



Clinical Report—Maternal-Fetal Intervention and Fetal Care Centers

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, COMMITTEE ON ETHICS; AMERICAN ACADEMY OF PEDIATRICS, COMMITTEE ON BIOETHICS

ABBREVIATION

IRB—institutional review board

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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abstract

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The past 2 decades have yielded profound advances in the fields of prenatal diagnosis and fetal intervention. Although fetal interventions are driven by a beneficence-based motivation to improve fetal and neonatal outcomes, advancement in fetal therapies raises ethical issues surrounding maternal autonomy and decision-making, concepts of innovation versus research, and organizational aspects within institutions in the development of fetal care centers. To safeguard the interests of both the pregnant woman and the fetus, the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics make recommendations regarding informed consent, the role of research subject advocates and other independent advocates, the availability of support services, the multidisciplinary nature of fetal intervention teams, the oversight of centers, and the need to accumulate maternal and fetal outcome data. *Pediatrics* 2011;128:e473–e478

The past 2 decades have yielded profound advances in the fields of prenatal diagnosis and fetal intervention. Ultrasonography and magnetic resonance imaging have led to the diagnosis of fetal anomalies that can affect many organ systems. Concomitantly, improvements in minimally invasive techniques and in the understanding of fetal physiology have allowed for more successful and less invasive or risky interventions for fetal diseases in utero. Intervention has been offered for a variety of fetal diseases, including structural abnormalities, cardiac arrhythmias, fetal metabolic diseases, and abnormalities of the placental vessels or membranes. Many of these diseases would be lethal without treatment; some (eg, spina bifida or hypoplastic left heart syndrome) are not necessarily lethal postnatally, but efforts to treat them in utero have been offered with the goal of improving long-term outcomes for the child. Many interventions are offered within the construct of a research protocol. Although fetal interventions are driven by a beneficence-based motivation (ie, a desire to do good, to improve fetal and neonatal outcomes, to ameliorate suffering), advancement in fetal therapies raises ethical issues surrounding maternal autonomy and decision-making, concepts of innovation versus research, and organizational aspects within institutions in the development of fetal care centers.

THE DECISION-MAKING PROCESS

The overarching goal of fetal interventions is clear: to improve the health of children by intervening before birth to correct or treat prenatally diagnosed abnormalities. This stems from a beneficence-based obligation to the fetus. Any fetal intervention, however, has implications for the pregnant woman's health and necessarily her bodily integrity and, therefore, *cannot be performed without her explicit informed consent*.¹ It is impossible to treat the fetus without going through the pregnant woman either physically (in the case of surgical treatments) or pharmacologically (as in the case of medications given to the woman that then cross the placenta to treat the fetus). Because the pregnant woman who chooses to undergo these procedures and treatments must assume some of the risk, respect for her autonomy requires a thorough discussion and evaluation of the maternal risks and harms of any of these therapies as well as her valid consent.² A pregnant woman's right to informed refusal must be respected fully.³

For many women, as well as the physicians caring for them, decision-making considerations relevant to fetal treatment may seem to parallel the parental decision-making process in determining treatment of childhood ailments. Women weigh the risks and benefits of the intervention for the fetus against the possible outcomes without intervention. For those few treatments that have been shown to be effective and be of low risk or minimal invasiveness, most women will agree to the treatment out of a beneficence-based obligation to their fetuses. Nonetheless, consent still must be based on the pregnant woman's assessment of her *own* interests. And, although a parental decision may, in certain circumstances, be overridden for a child after birth, even the strongest evidence for fetal benefit would not be sufficient ethi-

cally to ever override a pregnant woman's decision to forgo fetal treatment.^{4,5}

A pregnant woman will often assume quite significant risks for her fetus, and some women might find it difficult to forgo these interventions because of pressures from within themselves, from their families, from their communities, or even from their care providers.⁶ A pregnant woman's decision may be affected by factors such as her family's or society's expectations regarding her responsibility as a prospective mother, maternal feelings of guilt and her desire to try and make things "right," or even the psychosocial "therapeutic misconception," that is, the presumption that an intervention with no proven efficacy will actually work merely because it is *offered* by a center, is under a study protocol, or has been covered by the news media.^{7,8} The informed consent process should, therefore, contain reasonable safeguards against limits to voluntariness, ranging from undue influence to coercion.

Safeguards should be in place to protect women considering fetal research. One possible safeguard would be to have a research subject advocate who does not have direct ties to the experimental protocol so that this individual can act as an independent advocate for the pregnant woman, especially when the proposed intervention poses significant risks to the pregnant woman.⁹ This advocate should be non-directive in his or her support of the woman's decision and focus on meeting the woman's decision-making needs. Involving someone who has an understanding of the culture of research and yet maintains "separateness" from the research team can provide an ethical safeguard to support the pregnant woman.¹⁰ But even outside a research protocol, a pregnant woman receiving treatment that is not experimental may also benefit from an

independent advocate who might be her obstetric provider, a perinatal nurse, or a specially trained advocate. Other family members involved in these decisions also need consideration. Pregnant women have a variety of support persons, including spouses and partners of either sex. The interests of others involved vary depending on their relationship to the woman and fetus. Because families come in differing forms, the woman herself should define these relationships and determine who should assist in any decision-making. In this Committee Opinion, the American College of Obstetricians and Gynecologists (the College) and the American Academy of Pediatrics (the Academy) write about the interests of the father but recognize that the father of the fetus may be absent or uninvolved and that the involved partner may be a man or a woman biologically unrelated to the fetus.

In most cases, the father has a moral interest in the health of the fetus and the pregnant woman, just as he would have interests in the health of the mother and child after delivery. It is appropriate for women to involve fathers in these decisions for good reasons: they will usually be raising this future child together, they will make joint decisions about health issues, and their relationship may be one of mutual support in family decision-making. It may be problematic for a woman to proceed with these interventions without consulting the father. It must be recognized that postnatally, pediatric care commonly involves shared decision-making between a child's mother *and* father, making the recommendation not to grant any authority to the father in the prenatal period uncomfortable for many pediatricians. However, for the reasons stated earlier, the pregnant woman's interests and final decisions regarding fetal interventions assume priority in the

prenatal period. Although it may be appropriate and helpful for the father to be involved in these decisions and have complete access to information (with proper authorization from the pregnant woman), to assign him any authority to assent or dissent would unjustifiably erode the autonomous decision-making capacity of the pregnant woman. The College addressed paternal consent for research in a previous Committee Opinion.^{3,11} The College concluded that paternal consent for research on fetuses should not be required but recognizes that federal regulations continue to require this consent in some circumstances.

PREGNANT WOMEN REQUIRE INFORMATION ON RISKS, BENEFITS, OUTCOMES, AND ALTERNATIVES FOR BOTH THE FETUS AND THEMSELVES

One of the challenges surrounding fetal interventions is the difficulty in delivering information to prospective parents that is both thorough and unbiased. Not only do prospective parents need to be informed of the goals of treatment, but they also need to know about the sometimes conflicting data, or more commonly the paucity of data, that support offering or performing interventions. The risks and possible benefits to the fetus undergoing an intervention need to be weighed against the risks and benefits of obstetric and neonatal care without the intervention (which is often the standard of care). Moreover, the range of outcomes of all options must be presented, because prospective parents may erroneously believe that there are only 2 possible results: 1) success (fetal cure) or 2) failure (fetal death).

In addition to information regarding the risks and benefits to the fetus or neonate, women require a frank discussion of the maternal risks of any fetal intervention. The morbidity and

mortality associated with some interventions may be quite small (an amniocentesis needle and use of many maternal medications) or quite significant (the performance of a laparotomy and hysterotomy). Maternal hysterotomy may increase the risk of uterine rupture to rates as high as those after a classical cesarean delivery (4%–9%)¹²; these ruptures are associated with significant maternal and neonatal morbidities and mortalities. Moreover, these risks will persist in subsequent pregnancies as well. A thorough disclosure of these risks is always necessary.

INNOVATIVE AND EXPERIMENTAL CARE

One vital, though sometimes difficult, distinction that should be made to prospective parents concerns which fetal interventions are standard or evidence-based therapy and which are innovative or experimental. Certainly any intervention that is being studied as part of a research protocol requires formal institutional review board (IRB) oversight and an approved informed consent process. Federal guidelines indicate that novel interventions that deviate substantially from standard practice do not need to be performed within a research protocol but should eventually be developed into a protocol subject to IRB oversight¹³:

“When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is ‘experimental,’ in the sense of new, untested or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project.”

An attempt should be made to make clear to patients the distinction between the goals of therapeutic medi-

cine (eg, cure, treatment, or palliation) versus the goals of research (eg, answering a scientific question that contributes to generalizable knowledge). In addition, there is often a blurring of boundaries between research and innovative practice associated with the rapidly developing technologies used in fetal interventions that raises concerns about the protection of pregnant women and their fetuses from the risks of unproven therapies. Although the first few uses of a new intervention may be motivated by a desire to help particular fetuses, once feasibility and potential benefit have been identified, innovations should be subjected to systematic formal research as soon as feasible.¹⁴ This benefits science, because evaluation of new procedures might be hindered if new procedures continue to be considered “innovative therapy” rather than part of careful research. Pregnant women and their fetuses who undergo these interventions must have at least the same protections afforded to other research participants, and studies should be designed to assess the full impact of risks and benefits of these interventions on both the woman and the fetus, for both short- and long-term outcomes.

ALTERNATIVES TO INTERVENTION

The case of prospective parents electing to forgo fetal intervention also needs further exploration. Given the maternal morbidities and experimental nature of many fetal interventions, some women may understandably elect to carry the pregnancy to term but *not* to undergo fetal intervention. It is critical, therefore, for those centers offering fetal interventions to provide care, support, and appropriate referral services for these women and their families. For the fetus with anomalies such as spina bifida, this will involve postnatal neurosurgical treatment, which is currently standard care. For the fetus with lethal abnormalities,

this may take the form of access to palliative care or perinatal hospice programs. In the situation in which the fetal intervention is being offered in an attempt to avoid fetal death, these services could be offered alongside the intervention in case it is unsuccessful.

Finally, the clinical reality of serving women during pregnancy is that some women will elect pregnancy termination when facing the diagnosis of significant fetal anomalies. Centers offering fetal intervention should evaluate pregnant women in a timely fashion, counsel them adequately and nondirectly about all options, and, for women who might opt for pregnancy termination, have in place appropriate mechanisms, including the ability and resources for referral, to support these women through a difficult decision. An integrated palliative care, hospice, or bereavement service can help support women who elect to terminate their pregnancies as well.

Thus, the ethical provision of fetal intervention requires that women are not only well informed but also have, to the greatest extent possible, meaningful access to alternatives to intervention. Practitioners participating in fetal care centers may face significant difficulties in presenting in as nonbiased a fashion as possible these 4 distinct options: 1) fetal intervention, 2) postnatal therapy, 3) palliative care, or 4) pregnancy termination. Certainly each pediatrician, surgeon, and obstetrician involved in these decisions may have his or her own distinct views about the best course of action for any given disease entity, and thus, the counseling of the pregnant woman becomes complicated. Coordination of care and good communication between providers can help to minimize the conflicting information and opinions that may be given to patients.

OTHER NECESSARY SUPPORT SERVICES

The complex emotional stressors that pregnant women and their families may experience when considering fetal intervention may necessitate access to a variety of support services. These may include social services, palliative care and perinatal hospice services, genetic counseling, and ethics consultation, when appropriate.

FETAL CARE CENTERS

Diagnostic and therapeutic efforts are frequently being combined frequently and marketed in the form of fetal care or treatment centers. Fetal care centers can exist in many forms, having developed through a variety of multidisciplinary collaborative relationships among pediatric subspecialists, maternal–fetal medicine specialists, and radiologists. Often, they are free-standing centers, but they also can exist within established pediatric or obstetric departments. Regardless of their origin or site, they typically offer a wide variety of fetal diagnostic services as well as proven therapies and experimental practices of unproven benefit. These centers are driven by a beneficence-based motivation to improve fetal and neonatal outcomes and have frequently been the site of innovation and research that has furthered this end.^{15,16} It should be noted that most maternal–fetal medicine divisions already provide such fetal care along with care of pregnant women; these divisions routinely call on pediatric surgeons and other subspecialists to consult with pregnant women without having any direct affiliation with a formal “fetal care” center. The dilemmas that may arise in the context of fetal care are, thus, not unique to fetal care centers; many of these dilemmas are faced by anyone caring for pregnant women. However, in marketing these centers around the fetus and its

care, these centers require heightened scrutiny so that the needs and the interests of pregnant women are being adequately addressed.¹⁷

Conflicts of interest may arise in providing fetal intervention services, because these services may be financially lucrative for the institutions and may benefit the careers of the centers’ practitioners. Furthermore, institutional use of resources by a fetal care center for the few women and fetuses who may benefit from an intervention may not be the most just or fair distribution of resources. Even if centers do not perform an intervention in the majority of cases they see, this may simply mean that prenatal counseling is a major component of most “fetal care” and is, in fact, a good justification for the use of resources in this fashion.

Cooperation between fetal care centers should be encouraged to establish collaborative research networks (especially for rare diseases and procedures) and to support multicenter trials to accumulate more robust short- and long-term maternal and fetal outcome data on all categories of fetal intervention. In addition, the establishment of centers of excellence for those procedures that are particularly challenging and rare may help to optimize fetal and maternal outcomes.¹⁸ As with many rare specialty-specific endeavors, the balance of offering geographical access while having the quantity of cases necessary to develop clinical expertise and quality outcomes is difficult to achieve. Limiting interventions to a few centers of excellence for the sake of quality of care will create both geographical and financial barriers to access. Furthermore, those centers not participating in multicenter trials must consider whether to refer patients to centers that are participating to facilitate these research studies and find answers that cannot be discovered by offering interventions “off-study.”

OVERSIGHT AND GOVERNANCE

To protect the panoply of interests involved (fetal, maternal, professional, and institutional), centers performing fetal interventions should have organizational structures or groups to provide oversight of both clinical and non-clinical activities. Multidisciplinary teams should be assembled to oversee the care being offered and to ensure that appropriate informed consent is obtained. To protect the interests of the pregnant woman, such teams should include a maternal–fetal medicine specialist. Indeed, because of their particular training, maternal–fetal medicine specialists are best suited to direct the care of the pregnant woman undergoing fetal interventions. Neonatologists also should be involved, because they will typically be the primary physicians managing the care of the neonate and dealing with the medical consequences of the antenatal intervention. Including a variety of other professionals on the team, such as nurses, pediatric and surgical subspecialists, genetic counselors, chaplains, ethicists, and other members of institutional ethics committees, is vital. Ideally, this group would include members, both professionals and nonprofessionals, without direct ties to the center involved. This group can help explore conflicts of interest, distinguish between innovation and research, and ensure that pregnant women are not being unduly influenced, coerced, or taken advantage of in what may be a time of crisis.

There also may be clinical management conflicts that arise between the obstetric and pediatric staff caring for these women, because the focus of care of the 2 groups can differ. Organizational structures within fetal care centers that foster consensus building are crucial to resolving these conflicts. The obstetrician, however, must remain in charge of the pregnant wom-

an's overall care. Moreover, these centers must be able to provide the high-risk and obstetric critical care that these women often need; this may be a challenge when centers are housed in pediatric hospitals but it is necessary to optimize the well-being of the pregnant woman.

Finally, to protect against institutional conflicts of interest, an external advisory group may be necessary to monitor the center's nonclinical activities including marketing, outreach, and community relations. A memorandum of understanding should be developed that delineates the oversight group's authority to veto or halt activities that do not provide adequate benefits or pose inordinate risks.

RECOMMENDATIONS

To safeguard the interests of both the pregnant woman and the fetus, the College and the Academy make the following recommendations:

- Because it is impossible to treat the fetus without going through the pregnant woman either physically or pharmacologically, any fetal intervention has implications for the pregnant woman's health and necessarily her bodily integrity and, therefore, cannot be performed without her explicit informed consent.
- Distinctions should be made to prospective parents between which protocols are standard or evidence-based therapies and which are innovative or experimental interventions. Ordinarily, innovations should be subjected to systematic formal research as soon as feasible. Research must always be offered under proper oversight by an IRB.
- The informed consent process should involve thorough discussion of the risks and benefits for both the fetus and the pregnant woman. The full range of options, including fetal intervention, postnatal therapy, palliative care, or pregnancy termination, should be discussed. The informed consent process should contain reasonable safeguards against limits to voluntariness, ranging from undue influence to coercion.
- Safeguards should be in place to protect women considering fetal research. One possible safeguard would be to have a research subject advocate who does not have direct ties to the experimental protocol so that this individual can act as an independent advocate for the pregnant woman, especially when the proposed intervention poses significant risks to the pregnant woman. Similarly, a woman receiving treatment that is not experimental may also benefit from an independent advocate who might be her obstetric provider, a perinatal nurse, or a specially trained advocate.
- The complex emotional stressors that pregnant women and their families may experience when considering fetal interventions may necessitate access to a variety of support services. These may include social services, palliative care and perinatal hospice services, genetic counseling, and ethics consultation, when appropriate.
- The organization and governance of centers providing fetal interventions should involve a diverse group of professionals. Maternal–fetal medicine specialists and neonatologists should be included in this group. Including a variety of other professionals on the team, such as nurses, pediatric and surgical subspecialists, genetic counselors, chaplains, ethicists, and other members of institutional ethics committees, is vital. Ideally, this group would include members, both professionals and nonprofession-

als, without direct ties to the center involved.

- Cooperation between fetal care centers should be encouraged to establish collaborative research networks (especially for rare diseases and procedures) and to support multicenter trials to accumulate more robust short- and long-term maternal and fetal outcome data on all categories of fetal intervention. In addition, the establishment of centers of excellence for those procedures that are particularly challenging and rare may help to optimize fetal and maternal outcomes.

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