

Ethics of Fetal Surgery ^[1]

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1. Introduction

Surgeons sometimes operate on the developing fetuses *in utero* of pregnant women to treat a number of congenital abnormalities, operations that have ethical aspects. A. William Liley performed the first successful fetal surgery, a blood transfusion, in New Zealand in 1963 to counteract the effects of hemolytic [anemia](#) ^[6], or Rh disease, on a [fetus](#) ^[7]. The ethical discussions surrounding fetal surgery are complex and are still being defined, as fetal surgery represents an emerging field of *in utero* medical interventions that impact the quality of life for both pregnant women and fetuses. Such discussions involve the ethical relationships between parents, fetuses, doctors, and health care organizations like hospitals. What may benefit the [fetus](#) ^[7] may harm the pregnant woman, and what may benefit the pregnant woman could negatively impact the [viability](#) ^[8] of the [pregnancy](#) ^[9]. Risks to the pregnant woman include preterm membrane rupture, preterm labor, wound infection, hemorrhage, loss of [uterus](#) ^[10], damage to the organs near the [uterus](#) ^[10], and possibly death. Fetal surgery does not always improve the quality of life for the developing [fetus](#) ^[7], and the risks and benefits of fetal surgery must be weighed and discussed between the medical team, the pregnant woman, and her partner to customize the most ethical plan of action.

2. Fetal Surgery

Doctors currently use fetal surgery to drain blocked bladders, to repair heart valves, and to remove abnormal growths from fetal lungs. Two examples are as follows. Diaphragmatic hernias are one condition currently corrected by pre-neonate surgeons, whereby surgeons *in utero* repair the muscle that divides the abdominal and chest cavities of fetuses to facilitate proper fetal lung development. Surgeons have also succeeded in correcting myelomeningocele, a type of [spina bifida](#) ^[11], by closing the tissue over the fetus's spinal cord in the affected area.

There are three basic types of fetal surgeries. The oldest type is the open hysterotomy, characterized by a surgical incision through the multiple layers of the [uterus](#) ^[10], including the maternal abdominal wall, [uterus](#) ^[10], and the membrane surrounding the [fetus](#) ^[7]. Hysterotomy is a technique developed by pediatric surgeons Alfred de Lorimier and Michael R. Harrison in the late 1970s and early 1980s at the University of California in San Francisco, California. The second type of fetal surgery involves fetoscopy, whereby a surgeon uses a fiber-optic endoscope and [ultrasound](#) ^[12] to view the [fetus](#) ^[7]. With advances in surgical instrumentation and the lightweight, high resolution capabilities of the fetoscope, there are many benefits with this procedure compared to the more invasive hysterotomy, and many fetal surgeries are now performed using this method. A fetoscopy incision is much smaller than open fetal surgery and is less traumatic to the pregnant woman's uterine and abdominal walls, and it often lessens the likelihood of [premature labor](#) ^[13]. The third approach to fetal surgery, percutaneous fetal therapy, is the least invasive procedure and involves placing a catheter under continuous [ultrasound](#) ^[12] guidance into areas of the [fetus](#) ^[7] like the bladder or pleural space to drain excess accumulations of fluid.

Technological advances in neonatal intensive care units to treat premature births helped to advance the field of fetal surgery. Also integral are techniques to monitor the health of the pregnant woman post-surgery. Surgical intervention to correct a fetal anomaly is traumatic to a woman's body, and post-operative care involves bed rest, medications, and hospital stays. Often, surgeons will simultaneously and continuously monitor both the [fetus](#) ^[7] and the woman postoperatively until the birth.

Fetal surgery is rare and the option exists for only a small number of pregnant women, as many conditions must be met before fetal surgery is considered a treatment option. Specialized surgical and medical teams involved in such high risk procedures practice in few centers world wide. Additionally, considerations such as the risks and benefits of surgery, the likelihood of favorable outcomes, and the costs of the initial and follow-up procedures, are factors in the consideration to offer pregnant women the option of fetal surgery. Surgery is usually performed on a [fetus](#) ^[7] only when the quality of life for the infant after [gestation](#) ^[14] would be drastically lessened without surgical intervention. That is, if no intervention were to occur, the [fetus](#) ^[7] would die or have severe physical or neurological conditions. In some circumstances, post-natal repair of congenital anomalies is a safer option to improve the health outcomes for both pregnant woman and [fetus](#) ^[7].

3. Ethics, Decision Making, and Patient Status

The ethical issues introduced by the field of fetal surgery are complex because the medical intervention is always invasive, often experimental, involves at least two clinical patients, and the success rate is difficult to measure. Data on the benefits of fetal surgery are also intermittent and not standardized, with many organizations practicing fetal surgery in established and in experimental contexts to correct fetal anomalies. Randomized clinical trials to determine the success of fetal surgeries for both pregnant women and fetuses have been completed in only a few instances, such as with [twin-to-twin transfusion syndrome](#)^[15] and with myelomeningocele. More often, doctors attempt fetal surgery in clinical settings without reporting post-operative outcomes in medical journals.

There are several choices a woman and possibly her partner have following the [prenatal diagnosis](#)^[16] of fetal anomalies. Decisions must be made to either abort the [fetus](#)^[7] or carry the [fetus](#)^[7] to term, with additional consideration paid to the risks and benefits of pre- and post-natal surgical interventions. The pregnant woman and her partner's choice may also depend on further diagnostic tests, health of the pregnant woman, the couple's healthcare situation, and the proximity to medical centers that may offer a broader range of potential treatment options. Additionally, the pregnant woman and her partner's personal beliefs and morals also factor into the situation when considering the benefits and risks of surgical intervention.

Answers to the question of whether or not to perform fetal surgery rest not just on the pregnant woman's health, but also on the additional *in utero* care required for a [fetus](#)^[7] with congenital anomalies. A complex surgery that requires invasive fetal surgery may offer hope for a different outcome than the original congenital anomaly may suggest, but the benefits are weighed against the risks to both pregnant woman and the [fetus](#)^[7]. When a [fetus](#)^[7] requires specialized medical attention, that [fetus](#)^[7] is elevated to a new medical status as a patient, the interests of which may conflict with those of the pregnant woman.

The relationship between the pregnant woman and [fetus](#)^[7] offers a clinically complex situation for moral decision-making. There is no consensus agreement on the moral status of a [fetus](#)^[7] and therefore the treatment of the [fetus](#)^[7] can be questioned clinically, socially, culturally, politically, legally, and ethically. When a woman decides to continue a [pregnancy](#)^[9] to term, her [fetus](#)^[7] may be considered a patient. In developed countries fetal [viability](#)^[8] occurs at about Week 24 of gestational age. At just over 24 weeks [gestation](#)^[14], the [fetus](#)^[7] can be sustained and grow with technological support outside the [uterus](#)^[10]. Prior to [viability](#)^[8], the [fetus](#)^[7] cannot be sustained *ex utero*, and the moral status of the [fetus](#)^[7] is determined by the pregnant woman, based on her autonomy. It is not until the [fetus](#)^[7] is a patient that the physician has beneficence-based obligations to protect its life and health.

Ethical obligations to patients often involve a beneficence-based approach to care, one where the intention is to benefit the patient. Obligations to the [fetus](#)^[7] may exist when the potential for a positive medical outcome is greater than the risk of harm in therapeutic intervention. Patienthood at times applies to the unborn [fetus](#)^[7], when a [fetus](#)^[7] with congenital anomalies may be amenable to fetal surgery, but the [fetus](#)^[7] is not autonomous. Furthermore, beneficence for the [fetus](#)^[7] does not necessarily allow for nonmaleficence for the pregnant woman. For some, the pressure to do everything possible to save the [fetus](#)^[7], or to reduce or minimize anomalies, may be enough to weigh the minimal possible advantages to the [fetus](#)^[7] over the maximum risks to the woman and to the [fetus](#)^[7], even though the surgery may risk the pregnant woman's life without guaranteeing a successful outcome for the [fetus](#)^[7].

At the same time there are the beneficence-based and autonomy-based obligations to the pregnant woman. At any time prior to [viability](#)^[8], the pregnant woman may withdraw patient status of the [fetus](#)^[7] even after giving the [fetus](#)^[7] this status. The invasiveness of fetal surgery to the pregnant woman can detrimentally impact the [competence](#)^[17] of her [uterus](#)^[10] for the current [pregnancy](#)^[9] and for future pregnancies. Additionally, fetuses that die due to fetal surgery that a pregnant woman consented to may cause her more grief than would death resulting from the congenital anomaly in question.

4. Regulations and Oversight Groups

In many developed countries' healthcare laws, a pregnant woman must consent to an intervention that involves the [fetus](#)^[7], or the surgery will not be performed. In the US, federal regulations also require the consent of the father for fetal surgery and fetal research unless he is unable to consent because of unavailability, incompetence, temporary incapacity, or the [pregnancy](#)^[9] resulted from rape or incest. The physician reviews the procedure, its benefits, and risks in the form of [informed consent](#)^[18] to the pregnant woman and the father. The pregnant woman has, as an autonomous individual, the right to decide not to pursue the intervention.

Research on fetal surgeries often face further regulations. The surgeries to repair a malformation or to advance the life of [aetus](#)^[7] in the US fall under the 2009 Department of Health and Human Services Code of Federal Regulations Part 46 Protection of Human Subjects section 46.204 Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research. The [regulation](#)^[19] states that the researchers who obtain [informed consent](#)^[18] may proceed with the surgery in three cases: if it could benefit the pregnant woman; if it could benefit the pregnant woman and the [fetus](#)^[7]; or if there is no potential to benefit either the [fetus](#)^[7] or the pregnant woman but the surgery could offer important biomedical knowledge that cannot be obtained by any other means, with no greater than [minimal risk](#)^[20] to the [fetus](#)^[7]. It is unclear how the term [minimal risk](#)^[20] applies to a [fetus](#)^[7].

Fetal surgeries often fall under the category of clinical trials, and as such are subject to approval of the [Institutional Review](#)

Board ^[21] (IRB) where the fetal surgery is taking place. IRBs oversee clinical trials in medical settings, and the experimental trials in fetal surgery are often such clinical trials. The US government mandates that an IRB exist in all institutions where federally funded biomedical research on human subjects occurs. The IRB, in the case of fetal surgery clinical trials, mediates the interests of the fetal surgical team and the institution's obligation to follow federal regulations on human subject research. The IRB may consider issues such as the safety and wellbeing of patients, the risk to operating on a **fetus** ^[7], the social implications of operating on a pregnant woman, **informed consent** ^[18], and compensations. Differentiating between innovations, experiments, and standard treatments is a central role of an IRB. For many IRBs, new types or techniques of fetal surgeries should follow a path from consideration of the possibilities of fetal surgery, to clinical trials, to analyses that evaluate efficacy. Only then should fetal surgery be offered to pregnant women as a standard of care for fetal anomalies.

In the views of many ethicists, the reliable expectations of the proposed intervention on the **fetus** ^[7], on the basis of previous animal studies, should be life saving or should prevent serious and irreversible disease, injury, or disability to the **fetus** ^[7]. The researcher's protocol should involve the least risk for the mortality and morbidity to the fetal patient and the pregnant woman's risk for disease, injury, or disability is expected to be low or manageable.

Once fetal surgery has been demonstrated as evidence-based practice, scientific and ethical challenges remain. There are complex considerations that the pregnant woman and her partner must understand about the procedures and implications of the surgery. The IRB is responsible for managing the conditions around the innovation of the surgery. The impact on the pregnant woman as well as the future of the **fetus** ^[7] is largely determined by the surgical and medical team performing the surgery.

All US healthcare organizations receiving Federal funding must have a Bioethics Committee. In institutions where fetal surgery occurs, a Bioethics Committee might provide oversight of the healthcare team, the pregnant woman, the **fetus** ^[7], and other significant family members. The Bioethics Committee, in most healthcare institutions and healthcare systems, is established by the hospital or research institution where the surgery is performed, and it has physicians and staff who volunteer their time to provide consultations at the bedside in situations where moral and ethical concerns require attention. The Committee may become involved with specific questions about the circumstances that surround the surgery and the participants. The Committee may be asked to make recommendations about specific situations such as coercion, **informed consent** ^[18], or situations where conflict between parties exists.

Consideration of fetal surgery often involves nondirective, detailed, explicit discussion, and counseling about the medical, personal, social, and ethical issues and risks of the procedure, as well as other options available to the woman and **fetus** ^[7]. Many argue that the pregnant woman should understand the commitment she is making and the circumstances that surround her present and future needs and those of the **fetus** ^[7]. Weighing the benefits and the risks of each option is morally, ethically, and legally the right of the pregnant woman and her partner in circumstances where the best answers are as individual as the circumstances.

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