



# Ethical Considerations in Pediatric Surgery

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## Abstract

Ethical issues arise in pediatric surgery when difficult decisions must be made in the presence of uncertainty or conflict, and stakeholders are concerned about quality of life, informed decision-making, and access to scarce medical resources. This chapter provides the pediatric surgeon with a framework for ethical decision-making that relies on a best interest standard and includes a definition of this standard and also the appropriate application and limitations of the best interest

standard. Decision-making for adolescents includes a discussion of informed consent and assent. The best interest standard is discussed in the context of multiculturalism. Other issues include prenatal surgical consultation and fetal surgery, bariatric surgery, conflicts of interest, errors and innovation, and clinical research.

### Keywords

Ethical decision-making · Best interest standard · Informed consent and assent · Multiculturalism · Fetal surgery · Bariatric surgery · Conflicts of interest · Surgical errors · Innovation and research

## Introduction

In caring for the extremely premature neonate, the infant with multiple, life-threatening congenital anomalies or the child or adolescent with surgical disease, pediatric surgeons often encounter difficult ethical decisions about the use of advanced, life-sustaining treatments and operative interventions. The imperative to utilize new technology is tempered with concerns about quality of life, informed parental decision-making, and access to scarce medical resources. Pediatric surgeons, families, and communities ask the difficult ethical question: “We can do this particular intervention, but, should we?” This chapter provides the pediatric surgeon with ethical guidelines to utilize in clinical situations in which therapeutic decisions contain uncertainty or conflict and the next steps in the management of an infant, child, or adolescent pose challenges for the patient, parents, and physicians.

## Defining the Best Interests Standard

Since neonates, infants, and children cannot make decisions about the appropriate use of technology based on their own personal values, the central ethical question is framed in pediatrics as, “What is in the best interests of this infant or child?” An answer requires a unique and complex ethical framework that combines a concern for who

makes the decision and what decision is appropriate.

This best interest standard is based on several ethical principles and virtues. Beauchamp and Childress have articulated certain principles that are foundational in biomedical ethics (Beauchamp and Childress 2013). These principles include beneficence, non-maleficence, autonomy, and justice. The first two of these principles, beneficence and non-maleficence, refer to the obligation to promote the well-being of patients and to “do no harm.” The other two principles are based on relatively recent concepts. Respect for autonomy (self-rule) refers to the obligation to respect the right of competent persons to give informed consent for medical treatment and have control over their bodies, and justice refers to non-discrimination or involves the fair and equitable distribution of the benefits (and risks) of medical care to all persons.

Although principle- and duty-based ethics are prominent in contemporary bioethics, some ethicists make a strong case for virtue-based ethics. Pellegrino and Thomasma argue that virtue is derivable from the nature of medicine as a human activity and is an irreducible element in medical ethics (Pellegrino and Thomasma 1993). While ethical principles focus on the action or actions that give rise to ethical issues, virtue ethics emphasizes the moral character of agents (physicians). Pellegrino and Thomasma cite the relevance of such virtues as trust, compassion, prudence (cautiousness), justice, courage, phronesis (practical wisdom or common sense), fortitude, integrity, honesty, and self-effacement (Pellegrino and Thomasma 1993). In practice, a surgeon’s behavior is shaped both by the core ethical principles and by the special bond that sickness and the response to it creates between healer and patient. Additionally, pediatric surgeons are challenged by issues that are unique to surgery and the care of infants and children.

One of the most unique factors in pediatric ethics is that infants and children cannot decide for themselves. In the USA, parents are presumed to be the appropriate decision-makers for their infants and children (American Academy of Pediatrics Committee on Bioethics 1995), but they are

not unqualified decision-makers. Parents and pediatric surgeons must work together to make decisions that are in the “best interests” of infants and children (American Academy of Pediatrics Committee on Bioethics 1996). The term “best interests” is meant to capture a balancing of the benefits and burdens to this infant or child of a particular intervention.

In the mainstream medical culture in the USA, the term “best interests” was developed to focus attention on the need to assess the benefits and burdens of treatment for a particular infant or child from the infant’s or child’s perspective. In an effort to be as objective as possible, only the direct pain and suffering associated with an infant’s or child’s condition and/or proposed treatment was to be considered in conjunction with the benefit of continued life. The standard was proposed as a very strict one, regarding treatment as beneficial and in the infant’s or child’s best interest unless the infant or child were dying, the treatment was medically contraindicated, or continued life would be worse for the infant/child than an early death. A central feature of this narrow understanding of best interests includes its child centeredness, understood to mean the exclusion from consideration of the negative effects of an impaired infant’s or child’s life on other persons, including parents, siblings, and society.

A second key feature is its emphasis on the infant’s/child’s concrete experience of burden in the form of pain and suffering. In addition to the difficulties associated with assessing the burdens experienced by an infant/child, a narrow best interest standard cannot be applied to neonates and infants/children with neurological deficits so severe as to exclude the possibility of experience of any sort. Infants and children, who are not responsive to outside stimuli, for example, cannot experience pain and therefore cannot be burdened in the same way as conscious infants and children.

Some ethicists have appropriately pointed out that absence of pain is not the only morally relevant feature (McCormick 1974). A “relational potential” standard is necessary to augment a best interest standard. It is not morally obligatory to sustain life without any capacity for human relationship, even though life is not burdensome

per se. Just as the presence of pain unable to be relieved can preclude the attainment of those basic human goods that make life worth living, so the absence of fundamental human capacity can render a life devoid of the same basic human goods.

For the last few decades, the best interest standard has enjoyed prominence in pediatric ethics in the USA, although its limitations have also been clearly articulated. Critics argue that an infant’s interests are unknowable, that an interest’s appeal can yield counterintuitive results, and that others’ interests also deserve consideration.

An expanded understanding of best interests must take into consideration several competing ethical values. One value is respect for family autonomy or self-determination. Families ought to have the freedom to make important choices about family welfare independent of others. It is not so much that families have a right to make important decisions for their infants, as it is that families have the responsibility to make decisions and provide the necessary financial and other types of support. Families are an essential unit of care that is both valuable in themselves and instrumentally valuable to meet the social goal of caring for children. Since families are presumed to love their children and desire to do what is best for them, they have a unique claim to the decision-making role. Also, families have to live with the consequences of the health-care decisions that are made (American Academy of Pediatrics Committee on Hospital Care, Institute for Family-Centered Care 2003).

In a very real sense, the families’ interests are linked with the interests of the neonate or infant/child. An attempt to starkly separate infant/child and family interests is artificial and diminishes rather than enhances an understanding of the infant’s or child’s well-being. One can understand how the best interest standard developed in the context of imperiled newborns, where there is great uncertainty and no one has a longstanding relationship with the infant. The objectivity sought is comprehensible only because the infant is a stranger to all. Yet even in the case of newborns, most authors agree that parents should be the primary decision-makers. If family interests were irrelevant, it would be difficult to make sense

of such a presumption. Given this presumption in favor of parental decision-making and the fact that most infants are not strangers to their parents, a best interest standard would be better understood to include a more comprehensive understanding of a child-centered decision, one made by a family whose daily lives involve the love and care of their infant or child.

Another value that is in tension with respect for family decision-making is respect for professional integrity. Since “best interests” also contain an important focus on the uniquely medical interests of the infant, professional judgment plays an important role in describing and evaluating the benefits and burdens of health-care interventions (Baylis and Caniano 1997). Pediatric surgeons have independent obligations to the infants who are their patients, to promote their well-being and protect them from harm. They have a professional obligation to promote life and quality of life and to avoid such harms as killing, premature death, pain, and suffering. Little (2001) has identified five pillars of the surgeon-patient relationship: rescue, proximity, ordeal, aftermath, and presence. Although present in other therapeutic relationships as well, they have a special intensity in surgery. The term *rescue* acknowledges the elements of surrender and dependency that patients and their families experience when they have little control over the proposed surgical remedy. *Proximity* refers to the surgeons’ acknowledgment of the close, intimate interactions they have with their patients. *Presence* refers to both the virtue and duty to be visible and engaged throughout the entire surgical experience. In pediatric surgery, this professional obligation extends to the long-term follow-up of their patients, often into young adulthood.

A third important value in the discussion of best interest is that of justice as nondiscrimination (McCormick 1974). How do we understand the interests of a child in himself or herself, independent of how others may value him or her? What does society owe its children as a matter of justice? Infants do not only belong to their families, but they also are members of their community. Communities have an obligation to protect the most vulnerable among them, especially if they

are vulnerable to the neglect and abuse of their families. All infants deserve a certain level of health care, independent of what their families might choose for them.

An expanded “best interests” standard is an attempt to balance the benefits and burdens of a health-care intervention according to the values of the parents, pediatric surgeons, and the larger society. It should be clear that the model described represents its application in the dominant medical culture in the USA. Firstly, other cultures and countries may have a different understanding of what constitutes family and necessarily include others besides parents. Perhaps others, such as family elders, are the persons designated as decision-makers. Secondly, this particular model is based on Western notions of the importance of informed consent and respect for the autonomy (self-determination) of the patient and the family in the case of pediatrics. In other cultures and countries, families may not see their role as decision-makers at all but only in terms of doing what the doctor orders. Also, other cultures and countries may emphasize other core values such as responsibility to the larger family and community rather than autonomy (self-determination). Finally, the model described presumes a certain access to technology that is primarily available in developed nations. A concern for quality of life is different in developed nations where the issue may be the result of technology that is able to save life of diminished quality, as opposed to developing nations where diminished quality of life may be primarily a consequence of inadequate access to basic health-care services.

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### Applying the Best Interests Standard

How does the best interest standard work in practice? It must be remembered that the term is just a placeholder for a complex structure of values that must themselves be interpreted and applied. It is not possible to use the label “best interests” and expect it to do the moral work for us. It is always necessary to discuss the particular benefits and burdens of an intervention, according to the evaluations of all the parties involved. No one party

has a privileged view of the best interests of the infant.

Consider, for example, an infant born with an intestinal atresia. There are no associated anomalies and the infant cannot survive without operative correction. The pediatric surgeon recommends surgery to the parents because surgery would be in the best interests of their infant. The pediatric surgeon means, by the use of the term, that the possible benefits to the infant (life, restoration of function, reduction of pain, and suffering) outweigh the possible burdens (time in the hospital away from family, risk of death associated with anesthesia, pain and suffering associated with testing and interventions, and risk of compromised function). The calculation of best interests is based on the infant's diagnosis, prognosis, available treatment options, and the likelihood of their success. The anomaly is fatal without intervention, and the surgery is relatively low risk with a high likelihood of success. The pediatric surgeon wishes to preserve professional integrity by fulfilling the ethical obligations to promote the infant's welfare by saving the infant's life and restoring function and protecting the infant from harm. The pediatric surgeon is acting upon the values of what it means to be a "good physician."

Most parents would agree that surgery for an intestinal atresia is in the best interests of their infant. Out of their values to be "good parents," they strive to promote their infant's welfare and cope with the burdens placed on their infant and upon themselves. Most parents would agree that the outcome is good (life and restored function) and the surgery has a high likelihood of success with minimum burden (surgery, recovery time, and associated costs). Parents who refused such surgery in the USA would most likely be accused of medical neglect, and the power of the state would most likely be used to insure that the infant received the necessary care.

In other situations, a pediatric surgeon and parents may agree that stopping life-sustaining treatment would be in the best interests of a particular infant. For example, consider the case of a 23-week-old infant weighing 600 g who develops necrotizing enterocolitis (NEC). Following an

operation that leaves 15 cm of small intestine, the infant develops a grade IV intraventricular hemorrhage, worsening lung disease, renal failure, and ongoing sepsis. In this case, the mortality rate of the condition is very high, and the infant's quality of life is affected by the associated neurological, renal, and pulmonary complications. A pediatric surgeon and parents would be justified in withdrawing life support and instituting comfort care for this infant. It could be argued that it would be inappropriate to subject this already vulnerable infant, with little or no potential to interact with the environment, to the substantial burdens of life-sustaining technology for devastating bowel disease and compromised pulmonary and renal function. None of the treatments for devastating bowel disease, such as further surgery, the use of total parenteral nutrition (TPN), or a bowel transplant, would improve the infant's neurological condition. With little or no opportunity to experience things such as pleasure or comfort that we regard as benefits, inflicting pain or separation from family could be viewed as disproportionately burdensome or not necessary according to a relational potential standard.

Although most health-care professionals and parents would agree that further interventions are not in this infant's best interests, some parents would disagree and insist that "everything possible be done." In the USA, it is a very difficult matter both ethically and legally to stop life-sustaining treatment over the objections of the parents. Conflict resolution depends on a trusting relationship between the pediatric surgeon and the family. The family must be able to trust the pediatric surgeon so that they can rely on the pediatric surgeon's judgment. This trust begins with the pediatric surgeon's honesty: the commitment to disclose all relevant information, to insure that families understand what is being said and to respond to the questions and concerns of the family. Pediatric surgeons must also be compassionate, feeling for the infant and with the family as they endure this critical illness. The family needs to know not only that the pediatric surgeon cares for and about them and their infant, but that the pediatric surgeon will not abandon them on this difficult journey. It is vital in these so-called

“futility” cases, to understand just what the family means when they say “everything possible should be done.” The conflict may be a matter of misunderstanding the diagnosis and prognosis, and such false expectations can be often corrected with open, ongoing communication. But sometimes there is a real conflict between the values of the pediatric surgeon, the entire neonatal health-care team, and the values of the family.

Because families may differ in how they make value judgments about what constitutes an acceptable quality of life for their infants, it is essential to be able to elicit information about values and preferences from families. The authors have found the following questions useful. The questions are intended as subject guides only; each clinician must translate the questions into his or her own style:

1. What is your understanding of your baby’s/child’s current condition?
2. How has your baby’s/child’s illness affected your family?
3. What is most important in the care of your baby/child?
4. What do you fear the most? What would you like to avoid?
5. What are your family’s sources of strength and support?

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## Guidelines for Ethical Decision-Making

Ethical dilemmas most often arise when parents and pediatric surgeons disagree about what constitutes an acceptable quality of life or what constitutes the best interest of the infant or child. Whose judgment should prevail?

Pediatric surgeons can help insure that their ethical judgments are reliable through the application of an organized process (Little 2001). There are multiple versions available in the ethics literature, but they generally all contain the following components:

1. Identify the decision-makers. Are the parents involved? Are there nonparental legal guardians? Do the parents have the capacity to make

a decision? Who are the involved clinicians? Is the parent a mature minor?

2. Gather the relevant medical facts. What is the diagnosis? What is the prognosis? Are additional tests necessary for further clarification? Is there necessary information to be gathered from other clinicians?
3. Solicit value data from all involved parties. Do conflicts exist among the values of the patient, parents, other family members, and the physicians? Has the basis for the conflict been identified?
4. Define the available treatment options. With each option, what is the likelihood of cure or amelioration? What are the risks of an adverse effect? What is a minimum level of professionally acceptable treatment?
5. Evaluate possible treatment options and make a recommendation. Justify your choice according to the values of the various parties.
6. Achieve a consensus resolution. Have all parties articulated their viewpoint? Would more factual information help to resolve any disputes? Would a mediator (ethics consultant, ethics committee, or other trusted third party) be helpful?

Most of the time, ethical conflicts between pediatric surgeons and parents can be resolved with further communication, negotiation, and accommodation. But sometimes the conflict is so severe that the pediatric surgeons should consider appealing to an outside resource such as an ethics committee or withdrawing from the case based on conscientious objections.

The threshold is high for involving the courts in a decision about surgery for a neonate, infant, or child. Pediatric surgeons should invoke the power of the state to secure treatment for an infant or child only when that treatment is universally regarded as beneficial and the appropriate standard of care, making parental refusal equivalent to medical neglect, as in the previously cited case of the infant with an intestinal atresia (Glover and Caniano 2000). The classic case for court intervention involves treatment for a life-threatening condition in which the benefits are substantial and the burdens minimal, such as court-ordered blood

transfusions for pediatric patients (American Academy of Pediatrics Committee on Bioethics 1997). Courts are also not the appropriate venue when parents demand treatments that the pediatric surgeon regards as not being in the best interests of the infant. Conflicts are resolved best at the bedside among the parties who know the infant and the circumstances and those who will live with the consequences of the decision.

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### Informed Consent and Assent

When the pediatric surgeon is dealing with adolescents or young adults, the doctrine of informed consent is important. This doctrine is based primarily on the ethical principle of respect for individual autonomy but also involves beneficence and justice. Respect for patient's *autonomy* recognizes the right of each person to make their own decisions, while the principle of *beneficence* refers to the obligation to promote the well-being of the patient. Justice refers to the obligation to act in a nondiscriminatory fashion and to treat patients in the same manner as other patients under similar circumstances.

In some jurisdictions, and in certain specific circumstances, adolescent patients may be granted authority to make their own decisions about the health care they receive. There are two relevant concepts – the mature minor and the emancipated minor. Ethically, health-care professionals are obligated to involve mature minors in decision-making insofar as the minors are able. A mature minor is a person under the age of 18 who has the capacity to make informed health-care decisions – based on a clinical assessment of the person's emotional maturity, age, experience, intelligence, and the decision to be made. An emancipated minor is a person under the age of 18 who has sole or primary responsibility for his/her own support, is married and living away from parents or guardians, or is in the armed services. Mature and emancipated minor statutes may vary by local jurisdiction (English et al. 2010). In addition, there are other treatments that a minor can consent to by federal and/or state statute – treatment for addiction to or use of

drugs, treatment for sexually transmitted infections, and the use of contraception and pregnancy care (English et al. 2010). These instances of minor consent are based not only on respect for privacy and confidentiality but on the public health values of treating diseases and stopping their spread (infectious diseases). However, when an adolescent's consent to or refusal of surgery is in direct opposition to parental wishes, the assistance of an ethics committee, social services, or legal counsel may be required.

The concept of pediatric assent is also important. There is wide support that the *assent* of the pediatric patient should be sought as appropriate to their development, age, and understanding, in conjunction with informed permission from the parent or legal guardian (American Academy of Pediatrics Committee on Bioethics 1995). Pediatric surgeons have an ethical duty to familiarize themselves with their own institutional guidelines and appropriate local statutes for decision-making by minors.

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### Multiculturalism

The ethical concept of best interests that has been articulated is largely dependent upon the authors' own experiences in the medical culture in the USA. Some of the most difficult ethical issues that the authors' have personally faced involve a conflict between this Western medical notion of best interests and families making decisions for their infants and children from other cultures. However, there is something particularly compelling about such cases that call participants to value and respect cultural differences. Both the parents and pediatric surgeons are struggling to fulfill their role-specific obligations to be good parents and good physicians. But they literally see their roles quite differently. It is culture that provides the "lens" for each of us to view the world. One definition of culture states:

Culture is a set of guidelines (both explicit and implicit) which individuals inherit as members of a particular society, and which tells them how to view the world, how to experience it emotionally, and how to behave in it in relation to other people,

to supernatural forces or gods, and to the natural environment. It also provides them with a way of transmitting symbols, language, art and ritual. To some extent, culture can be seen as an inherited “lens”, through which individuals perceive and understand the world that they inhabit, and learn how to live within it. Growing up within any society is a form of enculturation, whereby the individual slowly acquires the cultural “lens” of that society. Without such a shared perception of the world, both the cohesion and the continuity of any human group would be impossible. (Helman 1990)

It seems obvious from this definition that there is no way to talk about best interests from outside a cultural perspective. All of our discussion, then, is in some sense cross-cultural. The narrow explication of best interests represents the perspective of the USA and perhaps predominantly the powerful status of its medical and legal culture.

The central question is not really whether or not we have a cultural perspective but whether we can judge some perspectives as better than others. This raises the difficult ethical question of cultural relativity. Cultural relativity refers to the following claims: (1) all moral judgments are relative to the culture in which they arise, (2) moral judgments across cultures are significantly different, and (3) there is no way to rank moral judgments across cultures (Garcia 1992).

The well-respected physician – ethicist, Edmund Pellegrino – accepts that culture is essential in the context of medical and ethical decisions but that there are also features of human beings as human beings according to which we can judge among cultures (Pellegrino 1992). It can be argued that there are some universal features that all cultures either should or would accept. An example would be that moral communities must allow democratic processes and cannot be oppressive. Other ethicists identify universal moral principles that underlie our commitments to be tolerant of cultural diversity (Beauchamp 1992; Macklin 1998). Without some principle of respect for persons, for example, there would be no reason to prefer tolerance of cultural differences.

A cultural perspective is particularly important to ethical theorists, who support the inclusion of

context and relationship in an ethical analysis, and to those working in clinical settings. As Carl Elliot writes:

Ethical concepts are tied to a society’s customs, manners, tradition, institutions – all of the concepts that structure and inform the ways in which a member of that society deals with the world. When we forget this, we are in danger of leaving this world of genuine moral experience for the world of moral fiction – a simplified, hypothetical creation less suited for practical difficulties than for intellectual convenience. (Elliot 1992)

The authors wish to support an ethical analysis that includes culture as an important feature but also acknowledges the role of the application of universal ethical principles. Like Pellegrino, the authors accept that there are some ethical principles that apply to all humans based on their humanity. Culture is necessary to understand what these principles mean and how they are applied with respect to each of the parties in the conflict. It is possible to be respectful of cultural differences and at the same time acknowledge that there are limits. What remains critical is the perceived degree of harm; some cultural practices may constitute violations of fundamental human rights (American Academy of Pediatrics Committee on Bioethics 1994).

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## **Prenatal Surgical Consultation and Fetal Surgery**

With the emergence of routine prenatal screening with ultrasonography (USA) and biochemical markers and maternal/fetal centers, there comes the need for increasing attention to the ethical issues that may arise with the prenatal diagnosis of fetal anomalies. Such issues may include (1) the possibility of prenatal intervention or termination of pregnancy; (2) the timing, location, and mode of delivery; and (3) potential postnatal surgical intervention (Caniano and Baylis 1999).

A prenatal surgical consultation should be guided by the same ethical principles of beneficence, non-maleficence, and justice that we have been discussing. And in addition, respect for the woman’s choice and her reproductive freedom



(respect for autonomy) takes on a profound relevance. There is disagreement about the role of termination of pregnancy within the fetal therapy discussion (Ville 2011). Because these issues involve the unique situation of having one patient physically located within another patient, balancing the values of the stakeholders can be particularly difficult (Mattingly 1992). Some would argue that the moral status of the fetus should almost never trump the autonomy of the mother (ACOG Committee on Ethics 2004). Chervenak and McCullough have proposed a framework that includes the fetus as a patient with beneficence and non-maleficence claims based on the fetus' ability to live independently or the mother's presentation of the fetus as a patient (Chervenak and McCullough 2009). The benefits of a proposed fetal surgery always must be considered in the context of the risk of the surgery for both mother and fetus. The informed consent process is particularly important and challenging. The role of other family members, including fathers, is debated. Family can be both a source of support and also of problematic coercion (Howe 2003).

But what is the role of the surgeon? Some would argue that the proper role of the pediatric surgeon is not only to give information but also provide a supportive, caring environment for informed decision-making. "Value neutrality and moral detachment on the part of the surgeon creates an obstacle to forming a professional relationship with prospective parents who are seeking compassion, honesty, and integrity, virtues cited by Pellegrino and Thomasma as being essential components of the physician-patient relationship" (Nwomeh and Caniano 2011).

One of the authors has suggested elsewhere the following as guidelines for pediatric surgeons during a prenatal surgical consultation (Nwomeh and Caniano 2011):

1. Empathize with the inevitable grief and sorrow that the prospective parents feel upon the recent unexpected and frightening diagnosis of a fetal malformation.
2. Candidly disclose the benefits, harms, and alternatives for the given fetal condition, and

offer recommendations that balance maternal and fetal interests.

3. Foster an atmosphere that facilitates the exchange of medical information and helping the prospective parents make decisions that are consistent with their own beliefs, goals, and values.
4. Promote responsible efforts to improve access to the full-range of prenatal services available at high-risk perinatal centers for women from all socioeconomic, ethnic, and cultural groups.

The potential for the maternal and fetal interests to diverge can be a major concern as everyone involved seeks the best interests of the mother and the fetus, respectively. As with other issues in pediatrics, judicial review should be viewed as only a last resort to resolve intractable conflict (American Academy of Pediatrics Committee on Bioethics 1999). Establishing institutional ethical guidelines and the assistance of an ethics committee consult may be helpful.

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### Ethical Issues in Pediatric Bariatric Surgery

With the recent success of adult bariatric surgeries, it is no surprise that bariatric operations in the pediatric population are increasingly recommended. Clinical evidence supports the need to address the serious comorbidities of childhood obesity such as type 2 diabetes, cardiovascular dysfunction, hypertension, obstructive sleep apnea, and dyslipidemias (Caniano 2009). But these surgeries are still innovative and much research remains to be done, especially about long-term outcomes with children.

The ethical issues are complex. The decision to proceed with bariatric surgery should be made only after it is determined that the patient's comorbidities could not be treated with less invasive means and there is a favorable risk/benefit profile, pre-surgery counseling and robust informed consent, and a comprehensive system of short- and long-term follow-up care (Caniano 2009).

Robust informed consent may be difficult in this population of morbidly obese adolescents considering bariatric surgery. There can be severe pressure from the media, lay publications, and the Internet, which highlight the benefits of this surgical intervention to achieve a socially desirable body habitus. Patients may not be able to appreciate the real operative risks and the irreversible nature of some of the proposed procedures. It seems like a “quick fix” when it actually involves many, if not all, of the lifestyle changes that are so difficult to make. Raper and Sarwer have described the elements of informed consent to be discussed with prospective adolescent bariatric patients and their families (Raper and Sarwer 2008).

Bariatric surgery may uphold the principle of beneficence for some adolescents. Although beneficence would favor less invasive measures such as caloric restriction diets, exercise programs, and behavioral therapy, these are not always effective. In one study, adolescent patients whose BMI exceeded 40 kg/m<sup>2</sup> had only a 3% reduction in BMI after 1 year of intensive medical weight management, a result that was insufficient to reverse comorbidities (Flum et al. 2007). The principle of beneficence would require a “reasonable” trial of medical/behavioral weight loss treatment, continuation of such treatment if proven effective, and surgery only if less invasive means prove ineffective.

The principle of non-maleficence also is important because of the well-known risks of surgery and such complications as lengthy hospitalizations, reoperative surgery, and other unanticipated problems. And adolescents may have difficulty balancing immediate benefits and low risks against the possible complications that may develop several years later and the uncertainty of outcomes decades after the operation.

The principle (and virtue) of justice is also implicated in bariatric surgery given the significant disparities in access to adult bariatric surgery for African-Americans, Hispanics, low-income individuals, and males (Flum et al. 2007). Pediatric obesity in the USA affects one in three socially disadvantaged children, with particularly high rates among African-American girls and Hispanic

and Native American children of both genders (Blacksher 2008). It is the socially and economically disadvantaged children who fare the worst on most childhood health indicators. Pediatric bariatric programs must consider issues of justice as fairness as they develop programs and provide access to the children most in need, in spite of their ability to pay.

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## Surgeons and Industry

Patients have benefited from the cooperative work of physicians with industry in the development of new tests, drugs, and devices. Many have argued that the improvements in the quality of medical care have been the direct outcome of industry support for medical education, research, and innovation. However, these industry relationships may also create conflicts of interest (COI), unduly influencing professional judgments and inducing physicians to perform unnecessary tests and treatments that may be harmful to patients and contribute to rising health-care costs (Brennan et al. 2006). The 2009 report “Conflict of Interest in Medical Research, Education, and Practice” issued by the Institute of Medicine (IOM) has urged serious consideration of this issue (Institute of Medicine 2009). The IOM stresses the importance of preventing bias and mistrust rather than trying to remedy damage after it is discovered and encourages the enactment of policies and laws that identify, limit, and manage conflicts of interests without negatively affecting constructive collaborations between the medical profession and industry (Institute of Medicine 2009).

Most medical institutions and professional organizations have adopted conflict of interest (COI) policies (Glover et al. 2012). A conflict of interest exists when a person entrusted with the interests of a patient, dependent, or the public violates that trust by promoting their own self-interest or the interest of third parties, such as hospitals, physician groups, or insurance plans. Some COIs are financial, like reimbursement incentives or personal investments in health-care facilities. Other COIs are personal or involve professional roles like responding to mistakes,

dealing with impaired colleagues, or the need to learn invasive procedures (Lo 2000).

COIs are ethically problematical for physicians because they can put at risk many important ethical principles, particularly those of fidelity (keeping promises), beneficence, and non-maleficence. If a physician's professional judgment is compromised, the well-being of the patient could be compromised as well. There are two main ways that physicians can manage their COIs – disclosure and avoidance. Disclosure of COI tends to dominate policies adopted by many institutions and professional bodies. However, there are distinct limitations to the power of disclosure alone as an effective way to manage COIs. Disclosure can actually give patients a false sense of security because patients can assume that a professional who discloses is actually more trustworthy, when, in actuality, the COI is not really managed but only disclosed. Telling someone you have this conflict doesn't necessarily mean that patients' interests are not being put at risk – only that the potential is now visible (Cain et al. 2005). Even a full disclosure may be too ambiguous to help patients determine whether bias is present. Some would argue that the only way to eliminate industry bias is to avoid it whenever possible. However, avoidance is not always possible, especially in light of industry-funded research that has the potential to benefit patients.

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## Surgical Error

The culture of medicine has changed to now require robust quality and safety programs and the routine disclosure of errors. The groundbreaking 1999 Institute of Medicine (IOM) report “To Err Is Human” (Kohn et al. 2000) focused attention on the high incidence of medical errors (as many as 98,000 patient deaths in the USA each year) and other serious negative effects on patient outcomes (prolonged hospitalizations, unnecessary suffering, and increased health-care costs).

In the past, disclosure of errors was not common and thought to be harmful both to patients and their surrogates, and to the health-care

professionals, and result in increased malpractice liability. But now disclosure is regarded as an ethical imperative. Disclosure respects and benefits patients and benefits physicians (maintaining their sense of integrity and increasing knowledge and skills from the mistakes). It is now thought that nondisclosure, rather than disclosure, is in fact, harmful. It harms the physician's reputation and undermines public trust.

When a surgical error has occurred, the pediatric surgeon should explain in clear language how the error occurred, the anticipated consequences, how the error will be managed in this patient, and what will be done to prevent the same error from harming others. In some institutions, it is routine practice to offer compensation for expenses incurred or early settlements. This practice can dramatically reduce malpractice claims, which are much less common in countries with no-fault compensation systems (Wei 2007).

It is also important that the surgeon offer an apology with the disclosure of the error. “Apology laws” have been enacted in more than 30 US states and several Canadian provinces and enable physicians to say they are sorry without the fear of increased liability (Wei 2007).

The culture of medicine has changed and so, too, has the culture of medical education. To meet the education needs of the next generation of physicians, medical schools and residency training programs are using simulation modules, virtual patients, and other novel educational strategies to promote quality and safety (Bell et al. 2010). The Accreditation Council for Graduate Medical Education (ACGME) has made the identification of medical error recognition and disclosure a core competency in medical education (Christmas and Ziegelstein 2009).

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## Best Interests and Innovation and Clinical Research

The best interest standard with its balancing of benefits and harms for individual patients and their families rests on the assumption of good information about the best proven surgical care in a shared decision-making process. Good

information relies on clinical research to validate the best approach, and in the current environment of cost containment, to validate the approach that brings the best outcome with the least costs, including financial costs. There is strong support for a professional and ethical obligation of pediatric surgeons to be involved in clinical research. According to the Committee on Pediatric Research of the American Academy of Pediatrics, all subspecialists, including surgeons, should be encouraged and supported to pursue research activities (American Academy of Pediatrics Committee on Pediatric Research 2001). The needs of newborns, infants, and younger children are unique and cannot be extrapolated from other research involving older children and/or adults.

But there are barriers to participation in research for pediatric surgeons as well as for parents and their infants or children. Caniano has noted elsewhere “that surgery, in contrast to other areas in medicine, has been historically free to develop new operations and treatments without the stringent requirements of animal testing and rigorous, prospective multi-institutional clinical trials in humans. The boundaries are often blurred between an operation that should be evaluated by a clinical trial before it is recommended for general implementation and an operation that is considered to be a refinement of an accepted procedure, and therefore not needing rigorous testing” (Caniano 2004). Other barriers include a misunderstanding of the meaning of “equipoise,” a concept necessary for the ethical conduct of research. Equipoise requires that the researcher believes that one surgery or treatment is no better or worse than another or even the use of placebo, because there is no evidence supporting one over the other. Surgeons treating critically ill children are often in a position of rescue and believe that doing something, even if it is not proven, is better than doing nothing and better than enrolling a child in a trial where they may not get the proposed treatment.

In pediatric surgery, there have been many advances through research and the development of innovative surgical techniques. Innovation involves the introduction of a new method, idea

or treatment, medication, or device to benefit the individual patient. Pediatric surgeons have been among the most notable surgical innovators, including procedures like appendectomy and pyloromyotomy, which may have never passed the rigor of randomized trials. Many innovative procedures have been widely adopted, without much evidence to support their advantage over standard techniques. In spite of the widespread acceptance of innovation, some worry that too little regulation creates the potential for abuse and can be harmful and dangerous (Nwomeh and Caniano 2011). The authors cite examples where such innovative procedures like sympathectomy for Hirschsprung’s disease and jejunoileal bypass for morbid obesity were subsequently abandoned and may never have been widely used in the first place if a stricter regulatory regimen were in place. They argue that pediatric surgeons must be conservative guardians in surgical innovation. They cite the work of McKneally who claims that the terminology of innovation has a seductive connotation of added value that attracts patients seeking the “latest and greatest” treatment (McKneally 1999). Instead, Robert Levine proposes that it should be replaced by the term *nonvalidated*, because it more accurately reflects the ethical and medical hazard entailed in new procedures (Levine 1988). This concept of a nonvalidated operation may be more transparent and honest because it communicates clearly the fact that the proposed operation has not been subjected to rigorous investigation. With this awareness, both parents and pediatric surgeons may move toward supporting the ideal of RCTs, when a state of clinical equipoise exists and before it is widely imposed on vulnerable and trusting patients and their families.

Even though there is support for this obligation of pediatric surgeons, and even patients, to be involved in research, there may be great hesitation because of the obvious vulnerability of the family and the infant or child. Researchers struggle to apply the standard of best interests by expanding the evidence base for pediatric practice for future patients on the one hand while also protecting the vulnerable patients in their care on the other hand. It is quite difficult to obtain parental permission

that is informed and voluntary under conditions of duress and within a short therapeutic window. It is also very difficult to balance the risks and potential benefits of the research itself. Research standards in both the USA and Europe state that any child should only be enrolled in research when it is absolutely necessary to answer an important scientific question. An important issue in both the USA and Europe involves whether and how pediatric research has to provide benefit to the participating children. In the USA, children can be involved in research that offers no direct benefit, but only if the risks of participation are minimal. Children may also participate in research that involves a minor increase over minimal risk, but only if there is a reasonable expectation of future benefit to those with the same condition (Flotte et al. 2006). Research guidelines from the Ethics Working Group of the Confederation of European Specialists in Paediatrics (CESP) state that “Children should not be involved in research that serves only scientific interests and does not provide any benefit to them” (Gill 2004). In a discussion of the ethical principles and legal requirements for pediatric research in the EU, Pinxten and colleagues state “...the principle of beneficence requires that biomedical interventions contribute to the welfare of these persons (in research). This can be achieved in two ways. First, biomedical interventions can generate benefits in the research subjects themselves. Second, the drawbacks of biomedical interventions can be balanced with a newly generated benefit, either directly to the minor research subject or to another beneficiary” (Pinxten et al. 2009). A requirement for direct benefit has serious implications for the selection of control groups and research designs that include a placebo. For the regulations in the USA, determining what counts as minimal risk or a minor increase over minimal risk is very complex. If protecting children in research is not to be translated into excluding children from research, special protections must be put in place.

In general, what are the requirements for ethical research? Emanuel and colleagues have proposed seven requirements for determining whether a research trial is ethical (Emanuel et al. 2000).

1. Social or scientific value
2. Scientific validity
3. Fair subject selection
4. Favorable risk-benefit ratio
5. Independent review
6. Informed consent
7. Respect for potential and enrolled subjects

Because of the special vulnerabilities of children, and especially newborns, three procedures have been proposed to improve protection of pediatric research participants (Flotte et al. 2006).

1. Pediatric data and safety monitoring committees
2. Robust assent processes
3. Decision monitoring that could verify the “informed” nature of the consent

A final issue for consideration is what special protections should be in place for research in developing countries, as an increasing amount of research is, in fact, multinational. Emanuel and colleagues have proposed an eighth principle – collaborative partnership – to be added to the seven requirements listed above (Emanuel et al. 2004). This principle emphasizes the need to develop partnerships among researchers, makers of health policies, and communities. It recognizes the importance of respecting the community’s values, culture, traditions, and social practices. And perhaps most importantly, this principle seeks to ensure that the recruited participants and communities receive benefits from the conduct and results of the research. Raising the issue of research in developing countries also raises the more general question of the role of culture in decision-making in practice, as well as in research.

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## Conclusion and Future Directions

The best interest standard is a complex amalgam of the values of pediatric surgeons, families, and broader societies (Bowyer 2016; Noritz 2015; Rhodes and Holzman 2014). The ethical principles of beneficence, non-maleficence, autonomy, and justice and the virtues such as trust,

compassion, prudence, justice, courage, phronesis, fortitude, integrity, honesty, and self-effacement provide a sound basis to navigate the ethical issues we encounter in pediatric surgery practice and research. Although there is no universal solution to a given ethical problem, we believe that an acceptable solution can be reached if these principles are followed. Formal teaching of clinical bioethics has been lacking in most pediatric surgery training programs (Robin and Caniano 1998). However, in recent years, several pediatric surgery training programs in North America have introduced formal case-based, practice-oriented ethics teaching sessions. In addition to all the topics discussed in this chapter, we suggest that such case studies include important ethical concerns related to child abuse, conflict resolution, and the disruptive surgeon.

As health care itself becomes increasingly multicultural and international, the need for cross-cultural ethical dialogue increases. There are no ultimate trump cards, just a genuine need for what one philosopher calls “communitarian perspectivalism” (Garcia 1992). Any healthy growing and self-renewing culture continually subjects itself to self-evaluation and evaluation by others. In this regard, the authors wish to point to the need for greater attention to the value of justice in the provision of health care around the globe. This chapter represents a tendency to look at the developed nations and evaluate the issue of not providing the most that can be done. This is obviously an ethical problem for the rich. What about the bigger ethical problem of not providing the basic minimum to infants and children everywhere – the ethical problem of not providing what poor parents want for their children and cannot afford? Certainly ethical dialogue needs to include what children around the globe are owed as a matter of justice – of fundamental human rights. Access to global health-care resources is a problem that affects all persons. The contribution of the medical marketplace to the disproportionate allocation of health care that exists cannot be ignored. Medicine must take responsibility for the emphasis on expanding new technologies in the market rather than meeting basic public health needs and the disproportionate burden it may place on the economies of developing nations or nations

committed to universal access to health care. A global cross-cultural perspective is essential to help expand the concept of “best interests” to include a necessary public health focus.

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## Cross-References

- ▶ [Childhood Obesity](#)
- ▶ [Clinical Research and Evidence-Based Pediatric Surgery](#)
- ▶ [Fetal Counseling for Congenital Malformations](#)
- ▶ [Fetal Surgery](#)
- ▶ [Innovations in Minimally Invasive Surgery in Children](#)
- ▶ [Patient- and Family-Oriented Pediatric Surgical Care](#)
- ▶ [Surgical Safety in Children](#)

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