so. But the physician knows it is being done in a way that it is not expected to be effective. To put it another way, the physician has a hidden agenda; the goal is not the patient's survival or improvement, but allowing the patient to die while somewhat protecting the family's feelings. Thus, in action and in word, the physician is deceiving the parents.

Paternalism. By calling a slow code, the physician is making a decision for the parents according to his or her belief about the best interest of their child. The parents are thus denied their right, as decision makers for their child, to informed consent or refusal. One of the very basic tenets of medical ethics, in some places codified into legal regulations, is informed consent. Truly informed consent requires two things: that the decision makers be informed and that they give free, uncoerced

consent. By leading the parents to believe that the physician expects the interventions to be effective, the physician withholds information that the parents would need to make an informed decision. Since they are making a decision based on incorrect information, it cannot be considered informed.

Patient-doctor relationship. Insofar as good relationships with patients and parents of patients are built on trust, the use of a slow code, by eroding trust, damages or destroys the relationship. True, parents may never come to realize that the "treatment" ordered was actually a slow code, but it is always possible they will figure it out. Even if they later recognize that ceasing treatment was a better choice for their baby, they are bound to resent that they were not told the truth.

Communication skills. What are physicians in training being taught when they are ordered to participate in a slow code? That doctors know best and parents are unqualified decision makers? That it is OK to deceive if your intentions are good? That the clever physician can find ways to avoid difficult conversations with parents, especially around life-and-death issues?

A Better Solution

It is our contention that physicians are led to use a slow code because parents are typically presented with a choice of two extremes: do everything or do nothing, i.e., do not resuscitate (DNR) [2] The problem is that for the physician, "do everything" means carrying out measures that are futile, interventions that are not expected to be of benefit and are likely to cause harm. Engaging in futile, possibly harmful measures is and should be morally unacceptable to them. For the parents, choosing DNR means giving up hope and choosing to let their baby die, which may be psychologically or morally unacceptable to them.

Viewing a slow code as a time-limited trial of some intervention or the use of some nonaggressive measures allows us to see it as a compromise or middle ground between the two extremes. It can be offered as a third option, one which provides an opportunity for the baby to respond if he or she can, but with the explicit understanding on everyone's part that the intervention probably will not work.

The advantage of proceeding in this way is that there is transparency and no need for deceiving. The decision is made by the parents and fulfills both the ethical requirement for informed consent and the physician's and parents' need to do something rather than nothing. The physician must explain to the parents why doing everything is not a good option: it is painful for the baby, will not save him or her, and will leave everyone with regrets. Limited, less aggressive measures are appropriate if the physician thinks there is at least some chance of their working based on scientific evidence and a benefit-burden calculation, not just paternalistic judgment. If the physician explains his or her reasoning and actively recommends this third option and it is agreed to by the parents, then it constitutes a paradigm of shared decision-making. It also represents effective doctor-patient communication and preserves an honest, respectful, and rewarding doctor-patient relationship.

Terminology can be important, so we recommend calling the third option a limited trial run or limited resuscitation, dropping the term “slow code” with all the negative connotations we have described. When physicians hear parents say “do everything,” they should recognize it as a natural and understandable emotional response to hearing that their child is not likely to survive. But we argue that there is a better and more ethically responsible response than calling a traditional slow code.

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ETHICS CASES
Can a Minor Refuse Assent for Emergency Care?
Commentary by Philip J. Rettig, MD

Dr. McKinney is working in the emergency department when an ambulance arrives with a frantic 12-year-old-girl, Micah, and her 8-year-old sister, Gracie. The paramedic quickly reports that the girls were home alone when Gracie found Micah sitting on the bathroom floor screaming and "covered in blood." No one has yet been able to contact the girls' parents. Micah is so frantic that she is unable to give Dr. McKinney any medical history.

After a rapid assessment, it is clear to Dr. McKinney that Micah is having profuse vaginal bleeding. However, he does not yet know the reason for the bleeding, and no one knows if the young girl was assaulted or suffered some injury. Alternatively, she could have a bleeding disorder of some sort. He knows that, in either case, a severe laceration or other injury could result in life-threatening bleeding, and decides that a vaginal exam is critically necessary for Micah's care. Recognizing that the Emergency Medical Treatment and Active Labor Act (EMTALA) protects his right to treat Micah without parental consent because of her life-threatening problem, he begins to try to examine her. She screams, "Don't you look down there, I don't want that! Stop it!" as she kicks and yells.

Dr. McKinney normally likes to seek the assent of young patients prior to any invasive exam, and Micah has clearly refused to provide her assent. However, he retains legal authority to perform this important exam, and begins to question the best way to proceed, as the exam will be impossible to perform on an uncooperative 12-year-old.

Commentary
Dr. McKinney is following several decades of best practices in caring for older children and adolescents in his "seek[ing] the assent of young patients prior to any invasive exam."

Since the American Academy of Pediatrics Committee on Bioethics' publication in 1995 of its policy statement "Informed Consent, Parental Permission, and Assent in Pediatric Practice" [1], there has been increasing recognition that minor children have the right to exercise a limited autonomy by being involved in and agreeing to decisions about the medical care they may receive. Advances in developmental psychology and appreciation for human rights for children have coalesced to support the current paradigm that children and adolescents clearly have the right to provide assent and, in some cases, independent full consent to medical care for themselves

years before the achievement of legal majority. Studies of cognitive development and of processes of hypothetical medical decision making have shown that youth from ages 14 or 15 differ little from young adults in their early 20s in how they make treatment decisions [2, 3].

Informed consent has three major elements: a medical decision should be made knowingly (i.e., "informed"), reasonably (.i.e., "competently") and voluntarily (i.e., "free of coercion") [3, 4]. Current practice allows such decision making by "mature minors," even though only three states recognize the "mature minor doctrine" formally by statute. Additionally, certain classes of minors may consent if they qualify as "emancipated" by virtue of being in the armed forces, being married, being themselves parents, or living apart and independent of parental financial and social support. Finally, minors may consent to services in certain categories of medical conditions, including care for sexually transmitted diseases, pregnancy and related conditions, and substance abuse or mental health problems. The minimum age for such categorical consent varies considerably among the states. The right to consent by mature minors applies not only to routine care or minor procedures, but most importantly to vital decisions about end-of-life care, resuscitation status, and institution of palliative care [5].

A rough rule of "7s" has evolved as a guide to whether assent or informed consent should be sought from minor patients both in clinical research and in routine medical care. Children and youth from 7 to 14 years of age should be asked to assent to care and receive basic information about the proposed care, its risks, and potential benefits. For youth ages 15 to 18 years, the process should be very similar to seeking informed consent from young adults of legal age [1], even if ultimate legal decision-making rights are reserved to parent or legal guardian.

Assent for care from older children and younger teens should include developmentally appropriate explanation of the patient's condition, facts about the proposed testing or treatments, clinical insight into the patient's understanding of and willingness to receive the proposed care, and expression of agreement or refusal of the proposed care. Assent to care should always include the option of refusal.

In this case, Micah has forcefully and unequivocally refused a genital exam which might optimize evaluation of her profuse vaginal bleeding. While she has the right to refuse assent for her care, her awareness of the possible severity of her bleeding, of the need for prompt evaluation, and then for appropriate treatment is clouded by her fear, embarrassment, uncertainty, and the worry that she'll get in trouble if she lets the doctor perform the exam.

Micah's almost hysterical response to Dr. McKinney's attempt to proceed with appropriate evaluation cannot be considered an "informed" or "competent" refusal. To try to proceed with an exam meant in part to rule out any genital trauma as the cause of her bleeding would necessitate an equally traumatic, at least psychologically, second assault and potentially do her great emotional harm.

Given that Micah has exercised her autonomy in refusing to agree to this exam, what can Dr. McKinney do to fulfill the principles of beneficence and nonmaleficence in a timely manner? Beneficence demands that he stabilize his patient hemodynamically, identify the cause of the bleeding, and institute optimal medical or surgical therapy. Nonmaleficence requires that he not traumatize Micah physically or psychologically in his attempts to treat her and that he not fail to act appropriately to diagnose and to treat her bleeding.

It is legal in every state to provide emergency medical care to a minor without parental consent. Minors may consent to emergency care if they have the capacity to do so. However, assent for emergency care is no more required than is parental permission. Under federal law, the Emergency Medical Treatment and Active Labor Act (EMTALA) mandates initial evaluation (a medical screening exam) and treatment for all patients presenting to an emergency department with an emergency medical condition. Neither parental nor patient consent or assent is needed for such care. Provision of appropriate care is mandated "up to and including surgical intervention or transfer…if needed" [6].

Legally and ethically, Dr. McKinney should render that evaluation and care which he deems most appropriate. But how exactly should he go about it?

If possible, a rapid and separate evaluation of Micah's presenting problem and clinical status from a second ED physician should be sought immediately; this will help assure the appropriateness of what might otherwise be considered an invasive exam. With a consensus that, with this inadequate history, vaginal trauma, accidental or intentional, might be the cause of the profuse bleeding, plans should be made for an emergent exam under anesthesia.

If the cause of bleeding is a vaginal laceration or uncontrolled uterine hemorrhage, either surgical repair or vaginal packing may be necessary. These can be done only under anesthesia, so the appropriate procedure is to do the exam under anesthesia. The minimal risk of general anesthesia is far outweighed by the potential benefit that a comprehensive and timely vaginal exam will provide in optimizing Micah's care. Micah should be told that she needs to go to the operating room and be put to sleep so the bleeding source can be found and then treated. Her assent to this approach should be sought. If she does not assent, then sedating her and appropriately anesthetizing her without her assent would be appropriate both legally and ethically.

Afterword

Several additional comments should be made about this case in addition to offering a possible approach to the clinical dilemma it describes.

Although new-onset profuse vaginal bleeding in a 12-year-old girl may be due either to accidental trauma, such as a straddle injury, or a sexual assault, the most common cause is an unusually heavy initial menses. When this bleeding is abnormal in

volume or duration, it is often evidence of a congenital bleeding disorder.

If Micah's condition is in fact caused by a bleeding disorder, ideally, she should have been educated by her parents that she needs to inform any doctor that she "bleeds easily" or "doesn't clot right." Alternatively, she might have a medical alert bracelet or necklace stating her diagnosis. Future improved electronic health records which contain summary problem lists and medication lists and which are more widely accessible might allow all regional EDs access to vital information in such a case.

Finally, one would hope that any 12-year-old girl would have been prepared for her first menses and told what to expect and what to tell a doctor or nurse if she started bleeding heavily, especially if she also has a known bleeding disorder.

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ETHICS CASES

Pediatric End-of-Life Decisions when Abuse Is Suspected

Commentary by Jalayne J. Arias, JD, MA, and Kathryn L. Weise, MD, MA

Sophie is a 7-month-old girl who was brought to the emergency department with symptoms that indicated increased intracranial pressure, including respiratory depression requiring intubation by paramedics during transit. A head CT revealed transtentorial herniation and large collections of blood, some of which appeared acute and some of which appeared chronic. There was also a nondisplaced occipital skull fracture. In the opinion of the chief of radiology, these were clear signs of nonaccidental trauma. An opthalmologist who detected multilayered retinal hemorrhages reached a similar conclusion.

Dr. Lopez, the attending physician in the PICU, assumed care after the patient was sent to the operating room, where a decompressive craniectomy was performed. The ED physician, Dr. Danner, contacted Dr. Lopez to let him know that, while they were still in the ED, Sophie's mother and her boyfriend acted very strangely and the story they gave to explain Sophie's condition did not match her injuries or the one they told Dr. Lopez. The police were called. They informed Sophie's mother and her boyfriend that a full investigation would take place and the specific charges brought against them could change depending on Sophie's ultimate outcome.

Now, 12 days later, Dr. Lopez has exhausted all of his medical and surgical therapies but Sophie continues to deteriorate. In a care conference with the family, Dr. Lopez and several colleagues encourage the family that withdrawing care is in Sophie's best interest, but the family insists on pursuing aggressive continued treatment. Dr. Lopez is concerned that the family is making this decision out of self-interest, instead of considering what is best for Sophie, though he knows that he will have trouble confirming or contradicting those suspicions.

Commentary

Sophie's case exemplifies the critical conflict in values and interests faced by numerous clinicians treating patients who lack the capacity to make their own medical decisions. Dr. Lopez and the medical team must weigh two competing ethical principles: (1) parental authority to make medical decisions and (2) Sophie's best interest. Generally, a parent's authority to make medical decisions on a child's behalf does not compromise the child's best interest. In some circumstances clinicians may become aware of evidence that a parent's decisions are contrary to the patient's best interest or that a secondary consequence—the threat of criminal charges, guilt, or numerous other factors—may be informing his or her motives. Families making end-of-life decisions for a child injured through suspected abuse

may be influenced by the threat of criminal charges, feelings of guilt, and numerous other factors. Clinicians, with the support of ethicists and legal professionals, must ultimately determine who the appropriate decision maker is and whether the best interest of the child is being served, regardless of the parents' motives.

Determining the appropriate decision maker for a child is different than appointing a surrogate for an adult patient. Clinicians generally presume that an adult patient is competent to make his or her own medical decisions, including whom to appoint as a surrogate. When an adult patient lacks capacity, the medical team may look to a surrogate appointed through an advance directives, or, when such a designation has not been made officially, statutes provide guidance about who the legal surrogate might be. In either case, surrogates for a patient who has previously been competent should be informed by the patient's previously stated wishes or by evidence of his or her values. Children, however, have not yet had an opportunity to appoint a decision maker, identify their wishes, or establish evidence of their values. State and federal law and various professional committees have traditionally protected parental authority to make medical decisions for their children, including withdrawing or withholding life-sustaining treatment [1, 2]. But parents' rights are not absolute and may be removed in limited circumstances, particularly when their actions place the child at risk of harm.

Parental authority relies on the presumption that parents will make decisions in the best interest of their child [3]. The "best interest" standard requires that the decision maker weigh the potential benefits and harms associated with a given decision. Scholars have debated what constitutes the best interest [3], but there is consensus that parents are usually best situated to determine it according to their family values. Evidence of a secondary gain or consequence complicates this assumption. Sophie's family may be genuinely motivated by a belief that continuing life-sustaining treatments would be in Sophie's best interest. However, the possibility that they are driven by the threat of criminal charges may seem to raise the question of whether the family can make a determination of Sophie's best interest.

It is difficult to know when a parent's decisions are contrary to the child's interest or would result in harm. The process of determining the best interest of a critically ill child relies on the child's medical status, prognosis, and the parent's or family's values. For children who are likely to survive and improve to normal function, the determination to continue with life-sustaining treatment is informed by the potential benefits of the treatment. Conversely, if a child is unlikely to survive or likely to suffer from severe neurological damage or continued severe burdens during life, the harms of continuing with painful treatment may outweigh potential benefit. Many cases fall between these two ends of the spectrum. The prognosis may be unclear or unknown.

Given differences in values and perceptions, clinicians and parents may disagree about what is in a child's best interest. Here, the medical team seems to be of the opinion that withdrawing life-sustaining treatment would be in Sophie's best interest

given her declining medical status. However, it is unclear whether continuing treatment will cause Sophie harm (e.g., long-term pain or discomfort) and whether there remains any opportunity for Sophie to improve. Clinicians, with support from legal and ethics professionals, may make the determination that a parent's decisions should not be respected *only* when the parent's decisions are clearly contrary to the patient's best interest.

If a parent is acting contrary to the best interest of the child, the medical team may seek judicial action. A state's authority to overrule a parent's rights stems from the doctrine of *parens patriae*. Under this doctrine, a state has the authority to protect the life and interests of individuals who are incapable of protecting themselves [3]. The American Academy of Pediatrics (AAP) recommends that a guardian *ad litem* be appointed "in all cases of child abuse requiring [life-sustaining medical treatment] in which a parent, guardian or prosecutor of the alleged abuser may have a conflict of interest" [4].

A guardian *ad litem* does not assume medical decision-making authority, but serves instead as an unbiased but compassionate advocate for the child's best interests [5]. In most states, the guardian collects information about the child's medical status, reviews law relevant to the circumstance, and makes a recommendation to the judge. Ultimately, a judge makes the final decision regarding withdrawal of life-sustaining treatment.

A majority of state courts have been reluctant to restrict parents' constitutional rights by removing a parent's decision-making authority. A determination that a parent's rights should be restricted requires clear and convincing evidence that a given decision is contrary to the child's best interest. This standard may be difficult to meet [2]. The AAP, too, supports a parent's right to make decisions regarding withdrawing treatment, even in cases of suspected abuse [4]. It recommends that decisions regarding life-sustaining treatment for children injured by suspected abuse should be determined by the same standards used in making decisions regarding other critically ill children.

Under the standards discussed above, Dr. Lopez and the medical team must separate the decision-making process from the cause of the potential injury and look only at whether continuing life-sustaining treatment is contrary to Sophie's best interest. Given Dr. Lopez's determination that he has exhausted all medical options, the team must then consider the burden to Sophie of continued support. They may be obligated to pursue discontinuing support if they conclude that continued treatment is not beneficial and would harm Sophie. These obligations stem from professional duties of beneficence and nonmaleficence.

A decision to discontinue life-sustaining treatment against the family's wishes will require the medical team to consult their ethics and legal advisors about removing Sophie's mother's parental authority through judicial intervention. Importantly, in cases when external factors such as known or suspected nonaccidental injury weigh

heavily on clinicians' perceptions, they should not lose focus on the patient's best interest. Dr. Lopez and the medical team should make decisions based on Sophie's best interest, not according to the secondary consequences for the family or the suspected cause of her injuries.

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MEDICAL EDUCATION

Teaching Trainees to Perform Procedures on Critically Ill Children: Ethical Concerns and Emerging Solutions

Traci A. Wolbrink, MD, MPH, and Jeffrey P. Burns, MD, MPH

There is little debate that pediatricians in training must learn to perform life-saving procedures. The crucial task is to find the optimal balance between the educational needs of trainees and safe, efficient patient care. Allowing a trainee to perform a procedure increases the risk of complications for the patient. Indeed, many feel that it is inappropriate to allow an inexperienced trainee to perform a procedure for the first time in a high-risk situation, such as the care of a critically ill child. Others argue that, unless we allow trainees such practice, we will have fewer and fewer clinicians able to perform life-saving procedures competently.

But does evidence from the literature demonstrate that there is a tradeoff between optimal patient care and future competence, that one can only happen at the expense of the other? How do we ensure the highest safety of the patient while ensuring that trainees get the necessary educational experience in the care of critically ill children? In this article, we attempt to answer this question and describe some of the emerging technologies that may facilitate the achievement of competency in pediatric trainees, while promoting a greater level of safety for the patient.

Since the introduction of the duty-hour limits by the Accreditation Council for Graduate Medical Education (ACGME) in 2001, concern has arisen that residents and fellows may not be getting as much training in procedural skills as they once did. Although this was not found to be the case for pediatric surgery trainees [1], it is generally felt that trainees in the nonsurgical subspecialties, such as general pediatrics, are performing fewer procedures.

No studies quantifying procedural experience before and after the introduction of duty-hour restrictions could be identified, but a recent study performed in the pediatric intensive care unit (PICU) at Children's Hospital of Philadelphia (CHOP) suggests that trainees may not have enough opportunities to perform procedures. The PICU at CHOP is a large, 45-bed tertiary PICU. During the 14-month study period, 180 orotracheal intubations were performed. Of these, 64 were performed by some of the 68 pediatric and emergency medicine resident trainees rotating through the PICU [2]. Therefore, even in a large, high-volume tertiary care hospital, some trainees do not have a chance to perform even one orotracheal intubation during their PICU rotation, highlighting the scarcity of opportunities. This scarcity is partly due to the infrequent need for some interventions, but also partly to the presence of nurse practitioners, physician assistants, and subspecialists such as interventional

radiologists or pediatric surgeons who may be asked to perform many of the procedures in the PICU.

Even when trainees have a chance to perform the number of procedures recommended by the certifying board, they may not feel comfortable in their abilities. A study of trainees in internal medicine [3] suggested that, to feel comfortable about their abilities, trainees need to perform more procedures (central line placement, knee joint aspiration, lumbar puncture, and thoracentesis) than the American Board of Internal Medicine recommends [4].

Requirements

The ACGME requires that general pediatric trainees must have "sufficient training in the following skills" related to critically ill children:

- basic and advanced life support
- endotracheal intubation
- placement of intraosseous lines (demonstration in a skills lab or Pediatric Advanced Life Support [PALS] course is sufficient)
- placement of intravenous lines
- arterial puncture
- venipuncture
- umbilical artery and vein catheterization
- lumbar puncture
- bladder catheterization
- procedural sedation
- pain management

and "exposure to the following procedures or skills" related to the critically ill child:

- chest tube placement
- thoracentesis

However, no minimum number of times performing each procedure is specified to meet this requirement [5].

The American Board of Internal Medicine (ABIM) does not require a minimum number of times either, but suggests that a trainee should be involved in each a minimum of five times [4]. Internal medicine trainees are required by the ABIM to demonstrate proficiency in a selected subset of procedures, including advanced cardiac life-support resuscitation, the drawing of arterial and venous blood, pap smears and endocervical cultures, and placement of a peripheral venous line. For the rest of the procedures, trainees only need to be able to *demonstrate their knowledge* of components such as indications, complications, and what information patients need to give informed consent. The ABIM suggests that medical simulation be used as the initial step in procedural training.

The ABIM further recommends that trainees who will be performing a procedure independently should be thoroughly evaluated and credentialed before doing so [4].

In the era of specialization, while all pediatric trainees should learn a minimum set of effective life-saving procedures, training in advanced skills such as endotracheal intubation and central line placement should be reserved for those who are specializing in emergency medicine, neonatology, anesthesia, and critical care.

Recommendations

Given the limitation in clinical opportunities for residents just described, we advocate that general pediatric trainees should, at a minimum, be competent in the performance of procedures necessary to stabilize a critically ill child until more specialized help arrives. This includes providing successful bag-mask ventilation, placing an intraosseous needle and intravenous catheter for vascular access, drawing arterial and venous blood, and performing pediatric resuscitation according to standard guidelines, i.e., Pediatric Advanced Life Support (PALS) or Advanced Pediatric Life Support (APLS).

General pediatric residents should have adequate knowledge to describe and understand the protocols and possible complications of more specialized procedures such as endotracheal intubation and central venous line (CVL) placement, but should not be required to perform them during generalized training. This would reserve opportunities to perform specialized procedures for trainees who will be expected to perform them independently as part of their clinical practice, such as pediatric fellows subspecializing in critical care. Even specialized trainees may never have the opportunity to practice procedures such as pericardiocentesis on a patient during their training because these situations are relatively infrequent and the context is often life-threatening.

To compensate for the limitations in training opportunities for pediatric residents, some have suggested allowing residents to perform procedures on patients undergoing cardiopulmonary resuscitation (CPR) or on the newly deceased. Kaldijan and colleagues argue that performing nontherapeutic procedures on patients during CPR is not consistent with ethical standards and that procedures should only be performed during CPR if they are medically indicated, the trainee is adequately supervised, and informed consent has been given [6].

The use of newly deceased patients for procedural training also requires special consideration. Burns and Truog have advocated that newly deceased patients may be used to practice nonmutilating procedures by trainees who need to acquire the procedural skills to fulfill their clinical role responsibilities, but only after appropriate conceptual training about the procedure has been completed and the family has given informed consent [7].

After determining which procedures pediatric trainees need to learn and which clinicians need to develop competency in additional skills to care for the critically ill child, training strategies must be developed and employed to educate trainees efficiently and safely. The traditional “see one, do one, teach one” approach is no longer practical or sufficient. Other educational modalities can ensure a basic

understanding and proficiency of the necessary procedures before the trainee touches a live patient.

We advocate a structured learning strategy that uses computer-based learning, task trainers, and high-fidelity simulation to demonstrate the conceptual and technical fundamentals of procedures, followed by observing and performing procedures on healthy adults and children in the operating room or other elective situations, before a trainee attempts to perform a procedure on a critically ill child.

Computer-based instruction can provide essential information about a clinical intervention, including its indications, required equipment, and procedural steps. This instruction can be delivered through printed text and images, video and animations, or, less commonly, a simulated patient experience. The *New England Journal of Medicine* has a repository of procedural videos on its website [8]. Computer-based learning has been shown to be as effective as traditional methods in teaching ultrasound guided CVL placement [9], adherence with sterile technique for CVLs [10], and difficult airway management [11].

After instruction in fundamentals, task trainers and simulation may then be employed to teach trainees such technical skills as peripheral intravenous and central venous catheterization. As computer technology becomes increasingly sophisticated, more realistic interactive simulations are emerging, including devices that can detect motion in three dimensions, such as Nintendo's Wii controller. At Games for Health 2010, Gredel Games demonstrated a prototype laparoscopic trainer that uses Wii technology [12].

Many studies have demonstrated that use of simulation improves skills in the clinical environment. For example, simulation training was shown to improve CVL placement technique [13, 14] and reduce complications from CVL placement [15]. Intensive simulation courses at the start of residency programs (so-called boot camps) have been shown to improve overall procedural knowledge and clinical skills [16-19].

Several studies, however, report that improvement in skills during simulation does *not* translate into improvement in clinical situations [2, 20]. In some cases, trainees felt more confident about their procedural skills after a simulation experience, but this was not borne out by their actual performance during the simulation [21]. Controlled patient experiences may help translate skills learning in simulation exercises into the clinical environment in a safe manner. These encounters may involve real patients in elective situations with adequate supervision by experienced clinicians. Intubation skills have been successfully acquired by medical students in this manner during their anesthesia rotations [22].

Conclusion

Evolving demands in health care require new methods of training, especially when it comes to the skills needed to care for critically ill patients. Training physicians requires no tradeoff with optimal patient care; the former goal can be met without negatively impacting the latter. But both goals can only be accomplished by developing a comprehensive program based on evidence from the literature about safe and effective training in life-saving procedures.

All pediatric trainees must acquire basic life-saving procedural skills, while opportunities to practice advanced critical care procedures such as endotracheal intubation and central line placement should be reserved for clinicians who will perform those procedures independently on critically ill children. Given the limited opportunities for experience and the availability of new educational modalities in most training programs, computer-based learning and simulation should be used to teach conceptual and technical fundamentals, followed by closely supervised, controlled patient experiences and, finally, real patient encounters.

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THE CODE SAYS
The AMA *Code of Medical Ethics*' Opinion on Confidential Services for Children and Adolescents

Opinion 5.055 - Confidential Care for Minors
Physicians who treat minors have an ethical duty to promote the autonomy of minor patients by involving them in the medical decision-making process to a degree commensurate with their abilities.

When minors request confidential services, physicians should encourage them to involve their parents. This includes making efforts to obtain the minor's reasons for not involving their parents and correcting misconceptions that may be motivating their objections.

Where the law does not require otherwise, physicians should permit a competent minor to consent to medical care and should not notify parents without the patient's consent. Depending on the seriousness of the decision, competence may be evaluated by physicians for most minors. When necessary, experts in adolescent medicine or child psychological development should be consulted. Use of the courts for competence determinations should be made only as a last resort.

When an immature minor requests contraceptive services, pregnancy-related care (including pregnancy testing, prenatal and postnatal care, and delivery services), or treatment for sexually transmitted disease, drug and alcohol abuse, or mental illness, physicians must recognize that requiring parental involvement may be counterproductive to the health of the patient. Physicians should encourage parental involvement in these situations. However, if the minor continues to object, his or her wishes ordinarily should be respected. If the physician is uncomfortable with providing services without parental involvement, and alternative confidential services are available, the minor may be referred to those services. In cases when the physician believes that without parental involvement and guidance, the minor will face a serious health threat, and there is reason to believe that the parents will be helpful and understanding, disclosing the problem to the parents is ethically justified. When the physician does breach confidentiality to the parents, he or she must discuss the reasons for the breach with the minor prior to the disclosure.

For minors who are mature enough to be unaccompanied by their parents for their examination, confidentiality of information disclosed during an exam, interview, or in counseling should be maintained. Such information may be disclosed to parents when the patient consents to disclosure. Confidentiality may be justifiably breached in situations for which confidentiality for adults may be breached, according to

Opinion 5.05, "Confidentiality." In addition, confidentiality for immature minors may be ethically breached when necessary to enable the parent to make an informed decision about treatment for the minor or when such a breach is necessary to avert serious harm to the minor.

Issued June 1994 based on the report "Confidential Care for Minors"; updated June 1996.

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JOURNAL DISCUSSION
Titration of Medication and the Management of Suffering at the End of Life
Wynne Morrison, MD, MBE

Billings JA. Humane terminal extubation reconsidered: the role for preemptive analgesia and sedation. *Crit Care Med.* Feb 2012;40(2):625-630.

Truog RD, Brock DW, White DB. Should patients receive general anesthesia prior to extubation at the end of life? *Crit Care Med.* Feb 2012;40(2):631-633.

A recent debate in the critical care literature concerns whether it is appropriate to provide "anesthesia" to patients who are undergoing compassionate extubation when a prolonged course of mechanical ventilation is no longer expected to provide benefit. Most of these patients will die following extubation. J. Andrew Billings has argued compellingly that many patients suffer during this process [1], and that the only way to prevent such suffering is to anesthetize the patients prior to extubating them. In a counterpoint article, Robert Truog and colleagues [2] believe that, while general anesthesia (or at least deep sedation) might sometimes be indicated, administering it to all patients when mechanical ventilation is withdrawn would be problematic. They emphasize that it is better to base care on the clinical circumstances of the individual patient and the values of the patient and family.

Clinicians balance conflicting concerns when managing medications at the end of life. No one wants the patient to suffer. Providing enough medication to prevent suffering therefore makes sense. On the other hand, most hope the medications themselves will not be the immediate cause of the patient's death, particularly if there is a chance that the patient would have survived if not given the medication. "Just enough" is therefore the goal. Billings prefers to err on the side of guaranteeing that there is no suffering, arguing for a preemptive rather than reactive approach. He emphasizes that his approach applies only to patients who are "terminal" and who might have some degree of consciousness that would enable them to experience pain or dyspnea. He refers to recent studies that document a previously unrecognized degree of awareness among patients in a minimally conscious or even persistent vegetative state in claiming that assessing a patient's pain can be very difficult.

Anticipating discomfort and treating it aggressively sound like appropriate goals, but there are problems with this approach, particularly in the world of pediatrics. One difficulty is that prognostication in pediatrics is challenging. In a recent multicenter study, two-thirds of children for whom palliative care consultations were sought were alive a year later [3]. Although there are concerns that many clinicians are overly hopeful in their prognostication [4], most intensivists, including those who

care for adult patients, can recall a handful of patients who unexpectedly survived after the withdrawal of a mechanical ventilator [5]. If there is a chance that administering an anesthetic agent at the time of ventilator withdrawal could cause the death of a child who would otherwise survive, then doing so before ascertaining that the child is suffering should be avoided. Billings states that preemptive treatment should be used only in patients for whom survival would be "unprecedented." Yet it is precisely the patients he wants to protect, those who may be partially conscious, who would be most likely to surprise the team by surviving.

In most cases, I agree with Truog and colleagues that medication can be titrated to achieve the goals stated above. Yes, it is necessary to trust that we are able to assess the patient's distress adequately. It is even possible that an ICU level of care will be required, at least initially, to have staff pay adequate attention to assessment and titration of medication. (Transferring a patient to a floor immediately after extubation if the staff can check in no more than a few times a shift is not adequate end-of-life care.) Both adult and neonatal studies indicate that, in most cases, careful titration of medication—even to very high doses—does not hasten death [6, 7].

For the vast majority of patients, comfort can be achieved with subanesthetic doses of medication, which also may make it possible for a family to hold and talk to their child for some period of time after the ventilator withdrawal. Will there be cases in which the doses of medication required approach what is typically considered anesthesia? Yes, but only when it has first been demonstrated that such levels of sedation are necessary.

Preparing medications and a plan for their escalation, if necessary—"proactive preparation"—is better than preemptive treatment. Whether deep sedation is called anesthesia or sedation may seem to be merely semantic, but suggesting that "anesthesia" is the appropriate course preemptively is more likely to lead to a deeper level of sedation than may be required.

The choice of term may also determine which clinicians are able to administer the drug and, hence, oversee ventilator withdrawal. Billings believes anesthesiologists should manage ventilator withdrawal since they are most familiar with the medications used. I would argue that an intensivist, or anesthesiologist-intensivist, should do so, for several reasons. An intensivist has much more experience in titrating medication and assuring the comfort of patients who are conscious or partially conscious rather than anesthetized, and an intensivist is more likely to have been involved in the prior care of dying patients than a general anesthesiologist. Thus, having the intensivist direct the management is likely to provide greater continuity for the patient and patient's family, since this physician was probably involved in managing the patient's illness and helping the family decide that it was time to discontinue the ventilator.

One means of minimizing suffering while making sure that the medications used are not causing or hastening death is a "rapid terminal wean": in anticipation of

discontinuing the ventilator, the clinician can decrease the ventilator settings to a low level and assess the patient's comfort [8]. A rapid wean, over minutes, is usually more appropriate than the prolonged (hours to days) terminal wean originally described in the literature [9]. If the patient becomes distressed during the weaning, additional narcotic or sedative medication can be provided before removing the endotracheal tube. As Truog mentions, the ability to make an accurate assessment requires that the patient not be receiving neuromuscular blocking agents. Pharmacologic paralysis can worsen suffering by hiding it and can immediately cause death without any justifiable beneficial effect. Similarly, any other medication that had the sole purpose of hastening death, such as potassium chloride, is inappropriate [2, 10].

How could a careful titration of medications unfold? A situation typical in my own practice raises the issues Truog discusses. Imagine that you are the attending physician in the pediatric intensive care unit caring for a 12-year-old boy who was struck by a car while riding his bike without a helmet just over a week ago. The severely increased intracranial pressure that he initially showed despite a decompressive craniectomy has now resolved, and he remains unresponsive, with fixed and dilated pupils and minimal cortical activity on electroencephalogram. An occasional breath over the ventilator is the only evidence of brainstem function. After many long conversations, his parents and you have come to the conclusion that it is not in his best interests to use aggressive interventions to maintain him in such a state, and you make the difficult decision to discontinue the ventilator. His parents, overwhelmed in their grief, ask if you can give him something to "make sure it is all over quickly." You gently explain that you cannot give anything that would cause his immediate death, but promise that you will make sure he is comfortable. You tell them that they can hold him or lie in the bed with him, and that you and his nurse will be right there with them to constantly assess whether he needs any additional medication to treat suffering.

You explain that there may be gasping or noisy breathing, and that his skin may change colors, but that all of these signs are common and do not mean that he is in distress. You let them know that with his current state of neurologic function you expect him to live for only minutes to hours following removal of the ventilator, but you prepare them for the uncertainty that is always present and the small chance that he will breathe adequately for a longer period of time. You tell them that there is no limit on the amount of medication that can be used if he is in pain or struggling to breathe, and you ask them to let you know immediately if they are concerned that he is. In this case, the medical team feels reassured that it is clear which medications are acceptable and which are not and confident that they can use their experience to titrate the medication so that the child is comfortable. In my experience, by using such careful titration, the ICU team can do a tremendous amount not only for the child but also to help the family get through what is likely the most difficult experience of their lives.

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STATE OF THE ART AND SCIENCE

Off-Label Use of Therapeutic Hypothermia for Infants with Hypoxic-Ischemic Encephalopathy

Naomi T. Laventhal, MD, MA, John D.E. Barks, MD, and Scott Y.H. Kim, MD, PhD

Physicians are often under pressure to use only those therapies that have been shown to be safe and effective in large randomized control trials (RCTs). This is a thorny issue in the newborn intensive care unit: neonatologists recognize the importance of evidence-based decision making [1], but must often rely on treatments that have precedents of clinical use, but little systematic evaluation [1]. Examples of seemingly benign therapies ultimately found to be harmful are reminders of the need for prospective evaluation of new therapies' short- and long-term effects. In the 1940s, neonatologists learned that supplemental oxygen, delivered abundantly to premature babies with respiratory distress syndrome, was toxic to the developing retina and associated with thousands of cases of blindness [2, 3]. More recently we have learned that systemic corticosteroids, seemingly a promising tool for decreasing the impact of bronchopulmonary dysplasia, appear to increase the risk of significant neurodevelopmental impairment [4]. The tension between the need for evidence-based practice and the need to "do something" is well illustrated by exploring the ethical implications of off-label use of therapeutic hypothermia for premature infants with hypoxic ischemic encephalopathy.

Background

Perinatal-neonatal hypoxic ischemic encephalopathy (HIE) is a serious condition caused by acute and unexpected disruption of blood flow and oxygen delivery to the fetus around the time of birth. Infants with HIE may be quite ill with neurologic dysfunction and multisystem organ failure. Roughly 60 percent of infants with HIE die or carry long-term neurologic impairment [5]; in the worst cases, infants are minimally interactive; require intensive support of breathing, circulation, and vital organ function; and are completely and permanently dependent on caregivers.

Until recently, there was no specific treatment for HIE. Supportive care was offered and, in some cases, withdrawn if the neurologic prognosis seemed particularly grim. In other cases physiologic function returned but full neurologic function did not, an outcome some physicians and parents consider to be a "fate worse than death" [6-8].

With improved understanding of the pathophysiology of HIE, we now understand that lowering body temperature attenuates the cellular response to hypoxic-ischemic injury, interrupting the cascade of events that appears to contribute to poor outcomes [9]. A number of large RCTs have shown that reduction of head or whole-body

temperature to 3 degrees below normal for 3 days is associated with a 40 to 50 percent reduction in death and long-term disability in term infants with moderate or severe encephalopathy [5], with side effects that are readily manageable and usually of trivial clinical significance. Initiation of therapeutic hypothermia (TH) within 6 hours of birth has rapidly become the standard of care in many NICUs around the developed world [10-12].

An early concern about TH was that treatment would not reduce the total number of poor outcomes but, rather, redistribute them from death to survival with severe neurologic impairment [13]. Fortunately, meta-analyses have shown that the absolute incidence of neurologic disability does not increase [14, 15].

Although the RCT results are reassuring, there is potential for serious adverse effects and sub-optimal outcomes, and current recommendations advise that TH only be used in a manner consistent with published protocols [16-18]. As researchers explore use of TH for infants who are gestationally younger or chronologically older, along with other "optimized" protocols, available recommendations are to limit these applications to clinical trials [19].

Therapeutic Hypothermia for Preterm Infants

Premature infants (born at 36 gestational weeks or younger) may be vulnerable to HIE, but the incidence in this population is unknown [20, 21], as they have traditionally been excluded from the diagnosis due to overlap between normal neurologic findings in this population and HIE diagnostic criteria [22-24]. Although most of the randomized trials included infants of 36 weeks gestation, experience with TH for premature babies younger than 36 weeks' gestation is largely anecdotal.

Prevention of hypothermia is a cornerstone of care for premature infants [25, 26], which complicates the use of TH in this patient population. In addition, the complexity of the developing brain (even among "late preterm" infants [27]) obscures our understanding of the impact of HIE, hypothermia, and other pathophysiologic states that accompany preterm birth [28]. One randomized pilot study comparing selective head cooling and supportive therapy for preterm infants began recruitment but was halted by the Food and Drug Administration due to safety concerns after the initial patients were randomized [29, 30]. Presently, the only possible approach to targeted therapy for premature infants with suspected HIE is the off-label use of TH.

Arguments in Favor of Off-Label Use of TH for Premature Infants

Considerations for individual patients. Theoretically, 1- or 2-week distinctions in gestational age are unlikely to result in significantly different outcomes and side effects, particularly as infants approach full term. Many routine neonatal therapies are based on this kind of reasoning, extrapolated from either clinical experience or studies in older children, infants, or even adults [31, 32]. Furthermore, in the absence of alternative therapies, are we not obligated try *something*, given the risk of poor outcomes for patients with HIE? This reasoning may resonate with many

neonatologists who face desperate parents and dire circumstances and seemingly have little to lose. In these situations, biologic plausibility may be the best foundation on which to base treatment decisions, and the acceptability of using an off-label therapy might be supported by proposing that, provided that parents are given the available information about possible risks and benefits and also offered standard (supportive) therapy, it is within their purview to choose off-label TH.

Societal arguments. This kind of boundary testing can play an important role in medical progress. Such arguments have been important in surgery, where the line can be blurred between trying something for the first time and gaining clinical experience with an innovative procedure [33, 34]. Subjecting a new surgical technique to randomization removes the advantage of allowing the skilled surgeon to "tweak" the procedure gradually [34]. Surely every minute change in a surgical approach does not warrant a RCT [35]; rather, the end result of a subtle series of changes can be systematically compared with the original procedure. Similarly, neonatologists could argue that refinement in neonatal procedures and therapy is a continuous process that drives progress in patient care and generates compelling hypotheses that can subsequently be tested.

Finally, neonatologists may find themselves in dire straits if they commit to using only therapies that have been systematically evaluated. Many routine practices, such as standardized cardiopulmonary resuscitation or use of total parenteral nutrition, have never been evaluated by RCT (and probably never will) because doing so would be ethically or logistically unacceptable. Furthermore, while RCT inclusion criteria may have excluded infants with comorbid conditions that affect trial endpoints (e.g., congenital anomalies), it generally does not follow that infants with those conditions should not be treated with therapies found to be effective in those trials—available clinical evidence is only one aspect of good patient care, which should also include individualized risk-benefit considerations [36].

Arguments in Favor of Limiting the Use of TH to Published Inclusion Criteria

Considerations for individual patients. Biologic plausibility may appear to be an adequate basis on which to treat an infant with an unvalidated therapy, but it fails to address the possibility that assumptions about safety and efficacy are incorrect. With so little knowledge of the epidemiology and natural history of HIE in premature infants and the potential for interaction of pathophysiologic injury mechanisms, complex factors that result in preterm birth, and hypothermia, there is no certainty that preterm infants treated with TH will be better off than those who receive supportive care.

An example of this is the possibility that among premature (as opposed to term) infants treated with TH, there *will* be a redistribution of poor outcomes from death to severe disability, rather than an absolute reduction in both. Studies of many neonatal interventions include formal neurodevelopmental evaluation at 18 to 24 months of age, adding at least 2 years from the completion of recruitment for publication of results. Without longitudinal evaluation of that sort, accumulated clinical experience

may shed some light on the short-term effects of providing TH to preterm infants with HIE without ensuring that the treatment is both efficacious and safe in the long run. Unless they are quite large, prospective registries may not adequately elucidate the effect of TH on complex, multifactorial outcomes like neurologic impairment.

From this standpoint, informed consent may be viewed as necessary but not sufficient to justify the use of off-label therapies. Despite their role as accepted surrogate decision makers for children, parents' decision making is constrained by law to choices that are deemed to be in a child's best interest. For example, in most cases parents may not refuse antibiotics for serious infections, surgical intervention for appendicitis, or chemotherapy for acute leukemia. Similarly, parents may not demand antibiotics for viral infections, X-rays that will not aid in diagnosis, or unnecessary surgery. Regardless of parental preferences, physicians retain the authority and responsibility to practice medicine within the confines of appropriate and rational care.

Societal arguments. A randomized trial of TH for preterm infants with HIE is being planned within the Neonatal Research Network (a network of academic newborn intensive care units that conducts multicenter studies funded by the National Institute of Child Health and Human Development). Rapid completion of the trial becomes more difficult if the therapy is being offered "off protocol," both by slowing the recruitment of patients and by potentially disturbing the state of equipoise that is needed for an ethically permissible trial [37].

Delaying the completion of clinical trials may extend the period in which patients are exposed to the possible harms of TH, such as bleeding and hemodynamic instability or even a higher incidence of neurologic morbidity and mortality. An example of this can be found in the breast cancer literature: women sought aggressive, unproven treatment outside of clinical trials, delaying the discovery that these risky bone marrow transplants were harmful, rather than helpful [38].

Even if the trials are completed, the results may be difficult to generalize if eligible patients are not well represented by the group of study participants due to recruitment difficulties. Conversely, if TH is found to be helpful in reducing the incidence of poor outcomes for premature babies with HIE, delay in completion of the trials may prolong the period in which some infants are denied this benefit [37].

Conclusions

Review of the ethical considerations for and against use of off-label TH for preterm infants with HIE does not resolve the question of whether or not this practice is ethically justifiable—there are compelling arguments on both sides. However, the framework used here can be applied to consideration of other off-label therapies in neonatal and pediatric patients; this includes review of available information about potential risks and benefits, careful balancing of parental autonomy and the child's best interest, an appropriate process of informed consent, and consideration of whether there is an opportunity to systematically evaluate the therapy. As new

treatments are introduced to neonatal intensive care, considerations for and against using off-label and unvalidated therapies should be similarly analyzed.

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HEALTH LAW

Minors' Refusal of Life-Saving Therapies

Valarie Blake, JD, MA

Rare but challenging are those cases in which teenagers, whether for religious or other reasons, refuse or seek to discontinue life-saving therapies. Unlike their adult counterparts, teenagers generally do not have the right to make their own medical decisions, and physicians, families, and sometimes the courts are left to make difficult choices that have implications for religious freedom, parental rights, and a child's well-being alike. Three stories help illustrate the key considerations a court generally weighs when asked whether a teenager should be allowed to refuse life-saving therapies.

Medical Decision Making: Minors and Adults

Adults with decision-making capacity have a long-recognized and legally protected right to make decisions about their bodies and health, stemming from interest in their autonomy and bodily integrity. This is emphasized by famous cases like *Cruzan v. Director Missouri Department of Health*, in which the U.S. Supreme Court recognized a competent person's "constitutionally protected liberty interest in refusing unwanted medical treatment" and set the evidentiary standard for proving an unconscious adult would want life-sustaining support removed [1], and *Bouvia v. Superior Court*, in which a California court allowed a 28-year-old woman with cerebral palsy to order withdrawal of the nasogastric tube that fed her [2]. The right to refuse life-saving therapies on religious grounds is also strongly defined, most notably the refusal of blood transfusions by Jehovah's Witnesses [3].

Whether the same rights apply to minors (typically defined as younger than 18, though the definition varies by state) is more complex. The legal norm for minors is that parents provide consent on behalf of the child and the child provides "assent" to the extent he or she is developmentally able to do so. Parents are deemed to be the natural and best decision makers for their children based on their "traditional interests in and responsibility for the upbringing of their child" and a "deeply rooted…belief that the parental role implies a substantial measure of authority over one's children" [4, 5]. Courts are generally hesitant to interfere with parental authority because they defer to family privacy and integrity [6]. Yet, the state also has a role in protecting the interests of those who cannot protect themselves, for example in cases of child abuse, when the rights of the parent conflict with the state's role as *parens patriae*, or "parent of the nation" [6].

Most states provide certain universal exceptions, instances in which minors can give medical consent. One is for emergency care when a parent is not available in time to

provide consent [7]. Another exception is for emancipated minors, who are deemed legally independent from their parents in all legal capacities, including medical decisions [7]. Some states have statutes that specify types of care for which parental consent is not required, such as treatment for sexually transmitted infections, treatment for substance abuse or mental health, or requests for contraceptives [8]. Lastly, states may have "mature minor" doctrines, under which minors can petition the court to recognize that they fully understand the treatments and consequences of their decisions and should therefore be allowed to make treatment decisions independently, either in contradiction to their parents' wishes or without consulting their parents [7]. Courts often view teenagers' refusal of life-saving therapies as an extension of the mature minor rules.

Cases of Teenagers' Refusal

What do courts consider when deciding whether to permit a teen to refuse life-saving therapies? Does the teen's opinion count more than the parent's, and how do courts weigh the teenager's age and maturity? While much depends on the particular state and unique facts of the case, three stories illustrate some common considerations.

E.G. E.G. was a 17-year-old Jehovah's Witness with leukemia who refused medically necessary blood transfusions on the basis of religious belief, a decision her mother supported [9]. Without transfusions, professionals expected E.G. to live no more than a month, and either way her long-term prognosis was poor—persons with her condition had a predicted survival rate of 20 to 25 percent [9]. Experts evaluated E.G. and agreed about the following: she was mature (one specialist placed her at the maturity level of someone between 18 and 21), her refusals were based on a sincere religious belief and not a desire to die, and she fully understood that the consequences of her decision would be death [9]. A trial court appointed a temporary guardian for E.G. to consent to transfusions on her behalf and found her mother guilty of medical neglect, but Illinois' highest court overturned the decision in 1989, holding that E.G. had a right to refuse the blood transfusions and her mother was innocent [9]. (At this point, the case was technically moot for E.G.'s purposes, because she had turned 18.) The court was swayed by the fact that E.G.'s mother agreed with the refusal and suggested that the outcome could have been different if E.G.'s mother had wanted her to seek treatment.

Daniel Hauser. Daniel Hauser was 13 and suffering from Hodgkin's disease when his case came before the Minnesota courts in 2009 [10]. Daniel had undergone a first round of chemotherapy and experienced common adverse side effects [10]. While several experts agreed that Daniel had an 80 to 95 percent chance of remission with chemotherapy and very little chance of surviving 5 years without it, Daniel and his parents agreed to end treatment [10]. The refusal was based on their religious practice of Nemenhah, a Native American healing practice in which Daniel was a medicine man and which forbade chemotherapy because of a prohibition against doing harm [10]. Daniel was unable to articulate why he opposed the chemotherapy beyond the notion of "do no harm," and experts placed his reading below a fifth-grade level [10]. The Minnesota judge required Daniel to receive chemotherapy on

the grounds that the state's interest in preserving life outweighed Daniel's and his parents' freedom of religion and the Hausers' parental rights [10]. The court permitted Daniel to remain in his parents' custody and to pursue alternative therapies in addition to the chemotherapy [10].

Shannon Nixon. 16-year-old Shannon Nixon died of diabetic ketoacidosis that was not treated in accordance with the Nixon family's views as members of the Faith Tabernacle church [11]. Shannon's parents were then convicted of involuntary manslaughter and child endangerment [11]. Shannon's case was unique because the right for a minor to refuse medical care was invoked as a defense against criminal charges after her death, rather than in seeking permission to forgo care during her life [11]. The Pennsylvania Supreme Court upheld the Nixons' criminal convictions but suggested that, while minors may consent to certain things, like donation of blood and treatment for controlled substance use, there needs to be a more stringent limit on refusals of care in life-or-death cases [11].

Relevant Considerations

Each of these three stories has unique driving forces, facts, and outcomes, but they share features that most courts take into account.

While not every refusal involves religion, many do, whether the belief is on the part of the child, the parent, or both. The freedom to practice religion is strongly undergirded by the First Amendment of the Constitution, which prohibits Congress from making any law that interferes with it [12]. Yet, the Supreme Court has limited this right in the context of parental decision making, saying that "parents are free to become martyrs…[b]ut it does not follow they are free…to make martyrs of their children" [13]. Here, courts look to whether the parents and children hold the belief sincerely and whether the minor has the ability to process and understand what his religion means for the course of care (as in Daniel's case) [10]. The courts may also question whether the refusal stems from a genuine religious claim or a general desire to end treatment, as in E.G.'s case [9].

Courts also consider whether the parent(s) agree with their child's refusal. While parents' rights can be trumped by the state, courts provide a great deal of latitude for parental decision making, as in E.G.'s case when the mother's agreement may have ultimately determined the court's decision [9]. In contrast, when the court did not believe the child had a true ability to express his or her wishes (as in Daniel's case) or did not have an opportunity to hear the child's perspective (Shannon's case), it favored protecting the child over granting decision making power to the parents [10, 11].

The likelihood that treatment will be curative is also an undercurrent in these cases. Even if E.G. had received the blood transfusions, her chance of long-term survival was only about 20 percent, whereas Daniel was expected to go into remission and had an 80 to 95 percent chance of long-term survival, and Shannon's condition was

treatable and not life-threatening if given prompt care [9-11]. Had E.G.'s chances of survival been greater, the outcome may have been different.

Lastly, courts consider and evaluate the minor's competency and level of understanding. Both E.G.'s and Daniel's cases involved testimony by experts about the minor's maturity, level of sophistication in articulating their religious views, and understanding of the consequences of refusing treatment [9, 10].

Courts dealing with teenagers' refusals of care must balance a variety of competing interests and values in reaching a decision that can have ultimate consequences for the minor. This is an area of law that varies greatly from state to state and by the specific facts of the case, and it is likely to continue to receive much attention from scholars, media, and courts.

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POLICY FORUM

Legal and Ethical Policies Regarding Research Involving Critically Ill Children

Tracy Koogler, MD

Parents who have children in the pediatric emergency department (PED) or pediatric intensive care unit (PICU) are under great stress; they are worried about the safety and health of their child, and they are asked to make medical decisions in a short time, sometimes with little information, and many times with unfamiliar physicians. Parental anxiety is increased when discussions of research enter the conversation. This paper examines the legal framework for research in pediatric emergency medicine and critical care and then looks at some of the ethical dilemmas that occur in research with critically ill children.

Legal Issues

The Department of Health and Human Services (DHHS) has established a set of rules for the protection of human research subjects that is codified in the federal register (45 CFR) [1]. Subpart D refers explicitly to pediatric research subjects. This section describes the rules an institutional review board (IRB) must follow when reviewing research involving children. First, it must ensure the following guidelines are met: (1) the risks to subjects must be minimized; (2) the risks to subjects are reasonable in relation to the anticipated benefits, if any; (3) subject selection is equitable; and (4) informed consent is obtained in a manner appropriate to the risks of the research.

The regulation then discusses risk levels and who must consent or assent to research projects that pose varying levels of risk and benefit. Minimal-risk research does not cause any foreseen potential harm to the child participating and includes those activities a child might do during a routine well-child visit or in daily life, such as play video games. All children can participate in this form of research and only one parent needs to consent. In most of these studies, a child 7 and older would also assent to participate.

The next level is research that offers the prospect of direct benefit to a subject and poses more than minimal risk. This form of research involves children with a disease or condition that might be improved or treated with the drugs, procedures, and devices that are part of the trial. This research requires one parent's consent and, in some situations, assent from the child. Many institutions waive the requirement of assent if the drug, device, or procedure is available only through the research protocol.

Finally, if a child is asked to participate in a trial that poses more than minimal risk and offers no direct benefit but will produce generalizable knowledge about a disease or condition that the child has, then both parents must consent. This may be a phase-1 drug study, genetic research, or tracking a tumor's progression by using sedated MRIs. Only children who have the disease or condition in question can participate.

Sometimes, pediatric emergency and intensive care physicians want to do emergency research, that is, research carried out when consent is not possible, such as during an attempt at resuscitation. This type of research falls under the emergency exception from informed consent (EFIC). EFIC requires that the subject have a life-threatening condition, available treatments are unproven or unsatisfactory, and informed consent is not possible because of the urgency of the situation [2]. Further, the risks and benefits to the subjects must be reasonable, and there must be a prospect of direct benefit to the individual. Lastly, the researcher must verify that there is no other way the research could be done.

If these criteria are satisfied, the researcher must obtain permission from the FDA, consult with community leaders, give a public disclosure in the community through newspapers, flyers, radio, or TV about the risks and benefits of the research prior to starting the project and then announce the results in the same manner at the end of the study. Finally, the subject and family must be told that the subject was part of the study as soon as possible. If the study has additional parts that continue after the family's notification, then the family or subject must have the ability to opt out of these as long as stopping the research early does not place the subject at risk of harm.

Ethical Issues

While the legal guidelines are straightforward, gaining approval for research studies in the pediatric ED or ICU can be complicated by the informed consent process. Parents of sick children in an emergency room or intensive care unit are under immense emotional distress and approaching them with a request that their child participate in research may only increase that distress. Nevertheless, the parents must understand the research sufficiently and feel comfortable consenting to it, even though their child may be extremely ill.

Most pediatric emergency medicine and critical care research falls into two categories: studies that pose minimal risk and those that pose more than minimal risk but also the prospect of direct benefit.

Minimal-risk and quality improvement projects. Although minimal-risk research and quality improvement projects appear straightforward, an IRB may require that clinicians wait for some period of time after a child's admission or arrival in the ED to approach a family about such research. The waiting period might last until a diagnosis and treatment plan are determined, just prior to discharge, or after 24 hours in the PICU. These waiting periods may seem to be inconveniences for the researcher, but it is unjust to burden an ill child and family for research purposes alone.

Drug research with a possible benefit to the subject. A research study that offers potential benefit to the sick child can be equally challenging for a parent to consider. If the researcher presents the study appropriately, he or she will say that it is not known whether the study drug offers any benefit over the standard of care and that is why it is being studied. This situation is known as "equipoise" and means that the expert medical community is uncertain of the therapeutic benefit of a study drug or procedure.

Parents of a very sick child often feel pressure to consent to the use of trial drugs because they believe the study offers their child the best chance of recovery or that, by enrolling, the child will get better care from the medical team. Parents may agree to the study, though preferring their child not participate in research.

Research in the PICU and PED also subjects parents to feelings of extreme guilt regardless of their decision. If they do not consent to research, they may feel guilty for denying their children a possible treatment. If they consent, they may feel guilty about exposing their children to a drug that may not help and has risks. Either way, parents are likely to feel uncertain about the decisions and the child's future. If research were not an option, the parents would consent to standard care, which, though scary, has demonstrated results and risks.

Emergency research. Emergency research compounds these issues. Placing a child in a research study without the parents' permission denies them the opportunity to make decisions for their child. Parents worrying about their injured child while a physician performs an experimental procedure on the child is ethically problematic. Having to meet parents, discuss the critical nature of their child's condition, and state that a research drug was used in the child's initial management can be difficult. Parents may be distressed that no one in the trauma bay told them about the research, that their voices were not sought at the most critical time in a child's life. They may link a poor outcome to the study rather than the critical condition of the child. EFIC research requires special consideration and oversight and should only be used after rigorous scrutiny of the protocol by the investigator, the IRB, and the community.

Conclusion

Research in the PED and PICU is essential to advance medical understanding of the efficacy of emergency interventions, both drugs and procedures. Yet researchers must be careful to minimize the additional stress that consent and participation in research entail for people in these circumstances. Minimizing distress and risks to the subject and family will ultimately lead to a more successful research experience for everyone, even if the intervention itself is unsuccessful.

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POLICY FORUM

Ethical Issues in Pediatric Emergency Medicine's Preparation for and Response to Disasters

Armand H. Matheny Antommaria, MD, PhD, and Brent D. Kaziny, MD

Disasters—naturally occurring events like earthquakes and pandemics or manmade incidents such as terrorist attacks—possess the potential to overwhelm our health care system. The emergency medical system is particularly vulnerable [1, 2]. In general, the response to a disaster consists of three phases: conventional care, contingency care, and crisis care [3]. Ethical analysis of disaster response requires a shift in emphasis from individual patients' needs to the needs of the population in order to maximize the number of lives saved. Key questions include how much should society invest in planning and how should we allocate scarce resources.

During a disaster, children may be disproportionally affected due to their anatomical, physiological, developmental, and emotional differences from adults. For example, because they breathe more rapidly and breathe the air closer to the ground, children are more susceptible to injury in fires or biological or chemical attacks. Young children also lack the cognitive and motor skills to escape from certain dangers. In addition, they have distinct developmental needs that should be addressed. Because under normal circumstances most children are relatively healthy, there are disproportionately fewer hospital services for children than for adults [1]. There is therefore the potential for a significant mismatch between the demand for and supply of pediatric emergency care in a disaster.

Conventional and Contingency Care

The development of sufficient surge capacity to maintain a standard of care during disasters that is functionally equivalent to the conventional standard relies on adequate space, staff, supplies, and special resources [4]. Children's particular needs should be addressed in each of these areas.

Space must be adequate not only for treating children but also for permitting them to be paired with a parent or caretaker. Caring for children also requires equipment and supplies of different types and sizes or dosages. For example, children require a variety of sizes of endotracheal tubes. During disasters, pediatric decontamination units must be able to provide water at warmer temperatures, higher volume, and lower pressure. Those delivering emergency services should be trained to treat children. Pediatrics has traditionally been a small component of the educational requirements for emergency medical technicians. The Institute of Medicine recommends defining pediatric competencies and developing clinical practice guidelines for pediatric emergency care [1]. Special resources include treating older

children in adult facilities or treating parents who accompany children to pediatric facilities [4]. One of the key questions is how much should society invest in creating surge capacity as opposed to interventions to prevent disasters or programs to meet other societal needs.

Crisis Care

If surge capacity is insufficient, it may be necessary to employ an altered standard of care. The ethical criteria for allocating scarce resources in a disaster are need, benefit, resource conservation, and random allocation. Medical resources should only be provided to individuals who need them—those who are sick or injured. They should be withheld from those who will not benefit from them—those who will die even with treatment. It is better to save two people, if possible, with the resources usually allotted to one. Finally, if there is no ethically relevant way to distinguish among those who need and will benefit from treatment, resources should be distributed randomly. Queuing and lotteries, however, have limitations in practice: those with more resources may be able to get in line sooner, and some may object to leaving such important decisions up to chance. Patients should not be triaged based on ethically irrelevant criteria such as race, gender, ethnicity, religion, or ability to pay [5].

There is significant controversy about the use of age, independent of prognosis, as a triage criterion [6]. Persad, Wertheimer, and Emanuel, for example, have proposed a "complete lives system" that prioritizes individuals between 15 and 40 years of age. They argue that society has made greater investments in the lives of adolescents and young adults than in the lives of infants and that adolescents and young adults are more capable of forming and valuing long-term plans [7]. Opponents of this view argue that age is not an accurate proxy for either society's investment or a person's ability to plan.

Much more public engagement is needed in the development of triage criteria [3]. For example, in contrast to Persad, Wertheimer, and Emanuel's position, the majority of respondents surveyed agreed that, if resources were severely limited, children should be given priority over adults [8]. Deliberative processes can be used to educate the public and inform policy makers.

Triage algorithms should be evaluated in terms of which criteria they evaluate and the accuracy and precision of their evaluations. Most algorithms for primary triage (triage that occurs before the initial medical intervention [3, 4]) are based on expert opinion rather than derived from statistical analysis of patient outcomes. They use physiological and observational data to sort individuals into the following categories of priority for curative treatment: immediate, delayed, ambulatory, and deceased or expectant (i.e., likely to die even if given the available treatment) [9]. Expectant patients should receive palliative care [3].

Validation studies of triage algorithms have used a variety of outcomes [10]. The primary study of the pediatric algorithms prospectively compared them against

injury severity scores, which focus on need rather than benefit or resource conservation. The algorithms showed poor sensitivity (0.8-41.5 percent)—they did not identify a substantial number of children who, in fact, required immediate treatment [11]. The utility of these algorithms in incidents involving chemical, biological, radiological, or nuclear elements is unclear [9, 10].

In contrast, the Sacco Triage Method (STM) is a mathematical model that considers both the probability of survival and the availability of resources in prioritizing victims for treatment. It sometimes gives priority to patients other systems categorize as "delayed." In a variety of simulations, STM produced higher numbers of survivors than Simple Triage and Rapid Treatment (START). For optimal results, however, STM requires software support and communication with incident command, which may limit its feasibility and utility in actual disasters [12].

The development of validated, easily implemented triage algorithms, specifically for children, should be a high research priority. In the interim it is an open question whether expert opinion is an acceptable alternative [6]. Even experts may not be able to reliably distinguish between patients or may misestimate the severity of illness. Individual decision making also introduces the possibility of conscious or unconscious bias.

Ideally, a team of experienced clinicians who are not involved in direct patient care should triage patients to differentiate the roles and limit conflicts of interest. Mechanisms should be in place to provide transparency, consistency, proportionality, and accountability [3]. Because alterations in usual expectations are likely to be very stressful, clinicians should be adequately trained beforehand and provided with appropriate mental health services afterward.

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MEDICINE AND SOCIETY

Adolescents' Right to Consent to Reproductive Medical Care: Balancing Respect for Families with Public Health Goals

Margaret Moon, MD, MPH

The 16-year-old patient in room A can consent to antiretroviral treatment for HIV, but the 17-year-old in room B needs a parent to consent to management of a gastric ulcer with famotidine. What does it say about our society that adolescents may seek health care independently for reproductive health but not for treatment of everyday medical conditions?

It says that we are a pragmatic people, willing to seek a balance among fairness, respect for families, and critical public health and safety goals.

A bit of history is necessary to gain perspective on the seemingly inconsistent set of standards affecting adolescent patients' rights to consent to care. The legal framework that supports a limited right for adolescents to consent to care has been in place for almost 50 years. In 1967, the Supreme Court emphasized that minors have constitutional rights, albeit limited [1]. Several decisions in the following decade extended and clarified the constitutional rights of minors to due process, free speech, and, finally, privacy rights and access to contraception. The *Carey v. Populations Services International* decision in 1977 made it illegal to prohibit the sale of legal contraceptives to minors and supported minors' right to privacy with regard to decisions about reproduction [2]. A key point in that decision was that sexual maturity, i.e., the capacity to become pregnant, rather than age or marital status, should determine access to contraception.

The social framework for adolescents and reproductive health was undergoing important changes while the legal environment was being redefined. The 1970s were notable for a rise in the average age of marriage, increasing the population of sexually mature but unmarried teens [3]. There was a lessening of the social pressure for pregnant teens to marry [4]. At the same time, abortion became legal. Inevitably, teenage sexual activity was more likely to lead to out-of-wedlock births and abortion. Even more important, public health and epidemiologic data revealed that teenage pregnancy was associated with poor outcomes for mother and baby [5].

Preventing bad outcomes for teens and their offspring was the prevailing impetus behind expansion of confidential care for reproductive health. The public health goal was avoiding or reducing unwanted pregnancy and optimizing treatment of sexually transmitted illnesses. Teenagers had to be willing to access care and seek information. Clinicians needed to be able to engage in open and frank discussions so

that appropriate care was offered. Most experts agreed then, as now, that adolescents would be less likely to seek necessary care for reproductive health issues if they had to involve their parents. To the extent that a requirement for parental involvement creates an obstacle to the provision of necessary care, it is counterproductive.

Most states have passed laws regarding minors' consent for confidential reproductive health services, addiction, and some mental health services [6]. Again, the identification of specific and narrowly defined categories of care to which teens can consent reflects the pragmatic intent behind confidential services. Teens are also able to give consent for emergency medical services when a delay in gaining parental consent would increase the risk of harm.

Although access to confidential services has become a cornerstone of adolescent health care, it is important to recognize that confidentiality is limited. Most states require that confidential care be available [6], but many states offer physicians discretion in limiting confidentiality in pursuit of the best interests of the minor patient [7]. Physicians may be free to disclose information to parents if they feel it is in the best interest of the adolescent patient. Despite promises of confidential care, parents might have full access to their children's medical records. Medical bills may reveal the type of care provided, further limiting confidentiality.

Support for confidential care for adolescents has always been a pragmatic notion, directed toward public health outcomes. It is not a normative statement about the relative value of the autonomy of adolescents and the rights of their parents. Most clinicians, including those most vigorously in support of confidential care, agree that the active involvement of a concerned and capable parent is the best possible situation for sexually active teens. Parents are in the best place to know the emotional needs of their adolescent—they are usually the best bet for consistent love and care and are, unlike minors, presumed to be competent decision makers. Parents also have legal and financial duties to care for minor children. In light of those duties, we honor parents' rights to direct the moral and spiritual upbringing of children—within specific limits. Unfortunately, it is obvious that some teens do not enjoy the support of capable parents. For those teenagers, access to confidential care may be necessary.

If we understand the limited nature of minors' rights to consent to care for specific reproductive and mental health services and their origin as a public health objective, it is a little easier to understand why the 17-year-old in room B may not be able to consent to routine care for a minor illness. While respect for autonomy of the patient is a basic principle of biomedical ethics, its application in the pediatric context is complex. Children are generally not considered to be autonomous, but support for and protection of developing autonomy is a fundamental goal of pediatric practice. Capacity to consent to medical care is a presumption for adults and incapacity is the presumption for minors. (On rare occasions, minors become emancipated by marriage, military service, or financial independence, thereby gaining full rights to consent to care.)

Presumptions are always flawed, and it is particularly absurd to anticipate that capacity magically develops on someone's eighteenth birthday. Ideally, individuals with the capacity to consent would be allowed to do so, no matter what their age. Assessment of capacity, however, is rarely straightforward for adolescents. Capacity to consent requires the abilities to communicate a choice, to understand the options, to reason effectively about those options, and to make an uncoerced decision. The level of capacity required varies with the risk of the choice to be made. The capacities to understand options and to reason effectively are tricky notions and often difficult to test. Life experience and cognitive capacity have significant impact on both. At every stage of adolescence, there is remarkable variability in cognitive development and experience and, correspondingly, variability in capacity to consent.

Adolescent care requires ongoing assessment of the developing level of autonomy and its practical application—capacity for consent. We presume incapacity, always ready to be wrong. The default is to rely on parents to help fill in the gaps in adolescent capacity to consent. Most parents begin to defer to their teenage children as the child's capacity grows. Physicians can support parents and teens in this shift in control, encouraging teens to take an active role in medical communication and decision making and helping parents learn to yield authority. This is the ideal for management of adolescents' medical care, slow and careful development of capacity guided by a supportive parent and an assessing clinician. Asking adolescents to make independent choices about such high-risk issues as sexual behavior, reproductive health, addiction, and mental health is no one's idea of an optimum safety net. It is pragmatic, it is necessary, but it is rarely satisfactory.

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