AMERICAN ACADEMY OF PEDIATRICS
Committee on Bioethics

Fetal Therapy—Ethical Considerations

ABSTRACT. Decisions to undertake fetal therapy involve a complex assessment of the best interests of the fetus and a pregnant woman’s interest in her own health and freedom from unwanted invasion of her body. Pregnant women almost always accept a recommendation for fetal therapy that is approached collaboratively, especially if the therapy is of proven efficacy and has a low maternal risk. Fetal therapy of unproven efficacy should only be undertaken as part of an approved research protocol. In recommending fetal therapy of proven efficacy, physicians should respect maternal choice and assessment of risk. Under limited circumstances when fetal therapy would be effective in preventing irrevocable and substantial fetal harm with negligible risk to the health and well-being of the pregnant woman, should the pregnant woman be opposed to the intervention, physicians should engage in a process of communication and conflict resolution that may require consultation from an ethics committee and, in rare cases, require judicial review. A physician should never intervene without the woman’s explicit consent before judicial review.

The practice of caring for a pregnant woman and her fetus has always had the dual goal of a good outcome for both. In pursuit of this goal, the pregnant woman has always had to consider undergoing her own risks or discomforts for the sake of her fetus. With recent advances in perinatal medicine, the pregnant woman and her fetus are increasingly viewed as two treatable patients. Fetal medicine is now well-established and offers a range of diagnostic and therapeutic modalities. However, the maternal-fetal relationship is unique because access to the fetus is through the pregnant woman. As a result, fetal evaluation and therapy have created a variety of ethical questions about a physician’s responsibility when the interests of a pregnant woman and her fetus appear to be in conflict.

Decisions by pregnant women concerning fetal diagnostic and therapeutic interventions clearly involve considerations as to what is best for the fetus. However, these decisions also involve the woman’s interest in her own health and freedom from unwanted invasion of her body because all diagnostic and therapeutic interventions on behalf of a fetus necessarily affect the pregnant woman and require her direct participation. Thus, fetal therapy poses a potential conflict between the pregnant woman’s own best interests, and her (and others’) perception of the best interests of her fetus. The dilemma of the surrogate decision maker (such as a son or daughter) who must balance his or her own interests and the interests of the patient (such as an elderly parent) is not new to medicine; however, in these other contexts, the surrogate decision maker’s health and freedom from unwanted bodily invasion are rarely directly affected by the decision. In addition, the pregnant woman’s physician may face a potential conflict between his or her primary responsibility for the woman’s health and well-being and a secondary responsibility for the health of the fetus.

Previously, making decisions about maternal and fetal well-being was the sole purview of the pregnant woman and her physician. This relationship developed during a period when virtually all interventions for fetal well-being were directed specifically toward the general health of the mother and not specifically for the fetus. Now, however, many therapeutic interventions can be directed toward specific medical and surgical problems with the fetus. In light of this complexity, it is beneficial for involved primary care physicians, pediatricians, and subspecialists (such as neonatologists, perinatologists, pediatric surgeons, cardiologists, and geneticists) to advise the obstetrician and the woman when complex fetal diagnostic and therapeutic interventions are contemplated. A team of consulting professionals should be brought together in a collaborative and multidisciplinary fetal treatment program with established policies on communication, diagnostic and therapeutic interventions, and quality improvement.

Pediatricians and other appropriate consultants should work with obstetricians to evaluate the potential risks and benefits of a given therapy for the fetus and to formulate treatment recommendations that consider the potential risks to the woman. Members of the health care team should assist the parents in making an informed decision about fetal therapy. This is best accomplished by communicating directly with the parents to ensure that information is understood and that the parents are aware of the broad range of possible outcomes for both the pregnant woman and her fetus. This is extremely important because in their desire to simplify their understanding of fetal interventions parents may believe that a therapeutic intervention will result in either the death of the fetus or complete correction of the problem. Counseling should insure that parents understand the range of possible outcomes between complete cure and death. Finally, the health care team should be supportive and available to the family, whatever their choice.
Fetal medical and surgical treatment is an evolving field. Many techniques involving fetal intervention are of uncertain therapeutic efficacy. Some fetal therapeutic interventions, such as prenatal steroids to prevent hyaline membrane disease and zidovudine to prevent the perinatal transmission of human immunodeficiency virus infection, are accepted practices of proven efficacy. Other interventions, such as fetal transfusion for hydrops secondary to parvovirus infection, are common practices but are less certain in their efficacy. Other fetal interventions, such as in utero repair of congenital diaphragmatic hernia, currently are considered research procedures and not standard medical practices.

If a fetal intervention is one of proven efficacy and has concomitant low maternal risk, the physician should recommend the procedure and emphasize, if necessary, the responsibility of the mother to accept some personal risk for the potential benefit to her fetus. An example of such a procedure is the use of intrauterine fetal transfusions to prevent the complications of Rh isoimmunization. If the woman refuses to undergo an intervention that poses a risk to her health and well-being, her choice and assessment of risk should be respected.

When fetal surgical intervention is discussed with families, it is important that procedures of unproven efficacy be clearly explained as such. By definition, the outcome of experimental procedures is uncertain; therefore, parents should not be pressured or made to feel obligated to participate. Diagnostic and therapeutic procedures of unproven efficacy should be undertaken with the voluntary informed consent of the pregnant woman according to a clearly defined research protocol that has been approved by the appropriate institutional review board. A pregnant woman should be discouraged from placing herself at undue risk where the potential benefit to the fetus is remote. Under such circumstances, physicians may refuse to offer such an intervention despite a pregnant woman’s insistence that something be done.

The following three conditions must be met for a physician to consider opposing the woman’s refusal of a recommended intervention: 1) there is reasonable certainty that the fetus will suffer irrevocable and substantial harm without the intervention, 2) the intervention has been shown to be effective, and 3) the risk to the health and well-being of the pregnant woman is negligible. When these three conditions exist, the woman should be informed that the decision creates a moral dilemma for her physician and an attempt should be made to persuade (not coerce) her to consent. It may be helpful, with the woman’s permission, to involve other family members in the decision. If refusal persists, the physician may wish to inform the woman that her decision may be unreasonable and that consultation with another physician, a hospital ethics committee, or others within the institution would be helpful.

Finally, only in rare cases should a physician consider any further action beyond that outlined above. Under no circumstances should a physician physically intervene without the explicit consent of the pregnant woman before judicial review, regardless of her lack of physical resistance. If a physician feels strongly that further intervention is necessary, judicial authorization is absolutely required. However, given the potential adverse consequences of forced medical or surgical procedures, court intervention should be seen only as a last resort.

The Academy cannot address interventions proposed solely for the benefit of the pregnant woman. Unilateral action without a judge’s authorization is never appropriate, except perhaps in a genuine emergency when the pregnant woman lacks decision-making capacity and has not previously expressed an opinion about a proposed intervention that is recommended by her physicians and/or other members of the health care team to be in her best medical interests. In all other circumstances, the pregnant woman’s choice must be respected, and may only be overridden when judicial authorization has been appropriately obtained. If the pregnant woman currently lacks decisional capacity, any prior expressions or family testimony about her views must be carefully evaluated, preferably with the assistance of an ethics committee or through judicial review, if they are to be used to justify fetal therapy. In the absence of a previously expressed opinion from the pregnant woman supporting fetal therapy, emergency interventions solely for the benefit of the fetus are ethically troubling and rarely, if ever, justified without judicial authorization.

As the benefits and risks of fetal therapy are defined more clearly, the physician’s role in assisting families in making decisions may be more clearly defined. Pregnant women almost always accept a physician’s recommendation for diagnostic and therapeutic fetal interventions when provided evidence of proven effectiveness and low maternal risk. However, all members of the health care team must be aware of the possible conflicts between women and their fetuses created by fetal interventions and must be prepared to address these ethical dilemmas.
REFERENCES


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