Concerns about the ethical care of children have been central to modern bioethics since its inception. Key milestones in pediatric bioethics include the controversy over the Willowbrook hepatitis experiments in the 1960s, acknowledgement of the importance of “assent” for adolescents by the National Commission in the 1970s, and the Baby Doe regulations about the treatment of neonates in the 1980s.

Nevertheless, the development of bioethical reasoning during the first thirty years was heavily focused on issues surrounding adults with decisional capacity and the principle of respect for autonomy. In fact, most of the groundbreaking judicial opinions about end-of-life decisions focus on protecting the rights of adults to make autonomous decisions about their care.

Even with the ever-expanding ethical considerations of culture and family, environment and public that phenomenologists, communitarians, and narrative ethicists (among others) have brought forth in relation to adult medical ethics, pediatric medicine and pediatric ethics begins already with a more expansive view of patient-professional interactions.

Any decision about an infant can never be said to be with an infant. Decisions about infants, then, are projections of familial, medical, and cultural values in hopes that these projections will either positively shape or allow for later development of the child’s own interests and values. Unlike adult medical ethics, pediatric ethics, then, begins within an acutely and powerfully experienced dynamic of patient–family–state–physician.

“Any decision about an infant can never be said to be with an infant.”

The classic example of a Jehovah’s Witness (JW) patient who needs a blood transfusion but whose religion prohibits it illustrates the differences...
Pediatric Medicine and Bioethics

This issue of *Practical Bioethics* focuses on pediatrics. The authors discuss a wide range of issues.

Ken Alexander, a specialist in pediatric infectious disease, analyzes the controversy surrounding a new vaccine for human papilloma virus (HPV). This vaccine is controversial because it prevents the complications that arise from a sexually transmitted disease but must be given to people who are not yet sexually active. Some worry that it will tacitly condone sexual activity. Debate rages in state houses across the country about how to deal with this new challenge in immunization ethics.

Kevin Kelly, Pediatrician in Chief at Children’s Mercy Hospital in Kansas City discusses his vision of the role of bioethics in a tertiary care children’s hospital. He focuses on the dilemmas associated with research and innovation. He also pinpoints the tensions between a focus on prevention and a focus on crisis-intervention.

Micah Hester, a philosopher from the University of Arkansas for Medical Sciences, analyzes the way in which pediatric bioethics differs from bioethical analysis of dilemmas involving adults. He recounts the case of Ashley, a prepubescent girl with severe neurological damage whose parents elected to have her growth attenuated and her uterus and breast buds surgically removed, as an example of the sorts of dilemmas that could only arise in pediatrics.

John Paris discusses the ongoing controversy about medically futile treatments. He focuses on the subset of cases that involve newborns at the borderline of viability, and advocates a prioritization of the infant’s interests over considerations of parental rights.

Pain and palliative care specialist Stefan Friedrichsdorf and Kaci Osenga analyze some of the ways in which palliative care can both raise and transform ethical dilemmas. Often, pain treatment is seen as putting physicians in a double bind, by which they must choose between pain relief and life-prolongation. Friedrichsdorf and Osenga show that sometimes effective palliation can also prolong life. They discuss the implications of this outcome for the moral theory of double effect.

(Continued on page 14)
A principle of pharmacokinetics teaches us that unless the drug reaches the site of action, it cannot be expected to exert its dynamic effect. With morphine the situation is that when the drug does not reach the patient, what hope is there for pain relief? (Ghooi & Ghooi, 1998)

Although comprehensive palliative care is the expected standard of care at the end of life (Council on Scientific Affairs, 1996; National Quality Forum, 2006), services for the majority of children with life-limiting or terminal conditions fall significantly below those for adults.

In the United States, more than 34,000 infants die each year before, during, or after birth as do many children with life-limiting conditions. In most countries in the developed world including the United States, the vast majority of infants, children and teenagers at end of life do not have access to multidisciplinary pediatric palliative care services in their community or at a children’s hospital.

Pediatric palliative care is for children and teenagers suffering from life-threatening or life-limiting conditions in which survival into adulthood is or may be jeopardized if curative treatments fail. As a result, pediatric palliative care may last over many years. According to the Association for Children’s Palliative Care and the British Royal College of Pediatrics and Child Health (2003), pediatric palliative care is an active and total approach to care, embracing physical, emotional, social, and spiritual elements. It focuses on the enhancement of quality of life for the child and support for the family and includes the management of distressing symptoms, provision of respite and care through [disease], death and bereavement.

### Ethics

The medical profession has long subscribed to a body of ethical statements, including the basic principles primum non nocere and voluntas aegroti suprema lex – “first do no harm” and “the will of the patient is the supreme law.” These principles apply to acute care, palliative care, and end-of-life care in pediatrics. The care of children and teens with life-limiting or terminal conditions has to be measured against the worldwide acceptance of these basic principles of medical ethics:

1. **Beneficence:** “Do good” — Healthcare staff shall relieve pain and distressing symptoms and provide emotional support.
2. **Nonmaleficence:** “Do no harm” — Painful procedures or life-prolonging treatments, which may be a burden to the child and which do not improve quality of life, shall not be performed.
3. **Dignity:** “Respect” — Healthcare staff shall focus on the dignity and interest of the child. Conflicting interests of staff or family members need to be addressed and resolved.
4. **Autonomy:** “Self-determination” — The autonomy of children and teens needs to be respected by including them in age-appropriate discussions about medical decision making whenever possible.
5. **Justice:** “Fairness” — All families caring for a child with a life-limiting or terminal condition need their child to receive state-of-the-art pediatric palliative care, regardless of health insurance status, financial abilities, religion, socioeconomic status, or immigration status.

### Principle of double effect

The theologian and philosopher Thomas Aquinas (d. 1274) is credited with introducing the principle of double effect. This principle explains the permissibility of performing an action aimed at producing a good effect, even if doing the action may lead to an unintended “bad” effect.

Thus, a pediatric palliative care professional may act to provide relief from distressing symptoms (such as pain or dyspnea) by prescribing opioids, even when an unintended adverse effect (such

(Continued on page 4)
Practical Bioethics

Principle of Double Effect in Pediatric Palliative Care . . .
(Continued from page 3)

as respiratory depression) may occur. This act stands in sharp contrast to euthanasia (ending a patient’s life to relieve suffering), which is against the philosophy of pediatric palliative care.

Case example
An infant whom we shall call Cathy was born prematurely with a significant lung defect (bilateral chylothoraces). At the age of three months she was ventilator dependent with a tracheostomy and experiencing increasing episodes of dyspnea, apnea spells, and discomfort. A palliative care consult was requested and during the care conference Cathy’s parents tearfully asked for sedation to unconsciousness, as they could no longer bear their daughter’s suffering.

Opioids, often combined with benzodiazepines, are the standard of care in the pharmacological management of children with dyspnea. In the NICU, Cathy, who weighed 3.9 kg, was started on a continuous infusion of morphine (opioid) with nurse-administered boluses delivered by a PCA-infusion pump. She also received a continuous midazolam (benzodiazepine) infusion with additional nurse-administered boluses as needed. Medical caregivers had titrating orders to escalate doses of each of these medications, and integrative therapeutic modalities were also used, including child-life, music therapy, and massage.

Cathy’s mother recently wrote,
We are so thankful that we had you to help us get her to where she is now. If we hadn’t found a drug combination that helped her to stay comfortable until she was able to get her transplant, I do believe that she wouldn’t have made it. Yes it was scary having her on so much sedation but it kept her alive and look at her now.

Case discussion
Cathy’s case demonstrates that palliative care does not mean “to give up,” but to provide the best possible pain and symptom management using a combination of pharmacological and integrative, nonpharmacological treatment modalities. Pediatric palliative care helps manage the vast array of distressing symptoms that children with life-threatening, life-limiting, and terminal conditions experience. Although the majority of our young patients die, a subgroup of children will survive and ultimately “graduate” from palliative care, as illustrated in this case.

Persisting myths and misconceptions have led to inadequate symptom control in children with life-threatening or life-limiting conditions. One of the most enduring of these misconceptions is the idea that using opioids to successfully manage pain and dyspnea will hasten death; therefore, opioids should be administered only as a last resort. In fact, it is a common experience of pediatric palliative care teams that administering opioids or benzodiazepines and/or both together with other comfort measures for the relief of dyspnea and pain actually improves the quality of life of these children, who subsequently live longer than expected and with greater comfort.

Education about the use of opioids and an understanding that tolerance plus physical dependence does not equal addiction is an important principle in pediatric palliative care. Further, pediatric palliative care providers advocate for the provision of comfort care concurrent with curative treatments and excellent pain and symptom management. Families no longer have to choose to receive either palliative or curative care. They are able to pursue both options simultaneously to maximize the child’s quality of life.

References


Thomas Aquinas. d. 1274. Summa theologiae II-II.q.64a.7.

Stefan J. Friedrichsdorf, MD, is medical director of Pain and Palliative Care at Children’s Hospitals and Clinics of Minnesota, Minneapolis.

Kaci L. Osenga, MD, also practices in Pain and Palliative Care at Children’s Hospitals and Clinics of Minnesota.
between the ethical concepts that we draw on in pediatric cases and those we rely on for cases involving adults. In the typical adult care setting, respect for autonomy leads us to begin from the position that if the adult JW patient has decisional capacity and refuses a blood transfusion, he or she has a right to do so, and that right confers an obligation on physicians not to transfuse. However, the ethical situation changes dramatically when the JW patient is a child.

“The paramount operative value in adult bioethics is ‘respect’; in pediatric ethics it would seem to be ‘prevention’.”

While courts have stated that parents are not allowed to make martyrs of their children, the ethical concern can be specifically stated in human developmental terms: Young children are not yet mature enough to “own” the values their parents project upon them. As such, we must protect children from harm that might entail that they never have the chance to mature into their own values system and beliefs. And in fact, many children do grow and develop, and “maturity” has no clear standard determination. So, how do we approach the case of an adolescent JW patient? Can a fifteen-year-old be said to “own” his or her stated values?

Whichever way we answer that question, simply asking the question implies that an expansive dynamic is already at play in pediatric ethics. If the patient were an adult, the default is to assume that she or he does own his or her values, but as long as we see the patient as a child (however old), the default is to assume that maturity should be questioned.

Another way to look at the difference between adult and pediatric ethics is that whereas the paramount operative value in adult bioethics is “respect,” the paramount value in pediatric ethics would seem to be “protection.” In fact, the focus on protection becomes clear in the persistent arguments over the limits of parental authority and the threshold for state intervention. While there is certainly a “positive” concern to provide care that will help maximize developmental potential in children, much is written about the “minimal” conditions of providing children with their basic needs or protecting them from harm. This is no trivial matter as it is at the point where harm has significant weight that state authority becomes the preferred tool for protection.

A recent case involving a developmentally delayed nine year old, the “Ashley Case” (a.k.a. “Pillow Angel”) from Seattle is a good example of the kind of situation in which the limits of parental authority may be tested. Nine-year-old Ashley has static encephalopathy. She will never be capable of participating in the medical decisions that confront her. Since her other bodily systems are intact, her parents and medical caregivers realized that she would continue to grow in size. Her parents express deep concerns for her in several areas:

- They fear that she would become too large for them to handle or for her to be comfortable in her wheelchair.
- They fear that she would continue to develop sexually and that menstruating would cause stress and make hygiene difficult.
- They fear that should they have to put her in the care of persons outside the family, she may be improperly cared for or sexually abused.
- They requested, therefore, that doctors stop her development by giving her high-dose estrogen, performing a hysterectomy, and excising her breast buds. These actions were performed.

“IT IS NEVER ENOUGH TO TREAT PEDIATRIC ISSUES (WHETHER CLINICAL OR RESEARCH) AS MERELY A SPECIAL APPLICATION OF ADULT-CENTERED ETHICS.”

Ashley’s case clearly raises concerns about what is the appropriate scope for decision makers who are not themselves the patient. In this case, unlike in cases involving adults who lack decisional capacity, it is not a spouse or adult children making these decisions for their mature-yet-incapacitated loved one; instead, it is the child’s parents — persons in whom a great deal of decisional authority has been placed since her birth.

Pediatric ethics, then, persistently faces a consideration of the scope of parental authority — an authority that reigns from birth until at least adolescence (possibly farther). Parents have this authority for good reason — they bear the burdens of raising their children to adulthood, and they have psychological and social commitments that go beyond basic responsibility, often manifest as deep and abiding love and care.

At the same time, Ashley’s case raises concerns about protecting a child who cannot (will never be able to) protect herself from undue harm. These parental requests are unusual. The actions that Ashley’s parents request are irreversible. They pose some medical risk. They make a statement about how the parents, healthcare professionals, and society look at disabled children and
the difficulties they pose to themselves and others. As such, physicians, on-site caregivers, and the state through child protective services must account for their complicity in and agreement to these procedures. Physicians need not agree to perform such procedures and the state has a legal mechanism that can be used to stop them.

Table 1 illustrates the ethical differences between our typical default approaches to adult and pediatric care.

<table>
<thead>
<tr>
<th>Adult-care Ethical Presumptions</th>
<th>Pediatric-care Ethical Presumptions</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Presumption of patient autonomy</td>
<td>• Presumption of patient incapacity</td>
</tr>
<tr>
<td>• Presumption of maturity of values</td>
<td>• Presumption of patient innocence</td>
</tr>
<tr>
<td>• Presumption of obligation to respect</td>
<td>• Presumption of need to protect</td>
</tr>
<tr>
<td>• Presumption of family insight</td>
<td>• Presumption of parental authority</td>
</tr>
<tr>
<td>• Greater potential for conflict between respecting autonomy and providing “benefit”</td>
<td>• Greater potential for conflict between parental authority and avoiding harm</td>
</tr>
</tbody>
</table>

The basic point is simple: it is never enough to treat pediatric issues (whether clinical or research) as merely a special application of adult-centered ethics. Of course, each patient’s care poses novel concerns and issues, but the “class” of situations we call pediatric requires particular ethical insights and tools. The field of pediatric ethics provides a kind of specialized reflection on these issues to better fashion useful tools to do significant and useful moral work in the care of children.

D. Micah Hester, PhD, is assistant professor of medical humanities and pediatrics at the University of Arkansas for Medical Sciences, and clinical ethicist at Arkansas Children’s Hospital, Little Rock, Arkansas. He also coordinates the Pediatric Ethics Consortium (http://www.pediatricsethics.org).

Although Ashley’s case is unusual, it shares certain features with other controversial pediatric cases. The parents want one course of action. The doctors may or may not agree. The child cannot speak for herself. The treatment must be undertaken within some specific time frame if it is to be successful. The law is unclear.

“As children grow older, there is greater concern for their ability to make their own decisions.”

Table 1.—Comparison of Ethical Presumptions in Adult and Pediatric Ethics

As children grow older, there is greater concern for their ability to make their own decisions.
Bioethics and Pediatric Medicine

A Conversation with Kevin Kelly

Dr. Kevin Kelly, MD, is the Joyce C. Hall Distinguished Professor and Chair of Pediatrics and the Pediatrician in Chief at Children’s Mercy Hospitals & Clinics in Kansas City. He also serves as Associate Dean at the University of Missouri Kansas City – School of Medicine.

Dr. Kelly received his medical degree from the Loyola University – Stritch School of Medicine in Chicago. He is board certified in Pediatrics, Pediatric Critical Care, and Allergy/Immunology. He is internationally known for his sentinel work on latex allergy in children and adults. He has authored or coauthored nearly 200 original scientific papers, reviews, and abstracts.

Practical Bioethics visited with Dr. Kelly about his work, bioethics, and healthcare reform.

1. What attracted you to Children’s Mercy and Kansas City?

The answer to this question is easier in retrospect now that I know more about the community and hospital. Initially, I was attracted to Children’s Mercy Hospitals & Clinics the way a moth is attracted to the light. Both the children’s hospital and community of Kansas City exude warmth and provide a clear vision for advancement of pediatric health in the United States.

I spent my career trying to make a difference for children on a grander scale than just my individual care as a practitioner. I worked the majority of my patient care career in pediatric critical care and allergy/immunology, but I also worked regionally as the Chief Medical Officer for Children’s Specialty Group (a joint venture of the Medical College of Wisconsin and Children’s Hospital of Wisconsin) and served as the initial CEO for Medical College of Wisconsin’s Physicians & Clinics of Illinois. During the interview process for Pediatrician in Chief at Children’s Mercy, I was struck by the potential [Kansas City has] that so many other communities could not realize.

Children’s Mercy Hospitals & Clinics is one of the finest pediatric institutions in the country. The people who work here are passionate about providing the best possible care to all the children who need our specialized services. Having been part of two of the most highly regarded children’s hospitals in the past, I quickly saw that Children’s Mercy and Kansas City have the ability to create one of the finest pediatric health systems in the country. We can attract thought leaders and experts to this gracious community to provide the best care for children.

3. What are the biggest ethical controversies in pediatrics today?

One of the biggest controversies in the ethical care of children revolves around the role of informed consent and assent from children and families coupled with the role of the institutional review board (IRB). Children’s hospitals must always advance the care of patients through innovation, but questions have arisen as to whether informed consent can actually exist for pediatric research.

I refer you to an article by Dr. Eric Kodish in the Journal of Pediatrics (May 2007), which cogently outlines the concerns we face in pediatric informed consent. Pediatric ethics is not simple because the elements required for informed consent may not always exist. These elements include disclosure, understanding, competence, and an abil-

(Continued on page 14)
The recent debate over expanding the State Children’s Health Insurance Program (SCHIP) suggests the ways in which children are at the cutting edge of health policy debates. On the one hand, children are always a sympathetic subpopulation for programs of universal access. Numerous polls show that most Americans favor universal healthcare coverage for children, regardless of ability to pay. Furthermore, pediatric healthcare is relatively cheap. Most children are healthy.

For healthy children, healthcare costs are low and predictable. They need routine screening tests and immunizations. They need care for acute illnesses that are usually brief, self-limited, and treatable on an outpatient basis. A small percentage of children have high healthcare costs for conditions like premature birth, cancer, unintentional or intentional injuries, or chronic diseases like asthma, sickle cell disease, and diabetes. Children make up about a quarter of the United States population and account for only about 5 percent of our health costs.

Nevertheless, proposals to provide universal coverage for children inevitably founder on the fundamental ideological rift that runs through our national political life. Should healthcare be provided to all children as an entitlement, regardless of ability to pay? Or should it be a means-tested program, provided only to the poorest children whose parents cannot afford health insurance.

This debate surfaced in the Clinton administration’s 1993 National Vaccine Initiative. In this proposal, the administration sought to make the federal government the sole buyer of vaccines and to provide them to all children regardless of ability to pay or insurance status. They argued that this would save parents money and insure universal access. At the time, a full battery of immunizations cost $244 on the open market. The government could have bought the same package for $122.

Opponents of the program characterized it as expensive and unnecessary since many children had private insurance coverage for immunizations. They proposed, instead, that the program be means-tested and target only those children who could not otherwise afford immunizations. Proponents like Secretary of Health and Human Services Donna Shalala argued that a universal coverage program would be cheaper for all and would acknowledge that preventive medical services are a basic human right. “We don’t ‘means test’ the right to public education, to clean air or clean water.”

The result was a two-tiered system, one in which those children whose families had higher incomes or health insurance coverage would continue to pay privately for immunizations while the public program was smaller and more targeted to the poor. The total cost of immunizations for all American children was higher than it would have been under the National Vaccine Initiative but the government cost was lower. Such a compromise is emblematic of the United States approach to universal coverage. It is piecemeal, ideological, and more expensive. We seem willing to pay a premium to have a system that reinforces our anti-government political sentiments.

The SCHIP debate exquisitely reflected this ideological polarization. SCHIP was created in 1997 as an optional expansion of Medicaid. It was passed by a Republican-controlled Congress and signed into law by
President Clinton. It was designed to provide coverage to low-income children who were uninsured and not eligible for Medicaid. Typically, they were families with incomes up to 200 percent of the federal poverty level, or about $41,300 for a family of four in 2007.

“Proposals to provide universal coverage for children inevitably founder on the fundamental ideological rift that runs through our national political life.”

President Bush vetoed the expansion of the program. He explained,

This bill would shift SCHIP away from its original purpose and turn it into a program that would cover children from some families of four earning almost $83,000 a year. In addition . . . government coverage would displace private health insurance for many children. . . . The bill also does not fully fund all of its new spending, obscuring the true cost of the bill’s expansion of SCHIP, and it raises taxes on working Americans. SCHIP is an incremental step toward the goal of government-run healthcare for every American.

One of the sponsors of the bill, Republican Charles Grassley, disputed these points:

The compromise bill discourages states from covering higher-income kids by reducing the federal matching rate for states that wish to expand eligibility over 300 percent of federal poverty limits. It rewards states that cover more low-income kids by providing targeted incentives. . . . So there is a very clear message to states . . . don’t spend money on higher-income kids unless you can prove that your state is covering your lower-income kids first. It is all there in black and white.

Health policy analyst John Iglehart characterized the debate as a “surrogate marker for healthcare ideology.”

Gail Wilensky, former administrator of the government Healthcare Financing Authority, noted that the real questions at stake in the SCHIP debate were ones about the nature and extent of the government’s role in financing healthcare for children,

Do we mean to publicly fund coverage for all below twice the poverty line or at least for those who do not have or choose employer-sponsored insurance? Are we willing to make the same commitment to those at three or four times the poverty line?

Hillary Clinton has proposed expanding SCHIP to cover all children living in families with incomes up to four times the federal poverty level.

“Polls show that most Americans favor universal healthcare coverage for children, regardless of ability to pay.”

On the other side of the ideological divide, Senators Richard Burr (R-NC) and Tom Coburn (R-OK) introduced the Health Care Choice Act of 2007. This bill proposes a universal healthcare tax credit, capped at $2,000 for individuals and $5,000 for families. They also want states to dismantle regulatory obstacles and create competitive marketplaces where individuals could buy the health insurance plan that best suits their needs, thereby lowering the cost of coverage. It is unclear what would happen, under such a plan, to those whose incomes are so low that they would not benefit from a tax credit.

In the run up to the next election, there seems to be an unbreakable stalemate between these two approaches to healthcare. The President and enough members of Congress oppose expansion of government programs to insure that proposals cannot pass. Most Americans seem to favor such expansions, at least for children. If the Democrats gain control of the White House and increase their majorities in Congress, the dynamic may change. The question then will be one of trying to harmonize disparate philosophies on the left, and appeasing various interest groups and stakeholders. It seems, though, that in 2009, for the first time in forty years, there may be the political will and the political dynamics in Washington to make significant reforms in the way we provide healthcare, at least for children.

Notes


John D. Lantos, MD, author of Do We Still Need Doctors?, is the John B. Francis Chair in Bioethics at the Center for Practical Bioethics. He is nationally recognized for his leadership in bioethics and pediatric medicine.
In a recent essay on treatment decisions for newborns, Robert Truog, director of clinical ethics at Harvard Medical School (2007), noted the great diversity of perspectives and cultural norms present in the United States. He proposed that respect for differing perspectives and minority viewpoints should lead physicians to tolerate the treatment choice of parents “even when we believe they are wrong.”

Truog’s position represents a dramatic shift from the consensus developed over the last forty years in neonatal ethics that the standard of care for newborns — who, unlike adults, are not able to formulate or articulate their personal values — should be the “best interests of the infant” (Paris, Ferranti, and Reardon, 2001).

That standard, unlike the “autonomy” model that prevails for competent adults, does not rest on the value of self-determination. Rather, it focuses on the protection of the patient’s welfare. Such protection is particularly important with regard to infants because they are seen not merely as the property of the parents, but as patients with personal interests and rights.

Two recent publications, the extensive report of the Nuffield Council on Bioethics in Britain on the “Critical Care Decisions in Fetal and Neonatal Medicine” (2006) and the policy statement of the American Academy of Pediatrics (AAP) on “Noninitiation or Withdrawal of Intensive Care for High-Risk Newborns” (2007), address the issue of caring for newborns born at the margins of viability. Where Truog yields the decision to the parents even over and against physicians’ objections that the decision in a particular case is “wrong,” the Nuffield Council and the AAP take the position that newborns are to be treated as any other patient — on the basis of their best interests. The implication is that although parents may and should continue to be involved in decision making for their children, they do not have the exclusive right to refuse — or demand — medical treatments for the child.

Although there is a wide range of interpretations as to what might constitute “best interests” in a marginally viable newborn, the Council Report concurs with the American Academy of Pediatrics’ position that treatment decisions for these infants can be divided into three categories:

1. When early death is very likely and survival would be accompanied by a high risk of unacceptably severe morbidity, intensive care is not indicated.
2. When survival is likely and the risk of unacceptably severe morbidity is low, intensive care is indicated.
3. In the “gray area” — where prognosis is uncertain but likely to be very poor and survival associated with a diminished quality of life — parental desires should determine the treatment approach.

When health professionals and parents agree on the level of care, there are no ethical problems on treatment choice. Difficulties arise when caregivers and families disagree on the care to be provided. Parents may demand that aggressive treatment be continued when in the medical team’s judgment such interventions are unavailing or inappropriate. Or parents may oppose treatments that the physician believes would offer substantial benefits to the baby.
In such cases, Truog advises deferring to the parents or seeking court intervention. The Nuffield Council cautions that going to court should be used as a last resort. Even then judicial involvement should be sought only when it is believed that what is being insisted on by one of the parties is wholly antithetical to the welfare of the baby.

A word of caution here is the observation that no American court has ever approved the withdrawal of a life-prolonging procedure over a family’s objections (Paris, Billings, et al., 2006). Further, going to court results in a costly and cumbersome adversarial process that ruptures the physician-family relationship and shifts attention from the clinical situation of the infant.

To obviate clashes between parents and physicians on treatment choices it is advisable, whenever possible, that prior to a delivery of an extremely premature infant parents jointly with the obstetrician and a neonatologist discuss survival rates and severity of potential disabilities. All involved should understand the provisional status of pre-delivery plans and the need for clinical assessment of the newborn to confirm pre-delivery assessments.

If the circumstance of the birth precludes prior discussion, the physician has the responsibility of making a clinical assessment of the infant’s condition at birth and then a judgment on whether or not to initiate resuscitation. In case of doubt, the physician should err on the side of treatment both to allow time for subsequent discussion with the parents and to formulate a more accurate evaluation of the infant’s status.

In making a decision, it is not rigid rules that are called for but a realistic assessment of the infant’s physical condition based on current data from the medical literature on survival and disability and the outcome data in the particular hospital. It is also important to be sensitive to differing cultural norms and family values. As in all medical decision making, the primary consideration in treatment decisions for newborns at the margins of viability is, and will continue to be, a commitment to act in the best interests of the patient.

**References**


John J. Paris, SJ, PhD, is Walsh Professor of Bioethics at Boston College, Chestnut Hill, Massachusetts.
Beginning just a few weeks after the Food and Drug Administration’s approval of the Gardasil vaccine, legislators in twenty-one states drafted bills to make human papillomavirus (HPV) immunization of eleven- and twelve-year-old girls a requirement for school entry.

This rush to mandate immunization, however well meaning, goes against the grain of some well-established decision-making processes. Typically, mandated vaccinations are approved after years of scientific study, activism, and negotiation. Mandating a vaccine is a big and, in this case expensive, public health step that requires thoughtful discourse.

Those who propose mandates offer compelling evidence in their favor:

HPV infections are common. By the time an American woman turns fifty, there’s an 80 percent chance she has, or has had, a genital HPV infection.

Cervical cancers kill. The American Cancer Society estimates that 11,150 new cases of cervical cancer occurred in 2007, and 3,670 women died of the disease. The emotional cost of HPV-associated diseases is also high: Just ask any woman who has been told that she has an abnormal Pap smear.

If the vaccine is given prior to exposure to HPVs (i.e., prior to the onset of sexual activity) there is justifiable hope that, with sufficiently high rates of immunization, herd immunity will confer protection even to the unimmunized.

Finally, mandating vaccination, at least as far as childhood vaccines go, increases immunization rates.

Given these arguments, mandatory immunization presents itself as an obvious choice; however, before we go committing large sums of public money, we should look at reasons not to mandate HPV immunization.

Perhaps the greatest barrier is cost. Vaccine acquisition cost is $120 per dose. Paying for a three-dose regimen, and assuming a $30 administrative cost per dose makes the total cost $450 per vaccination. Multiplying this cost times two million (the female annual birth cohort in the United States) gives a total cost of almost $1 billion.

Central to any decision to mandate a vaccine should be an analysis of costs and benefits. Simply put, will the money spent paying for and administering the HPV vaccine reduce the future costs extended for the care of women with HPV-related diseases? Currently, 90 percent of the cost of prevention and treatment of HPV disease is Pap screening. Because the HPV vaccine prevents only 70 percent of high-grade cervical dysplasias and cervical cancers, immunization does not excuse us from continuing screening programs. The vaccine will suspend only a small portion of the cost of preventing and treating HPV-related diseases.

Immunization mandates for school attendance raise other questions. Are we mandating the vaccine for the right reasons? In contrast to polio, measles, mumps, and pertussis transmission, transmission of HPV is anything but casual. Is it right to require for school attendance immunization for a disease not acquired at school? Mandated immunization to prevent polio, measles, mumps, and pertussis was readily accepted in part because disease morbidity was high, mortality was significant, and there were no treatments to change the course of these diseases.

“The rush to mandate immunization, however well meaning, goes against the grain of some well-established decision-making processes.”

Treating HPV-associated diseases is expensive. An estimated $3.4 billion is spent annually in the United States on screening and treating cervical cancers and pre-cancers; another $200 million is spent treating genital warts.

The emotional cost of HPV-related diseases is high.
Human Papillomavirus Vaccine

life-threatening infections. In contrast, HPV-related morbidity generally is low, and appropriate treatment of a woman’s cervical dysplasia almost eliminates the likelihood of her developing cervical cancer. Because of present-day screening, progression to cervical cancer is becoming increasingly rare; indeed, cervical cancer rates are dropping about 4.5 percent each year.

Some object to promotion of the HPV vaccine on moral and religious grounds. Many argue that immunizing adolescents against a sexually transmitted infection gives tacit permission for premarital sexual activity. Others argue that the reduction of cervical cancer risk removes cancer as a potential penalty for premarital sex. Ethicists pose other questions: Do immunization mandates intrude on parental rights? If so, do the individual and societal benefits of immunization warrant overriding parental autonomy?

“Will there ultimately be a time for mandating HPV immunization of teenage girls?”

Considering the arguments for and against mandatory immunization, my views are as follows:

Is this a good vaccine? Yes. It has the potential to prevent a significant amount of human misery and a relatively small number of deaths. How do I feel about the vaccine? Following lengthy discussions with each of them, my teenaged daughters both have received their three-dose series. They also got flu shots. The HPV vaccine has led to a lot of open, honest discussion between our daughters and my wife and me.

Can cervical cancer be prevented in less expensive ways? Pap screening will remain an essential part of women’s healthcare for the foreseeable future. Pap screening may still be less expensive and every bit as effective for cancer prevention as mandated vaccination; we don’t know yet.

Can cervical cancer be prevented in ways that are less intrusive? Abstinence programs aren’t as effective as advocates would have you believe. Compared with inflicted morality, immunization will be a lot less painful, and will work a whole lot better.

Will immunization promote premarital sex? This is a new verse to an old song. Similar charges have been leveled against the introduction of oral contraceptives, the proposed use of an HIV vaccine, the use of the morning after pill, and the appearance of Elvis Presley on the Ed Sullivan Show. My reading of the medical literature leads me to believe that none of these has led to increases in sexual activity. The HPV vaccine won’t either.

Should we mandate the HPV vaccine as a school requirement? There is no doubt that this is a good vaccine capable of preventing cervical cancer. What remains unsettled is whether mandating immunization is the best use of our healthcare dollars.

Before we mandate HPV immunization, we need to have more discussion to make sure that our priorities are in order. In the bigger picture of life for American women, cervical cancer is an uncommon cause of death; Pap smears have seen to that. Instead, accidents, homicides and suicides rank among the leading preventable causes of death of young women.

I recently read in the Chicago Tribune about the crash of a car loaded with nine teens; five died. None wore a seatbelt. As often occurs, alcohol was involved. For $450 per girl in the car, might we have been able to prevent such an accident? Perhaps the money would be better spent putting police on the streets, alcohol abuse prevention programs in schools, or teen-oriented alcoholism treatment programs in our communities.

“Do immunization mandates intrude on parental rights? If so, do the individual and societal benefits of immunization warrant overriding parental autonomy?”

However well intentioned, our immediate desire to prevent cervical cancer with a vaccine may not be good public policy. Before we leap into mandating HPV immunization, we should first assure ourselves that we are getting the maximum benefit from the dollars we spend. To do this, we must have time to deliberate.

Will there ultimately be a time for mandating HPV immunization of teenage girls? Probably, yes. Are we ready to do that now? No, not yet.

Kenneth Alexander, MD, PhD, is associate professor of pediatrics and chief of the section of Pediatric Infectious Diseases at the University of Chicago. His research interests include basic science studies of papillomavirus replication and transcription, viral interactions with the innate immune system, and promotion of immunization among medically underserved adolescents.
Finally, I discuss the prospects for health reform in pediatrics in the next few years. There seems to be more political will for change than there has been for at least a decade. The political configuration in Washington after the November elections will determine whether that political will can be harnessed to meaningful reform.

The unifying theme of all these issues is that they all concern children and reflect the central concern of pediatric bioethics – the best interest of the child. That focus demands a different sort of moral reasoning from that which prevails in adult bioethics with its intense focus on patient autonomy. Pediatric bioethics is less about the rights of patients than it is about the duties and obligations of caregivers.

As a pediatrician, I talk about healthcare differently than many other people do. I believe that the average person thinks of healthcare as a system of hospitals, clinics, doctors, providers, pharmacists, and diagnostic testing centers. We spend most of the money on what Dr. Brent James, one of the world’s premier quality healthcare leaders at Intermountain Healthcare, refers to as “rescue care.” In reality, 90 percent of the “health equation” is determined by behavior (e.g., the use of alcohol, drugs, or tobacco and obesity), genetics (we are our parents), and environment (e.g., clean water, safe food, car seats, bike helmets).

When people talk about infant mortality rates and healthcare being a problem in the United States, they are not talking about rescue care! The United States does “rescue care” better than any country in the world. I would not have my child’s heart operated on anywhere in the world except in the U.S. health system. However, if I wanted to prevent what could be prevented, then I might live elsewhere.

We do not spend enough of our energy (i.e., money) on prevention. If people agree that full healthcare reform involves changes in behavior and environment in the context of genetics, then we may get somewhere. Right now, failure to invest in health promotion has left us where we are. Despite my “glass half full” approach to many things, I tend to only hear us focusing on “healthcare payment” reform. I am hopeful that future conversations will also consider functional healthcare reform so that we become the greatest national model of disease prevention and delivery of healthcare.
Greg, sixteen years old, is the only son of a farm family in rural Decatur county. Diagnosed with acute lymphocytic leukemia when he was seven, Greg was sent to live with his uncle so that he could be treated at a pediatric oncology center. His family, especially his mother visited him in the hospital, and each time Greg begged her to take him home.

His mother comforted him but insisted that he stay with her brother until the initial chemo and radiation treatments were complete and through the second phase of high-dose chemotherapy that the doctors hoped would prevent the cancer from spreading to the brain and spinal cord. When, at last, the doctors told the family that the cancer was in remission, they also said they were confident that Greg could get his maintenance chemotherapy closer to home.

Greg’s return was wildly celebrated, but from the beginning he had difficulty adjusting. He had trouble concentrating on his schoolwork, and his bones and joints ached so that he had trouble getting anywhere on time. His father coached him: “Come on, Son, it’s over, you’ve got to try harder.”

During the past year and a half, he has had multiple relapses. He has been in and out of the county hospital innumerable times. His current chemotherapy regimen involves treatment every two weeks, and he is experiencing a significant amount of nausea and vomiting. During the two-week period of each course, he feels well for five to seven days. Then the cycle starts again.

Greg is “fed up” with chemotherapy, he tells his older sister, one of three who drives him back and forth for treatments. He is “tired of being miserable most of the time,” and “tired of being tired.” Later, he begins to talk with his sisters and tentatively to his doctor about stopping treatment. He is aware that without chemotherapy he will soon die, and he has a realistic understanding of what death means.

The sisters panic and tell their parents about Greg’s thoughts. His parents do not want to stop treatment. They believe that the chemotherapy may result in remission for a significant period of time.

Case Studies are a regular feature of Practical Bioethics. For more cases, visit www.practicalbioethics.org or ask about our online discussion group. We welcome your response to this case. Please email your comments on this case to bioethic@practicalbioethics.org.

Reflect on and discuss the following questions with your ethics committee or other colleagues. Then compare your responses with Rosemary Flanigan’s commentary on page 16.

1. Role play the exchange that takes place when Greg’s older sister comes to the hospital to drive him home, and the two of them talk to Greg’s doctor.
2. Role play the exchange that takes place when Greg’s parents, his sisters and Greg confront the issue of stopping treatment.
3. Discuss Greg’s decision-making capacity; justify your conclusion.
4. What is the strongest argument supporting the position that minors with decisional capacity should be allowed to make treatment decisions?
5. What is the strongest counter-argument?
6. How can one convince parents that children with developing decision-making capacity ought to have more to say about their treatment?
7. How would you argue Greg’s right to name a surrogate decision-maker other than his parents if his parents fail to agree with him?
8. Conflict resolution in this encounter is paramount. What elements of conflict resolution are especially relevant here?

©stockexpert.com/Bina Sveda

“From the beginning, he had difficulty adjusting.”

Rosemary Flanigan, PhD, is professor emeritus of Rockhurst University and a program Associate in clinical and organizational ethics at the Center for Practical Bioethics.
Among the questions raised by Greg’s desire to discontinue treatment is the bearing that age has on the capacity of a person to make autonomous decisions. Is Greg’s judgment, however much it contradicts his parents’ wishes, one that he and they can trust? It is not apparently a snap judgment although it doesn’t appear to have been fully formed when he first mentioned the idea to his sister. “Later,” the case continues, “he begins to talk with his sisters and tentatively to the doctor about stopping treatment.” What weight should be given to his experience and developing ability to participate in decisions affecting his future?

In 1991, Midwest Bioethics Center (now the Center for Practical Bioethics) convened a task force to study issues relating to the participation of children in decision making regarding their care. The task force began by distinguishing three classes of minors:

- Those without the capacity to participate in decision making in a meaningful way (e.g., infants, toddlers, pre-school age children).
- Those with a developing capacity to participate (e.g., elementary school-aged children).
- Those who have achieved the capacity to make most healthcare decisions (e.g., mature minors, emancipated minors, and most senior high school-aged young adults).

The task force then proposed a model that honors children in all three categories. The most important component of the model is child assent. Believing strongly that minors exhibit a developing capacity for autonomy and participation and have an evolving sense of self and their own life stories, the task force proposed that healthcare providers always solicit the child’s assent to any healthcare treatment. Assent is the free expression of a child’s willingness to undergo a specific treatment based on the child’s knowledge and understanding.

Second, while recognizing that parents and guardians have a legal right to consent to their children’s healthcare treatment, the task force proposed the concept of informed parental/guardian permission in lieu of parental consent. Informed parental/guardian permission is a process by which the parents or guardians of minors grant or deny permission to the provision of recommended healthcare interventions for children or wards.

Third, the task force proposed that the age of decision making for healthcare treatment should reflect the fact that many minors achieve decisional capacity at much earlier ages than is recognized legally. Therefore, the task force proposed that all persons with decisional capacity have the right to make healthcare treatment decisions, that is, are capable of engaging in the informed consent process.

Applying these insights to Greg’s case means seeing him as among that group named “mature minors.” At a minimum, it should be determined that Greg understands his health problem, his treatment options and their potential benefits and burdens, and the consequences of treatment options, including nontreatment. To this end, it is essential that the best clinical judgment be secured about whether chemotherapy may result in remission for a significant period of time. Much of Greg’s “fed-up-ness” centers around not seeing that an end is in sight.

The ultimate commitment of the task force was to a shared decision making model, one that respects the importance and distinct roles of children, parents, and providers. In that sense, it is of paramount importance that a trusted friend of both Greg and his parents be present during the discussions. In conflict resolution, this trusted friend will play a major role.