In part 1 of this 2-part series, the pathophysiology of myelomeningocele was presented and the associated complications discussed. The pros and cons of immediate postnatal closure and intrauterine intervention were evaluated. In part 2, the medical and legal ramifications as well as ethical issues of intrauterine interventions versus delayed closure until after birth are explored.

Professional Gaps

Repair of a myelomeningocele (MMC) in a newborn requires skilled anesthetic management. Moreover, these babies frequently undergo placement of ventriculo-peritoneal shunt a few days later, followed by many revisions. Most anesthesiologists have not had experience with newer technologies that allow for prenatal repair of the defect with significantly lower complication rates. In addition anesthesiologists may be unaware of the nuances of the ethical and legal ramifications of intrauterine interventions.

Learning Objectives

At the completion of the activity, the reader will be able to:

1. List 3 criteria used by medical ethicists to define the fetus as a patient in the context of fetal surgery
2. Understand the controversy surrounding the fetal status as a patient
3. List the 4 interests of the state that are weighed against an individual’s right to refuse medical treatment
4. Compare the legal implications of pregnant women refusing fetal surgery to those of living related organ donors without medical competency
5. Understand the situations in which a woman has the right to refuse treatment
6. Explain the origin of the court system’s interest in preservation of fetal life in cases of compelled obstetric care
7. Describe the physician’s obligation(s) to care for the pregnant woman and fetus in the context of MMC repair
8. Understand the barriers to informed patient consent for fetal surgery
9. Describe the recommendations of the Maternal-Fetal Medicine Task Force for non-directive, prenatal counseling of a woman considering fetal surgery
10. Accept the controversies that surround intrauterine surgery

Case

The fetus of a healthy, 19-year-old nulliparous woman was diagnosed with spina bifida after routine pre-natal ultrasonography was performed at 21 weeks’ gestation. Her obstetrician referred her to a fetal care center where she underwent preoperative evaluation for prenatal MMC repair. Joined by her fiancé, she met with the obstetric and pediatric anesthesia team. As the discussion led to maternal and fetal risks of general anesthesia, the patient grew tearful, stating, “I don’t think I can go through with this surgery.” Her fiancé explained that he desired prenatal neurosurgical repair, as a family friend had read about its benefits online. Unable to console her, he turned to the anesthesia team and asked, “She can’t refuse a surgery that would allow my son to walk, can she?”

Introduction

While the procedure is not completely curative and not without risk, prenatal MCC repair represents a novel standard of fetal surgery to improve the health of infants affected by a non-life-threatening condition.2 This represents a significant change in practice since fetal surgical intervention was traditionally used only in circumstances where the fetus or infant was likely to die upon birth.3 The short and long-term advantages in children’s health and well-being offered by prenatal MMC repair must not only be weighed against the complication risk to the fetus, but also to the mother as this procedure offers no direct maternal benefit. Developments in fetal surgery for non-lethal conditions thus raises ethical and legal debate about how fetal interests should influence a woman’s choices, including whether she may refuse intrauterine interventions that present lifelong advantages to her child.3

Ethical Considerations of Fetal Surgery

From an ethical standpoint, the status of the fetus and the duty to treat a fetus in utero are a matter of controversy. Recognized by Rodrigues as the “most acknowledged ethical framework for maternal-fetal surgery”27, Chervanek and McCullough’s28 conceptualization of the fetus as a patient conveys a specific status worthy of consideration when presented to a physician for care. Status as a patient does not require one be identified as a person in any morally relevant sense but is instead the result of special social interactions.28

In the case of fetal surgery, the fetus is defined as a patient by the existence of:

1. the reliable prospect that the fetus later achieves moral status of a child, then person;
2. interventions that, from a medical standpoint, offer reliable expectation of benefit; and
3. its position in the relationship with a physician.27
The physician’s “fiduciary responsibility” – i.e., the obligation to act in good faith with regard to the interests of another – is the basis for defining the fetus as a patient, but the fetus becomes a patient only through the autonomous choice of the pregnant woman. Her decision to present her fetus to the physician’s care along with her decision to continue the pregnancy to term conveys to the fetus its future moral status as a person. According to Chervanek and McCullough, the pregnant woman is under no moral obligation to present her fetus to medical care, even when an intervention exists that may benefit the child that will grow from the fetus. The mother is free to reverse the patient status of her fetus at any point before the gestational age of viability because no medical intervention is reliably expected to benefit her fetus if born during the previability period. The mother is permitted to take “only reasonable risks” when contemplating medical interventions that offer benefit to a viable fetus or child. The physician is expected to respect the autonomous choices of the pregnant woman who possesses an independent and implicitly different moral status from the fetus.28

Rodrigues et al.27 challenged Chervanek and McCullough’s moral concept of the fetus qua patient, arguing that “the connection between a woman and her fetus can hardly be described as a physician-patient relationship.” Instead of the physician’s duty of beneficence, a woman possesses her own moral status as a patient with equal claim to appropriate care and the reliable expectation of medical benefit. Even the woman’s status as a patient is questionable in the context of fetal surgery defined as a series of interventions focused on benefitting the fetus and not directly benefitting the pregnant woman. Rodrigues et al. conceded that potential psychosocial benefits of fetal surgery for the pregnant woman are worthy of consideration, however they are not the apparent primary aim of surgery. Whether the fetus is or can become a patient in its own right is not self-evident. This status as a patient separate or separable from the pregnant woman is attributed to the depiction in fetal surgical literature of pregnancy as a situation of conflict. The woman and fetus are presented as potential antagonists and used to “justify the clinical and social value” of fetal surgery and the surgeon’s “own personal moral obligations” to the fetuses upon whom he/she operates.27

Dickens and Cook3 refer to the concept of the fetus as a patient as “benign fiction.” They argue that a fetus is not a patient in the same sense as a born child, but “only by metaphor [and] analogous to a patient when the woman who carries it, and wants care for it, is a patient.” While women with the intent to bear children have ethical responsibilities before birth, they are “entitled to balance those responsibilities against other responsibilities they feel toward the well-being of others, such as existing dependent children, their partners, parents and other family members”. Complicating the decision-making process is the common belief of some pregnant women and their partners that their fetuses are “already babies”, a conviction “that arises when a status is advocated instrumentally, particularly in order to limit women’s claim to abortion.” Imposition of a third party’s priorities over the pregnant women’s choice is unethical, even in specific fetal surgical scenarios where conflicting duties of care for these individual but inseparable patients may arise.3

Legal Considerations of Fetal Surgery

To the best of the author’s knowledge and at the time of this publication, there has not yet been a case brought by the state or individual to compel a woman to undergo fetal surgery. While the current trend is that women have gone and continue to go to “extreme measures to protect and ensure the health of their unborn” fetuses, the concern for women refusing to consent to an intrauterine procedure has been presented.29 Therefore, issues pertaining to the nature of fetal interests versus maternal interests and the physician’s responsibilities toward the fetuses versus such duties toward pregnant women are worthy of discussion.
**The Right to Bodily Autonomy and to Refuse Medical Treatment**

The right of every individual to “the possession and control of [her] own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law” (i.e., bodily autonomy) is considered one of the most sacred, most carefully guarded rights in the United States. The U.S. Supreme Court has ruled that a competent person has a constitutionally protected right to refuse medical treatment. The right itself is not absolute, meaning from a legal standpoint, that it must be balanced against the state’s interests of preserving life, preventing suicide, maintaining the ethical integrity of medical practice, and protecting innocent third parties.

While there is no legal precedent for a compelled fetal surgery ruling, the implications of invasive surgery on women for the sake of their born children and the right to refuse surgical risk without direct medical benefit have been applied to cases of living relative organ donations. These cases typically arise when a minor or mentally incompetent patient is the only known match for organ donation, and the institution will not perform the donor’s surgery without a court order. In either instance, a patient’s parent or legal guardian must first consent to the transplant as the court has no power to authorize an operation where the donor’s own life is not in danger and the donor receives no direct benefit. In the case of a patient once competent now incompetent, the court applies the “substituted judgment standard”, or ruling deemed as close to the patient’s likely wishes as possible. A “best interests standard” is applied for minor or incompetent patients when determination of the wishes of that patient is impossible due to patient age or lifelong mental impairment. Interestingly, a court ruling to compel organ donation requires evidence of likely psychological benefit to the patient. In settings where “the donor will not receive a psychological benefit from the donation, or where the physical or psychological risks to the donor would outweigh the psychological benefit to the donor,” the court will not compel the donation. The court also requires that the case present a satisfactory support network for the patient and is unlikely to grant the petition where the caregiver for the patient opposes the donation as “it cannot be in the [donor’s] best interests to undergo a procedure without constant reassurance and support by a familiar... and trusted” adult. The conclusions thus extracted are: compelled organ donation, with due surgical risk and no direct medical benefit, requires optimal adherence to the patient’s wishes along with evidence of expected psychological benefit to and adequate support of the donor. If the court were to compel the donation without these criteria, it “would change every concept and principle upon which our society is founded... defeating the sanctity of the individual” and “imposing a rule which would know no limits.”

**Reproductive Rights and State Interests in Fetal Life**

In cases of pregnant women refusing consent to medical procedures, courts do not require that the women receive psychological benefit or social support. The historic examples of the argument for compelled intervention on a pregnant woman (i.e., emergent cesarean delivery or blood transfusion) have been founded upon either state interests in preservation of fetal life or upon the Roe limitations of reproductive freedom. The ruling of Roe vs. Wade in 1973 concluded that once a woman elects to “carry the fetus to term, she is no longer free to take action that would endanger the fetus.” In the words of Justice Blackmun of the US Supreme Court, “at some point in pregnancy... interests become sufficiently compelling to sustain regulation of the factors that govern the abortion decision... a state may properly assert important interests...in protecting potential [i.e., fetal] life”. From a legal perspective, this definition of fetal interests or of state interests in the fetus does not require determination of the fetus as a human being, and therefore does not promote common law interests of the fetus to the status
of constitutional right. The ruling focuses instead on the period of viability, defined as the point in gestation where the fetus possesses the “potential to live outside the mother’s womb, albeit with artificial aid,” beyond which the choice accessible to the woman to terminate her pregnancy is increasingly restricted. The state’s interests are not compelling unless the fetus is viable, and after the point of viability, the state’s interest in the fetus is not so compelling that the state may override a woman’s rights to autonomy, privacy, and religion.29 (As a side note, this establishment of viability has been criticized as “illogical” in what are considered ground-breaking cases of pregnant women ingesting illegal substances during the third trimester and being prosecuted for child neglect, child abuse and distribution of drugs to a minor.29 A woman cannot be found criminally liable during the period of previability because she maintains the right at this time to terminate her pregnancy. With the most critical period of organogenesis and development occurring long before viability is established, the greatest opportunity of the state to protect the fetus in utero is lost.)

The “waiver” of maternal due-process rights presented by the Roe vs. Wade case may be inappropriate for fetal surgery cases because even after a woman makes the decision to carry her pregnancy to term, she “does not waive her right to conduct the labor and delivery in a manner she desires”.32 Although this ruling allows the state to proscribe abortion, it should not extend to compel “physician intrusions into the pregnant woman’s body against her consent”.32 Recognizing a state interest in the well-being of the fetus does not deem that interest superior to the pregnant woman’s right to decide actions taken regarding her health and welfare. This right is an established part of the common law rights of bodily integrity and self-determination, and is included in the privacy rights found in the Fourth, Eighth and Thirteenth Amendments to the United States Constitution.29 While many women express apprehension over the detrimental effects that even uncomplicated pregnancies may have on their bodies, they may react strongly to the consideration that one of these effects could be a state order to undergo invasive medical procedures. If the enforcement of this policy deters women from becoming pregnant or maintaining their pregnancy, how can the state argue it truly has an interest in the welfare of families and children?

Multiple problems arise when holding the state interest in preservation of fetal life above the pregnant woman’s right to autonomy, not the least of which is the risk of undervaluing a woman’s convictions—be they religious, psychological, or simply to experience a “natural,” de-medicalized pregnancy and delivery. Also importantly, while prior rulings to compel an emergent cesarean delivery to be done for preservation of fetal life, the fetuses’ ensuing quality of life has not been addressed during these proceedings.30

The diagnosis of MMC impacts the lives of both the children and adults affected with the disease as well as the lives of their caregivers. While not weighed by the courts against the interests of the state, the woman faced with treatment options of a fetus diagnosed with MMC must consider her responsibilities to other members of her family and community, as well as other aspects of her physical, social, psychological, professional and financial well-being.33 The time devoted to a person affected by MMC has been reported to be 29% of a single caregiver’s daily wake time.34 Lifelong management of MMC is associated with a substantial economic burden; the estimated 2010 direct medical cost per person during the average lifespan of $285,959 to $378,000 does not include the approximate $52,570 attributed to nonmedical costs, including special education and development services, over the individual’s lifetime.35 Lawmakers nationwide require insight from caregivers and patient’s perspectives in addition to information pertaining to direct and indirect costs, in order to appreciate the overall impact of this chronic medical condition33.
**Physician Responsibility**

Finally, what are the legal responsibilities of the physician to the pregnant woman and the fetus regarding MMC repair? In general, the physician’s obligation to promote fetal health is uniquely derived from the physician’s fiduciary responsibility to the pregnant woman, eliminating any legal requirement to view the fetus as a separate entity in order to adhere to a duty of care. The American College of Obstetricians and Gynecologists (ACOG) specifically advises physicians against seeking court order to compel medical care, citing the destructive effect on the physician-patient relationship as to why legal action is rarely justified.

Dickens and Cook cautioned that the physician bears legal obligation of care to counsel patients in all reasonable treatments from which fetuses or children would benefit. They hypothesized that as prenatal MMC repair matures into an indicated alternative to standard postnatal care, physicians may encounter legal liability for negligence in failure to inform women of availability of this procedure. The physician may also be found liable to children themselves who potentially could have avoided morbidity or mortality by prenatal MMC treatment.

The American Academy of Pediatrics (AAP) in collaboration with the Surgical Sections of the AAP, advises that the physician make “an independent judgment in each case on the basis of facts and circumstances” presented by the patient. The recommendations of the AAP for determining when and who to refer for surgical specialty care acknowledge that implementation may be difficult in communities of varying access to major medical centers. However, the AAP cautions, limited access “does not negate” the value of the recommendations. The physician may assume the role of “fetal advocate” in light of this legal obligation to promote fetal health; however promotion of the fetal interest over those of the pregnant woman and without her informed consent is unethical.

The prenatal counseling and consent process provides the patient with critical information to factor into her decision whether to proceed with fetal surgery. Pursuit of the patient’s informed consent also consequently serves to convey respect for the patient’s autonomy. Challenges of the consent process include vulnerability of the pregnant woman due to her beliefs and anxiety regarding potential disabilities of her unborn children as well as the physician’s professional biases. The inherently high degree of uncertainty in pregnancy may result in perception of the physician’s described approach to treatment in times of crisis as the only valid solution, virtually guaranteeing acceptance of the physician’s recommendation and circumventing the process of informed consent. Clearly, the consent process can create barriers. The physician’s focus on the fetus can mistakenly identify the views of the pregnant woman as a barrier to be overcome in order to access the fetus. While the physician may perceive the conflict between woman and fetus, it actually exists between the woman and physician.

The fetal MMC Maternal-Fetal Management (MFM) Task Force was first assembled by the Eunice Kennedy Shriver National Institute of Child Health and Human Development to promote knowledge of the indication and benefit of fetal surgery in the management of fetal MMC. Comprised of representative professional society members directly involved with the prenatal diagnosis and perinatal management of pregnant women carrying fetuses with MMC or with the immediate and/or long-term management of patients affected with MMC, the task force develops practice criteria for the purpose of medical and surgical leadership, not legal or regulatory practices. Recommendations of the MMC MFM task force for standardized, non-directive prenatal counseling prior to obtaining informed patient consent include explanation of how the prenatal MMC diagnosis is made, long-term outcomes associated with standard postnatal MMC repair, and review of management options (i.e., termination of the pregnancy, postnatal MMC repair, or prenatal MMC repair). ACOG guidelines recommend the provision
of a copy of the Management of Myelomeningocele Study (MOMS) trial publication to each patient considering prenatal MMC repair, along with a thorough discussion with members of the fetal care team to discuss both fetal and neonatal outcomes. Institutional experience and outcomes should also be fully disclosed to the patient. Due to the non-emergent nature of MMC repair as well as the significant emotional and financial burden the procedure may place on the patient and family members, the MMC MFM task force emphasizes that counseling should be a multiple day process including psychosocial assessment of the family unit. Finally prenatal counseling should include a reflective period of at least 24 hours for the patient to thoroughly contemplate the risks and benefits of MMC repair.

### Conclusion

Broader indications for fetal surgical intervention now include non-life-threatening conditions. Expansion of maternal-fetal surgical care centers is evident around the world. Anesthesiologists require an understanding of these advancing procedural techniques in order to evaluate the potential benefits they offer and the threats they pose to pregnant and fetal patients. The decision-making process undertaken by the pregnant woman— not to mention the monumental investment of energy and valuable resources on the part of the patient and the entire multi-disciplinary fetal surgery team—demand appreciation for the ethical and legal considerations for all involved in her care and the care of the fetus and child.

### Management of the Case Presented

The obstetric anesthesiologist gently explained to the patient and her fiancé that their appointment with the anesthesia team was only one component of a preoperative evaluation process, concluding that “no decision about a fetal surgical procedure will be made today.” She and the pediatric anesthesiologist permitted the patient and her fiancé a few moments alone in the conference room before returning at the patient’s request to continue the discussion. The anesthesia teams described the anesthetic plan to permit deep uterine relaxation during the prenatal MMC repair and how the medications involved would increase her risk of post-operative nausea and vomiting and blood transfusion. They answered the patient’s questions regarding how the patient and the fetus would be continuously monitored throughout the MMC repair and following surgery. The patient and her fiancé returned for their next scheduled prenatal counseling appointment the following day. At that point, they asked again to meet with the obstetrician, neonatologist and anesthesiologist. After considerable discussion, the mother agreed to surgery. It was scheduled for the following week.

In the preoperative holding area on the morning of the procedure, a lumbar epidural catheter was placed, tested and capped. Sodium bicarbonate solution was given per os to reduce risk of aspiration pneumonitis. Rectal indomethacin was administered for prophylactic tocolysis. The patient was transported to the operating room where she was placed in left-lateral tilt and routine monitors were initiated. A rapid sequence induction was performed, followed by the placement of a radial arterial line and gradual deepening of the inhaled anesthetic to greater than 2 minimum alveolar concentration (MAC). Mean maternal arterial pressure was maintained via titration of continuous phenylephrine infusion while intravenous fluid administration was restricted to less than 2 liters. Fetal heart rate and oxygen saturation were monitored via fetal pulse oximetry and continuous fetal echocardiography. At the start of uterine closure, tocolysis was achieved by magnesium sulfate (loading dose over 20 minutes, followed by continuous infusion). The patient was weaned from volatile agent as the epidural was incrementally dosed for postoperative pain control. The neuromuscular blockade was fully reversed and the patient’s trachea was extubated. She was transferred to the PACU in stable condition.
REFERENCES

27. Rodrigues HCML, van den Berg PP, Düwell M. Dotting the I’s and crossing the T’s: autonomy and/or beneficence? The


Post-test

1. According to Chervanek and McCullough, the status of the fetus as a patient is defined by all BUT

   a. The existence of a reliable prospect to achieve moral status of a child
   b. The position of the fetus in the relationship with a physician
   c. The self-evident right of the fetus as a person
   d. The existence of intervention offering medical benefit

2. According to Rodrigues et al., who are the potential antagonists depicted in fetal surgical literature used to justify the value of fetal surgery?

   a. The surgeon and fetus
   b. The pregnant woman and fetus
   c. The surgeon and pregnant woman
   d. The fetus and born child

3. The right to refuse medical treatment must be balanced by law against the state’s interest in all of the following EXCEPT

   a. Preservation of life
   b. Prevention of suicide
   c. Maintenance of the unquestioned authority of medical practice
   d. Protection of innocent third parties

4. Compelled medical intervention for a pregnant woman is comparable to that for a minor undergoing organ retrieval for donation in that

   a. Consent of a legal guardian is required
   b. Adherence to the patient’s wishes is prioritized
   c. Psychological benefit is required
   d. No direct medical benefit is anticipated

5. The case of Roe vs. Wade ruled that the state interest in fetal life could allow the court to proscribe what maternal decision during the viable period of gestation?

   a. Termination of pregnancy
   b. Reckless driving
   c. Cocaine use
   d. Refusal of blood transfusion
6. Which of the following weighs against the state’s interest in preservation of fetal life?
   a. Gestational age
   b. Medical prognosis of the born child
   c. Maternal economic status
   d. Maternal marital status

7. The physician bears legal obligation of care for women and their fetuses diagnosed with MMC to
   a. Calculate the woman’s risk of conceiving a fetus with MMC prior to pregnancy
   b. Counsel the pregnant woman in all reasonable treatments from which her fetus/child would benefit
   c. Seek legal counsel to compel prenatal surgical repair of the fetus with MCC
   d. Report the woman’s decision to refuse fetal surgery to child protective services

8. Which of the following factors is NOT a barrier to the process of informed consent for intrauterine MMC repair?
   a. A pregnant woman’s anxiety for the potential disabilities of her unborn child
   b. A physician's professional biases
   c. The inherently high degree of uncertainty in pregnancy
   d. The emergent nature of surgical repair upon diagnosis of MMC

9. Which is NOT a recommendation of the MMC MFM Task Force to be included during non-directive, prenatal counseling for a woman considering intrauterine MMC repair?
   a. An explanation of how the prenatal MMC diagnosis is made
   b. A discussion of long-term outcomes associated with standard postnatal MMC repair
   c. A home visit with an adult patient affected by MMC
   d. A review of MMC management options

10. The MMC MFM Task Force recommends a reflective period following the patient’s prenatal counseling prior to giving consent for surgery for how long?
    a. No limit
    b. 24 hours
    c. 48 hours
    d. 72 hours