

# Team of bioethicists calls for rigorous trials for experimental fetal therapy

December 14 2017, by Archana Nilaweera

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Citing uncertainties about the risks and benefits of an experimental therapy for fetuses whose kidneys do not develop, bioethicists at Johns Hopkins and a team of medical experts are calling for rigorous clinical trials in the use of a potential treatment known as amnioinfusion.

Bilateral renal agenesis, the absence of both kidneys at birth, occurs in 2.88 per 10,000 [live births](#), meaning about 1,100 pregnancies are affected by this condition annually in the United States. The condition has been considered uniformly fatal because without functioning kidneys, the fetus' lungs also do not fully develop. However, serial prenatal amnioinfusions might be able to overcome problems with lung development. The treatment consists of infusing saline solution into the amniotic sac to allow the lungs to develop. The idea is to support the fetus so that, after birth, the baby can undergo dialysis and ultimately [kidney](#) transplantation.

Amnioinfusion was popularized by a well-publicized birth in 2012. The child is still living.

The article, published online ahead of print in *Obstetrics & Gynecology*, calls for a closer look at the ethical issues related to amnioinfusion. Because the [intervention](#) is still experimental, careful research must be done to assess the safety and efficacy of the procedure. Specifically, the authors call for a closer examination of 10 key [ethical issues](#) relevant to amnioinfusion:

- Potential risks and benefits +Clinical care compared with innovation compared with research
- Counseling of expectant parents
- Consent
- Outcome measures
- Access and justice
- Conflicts of interest
- Effects on clinicians
- Effects on institutions
- Long-term societal implications

These infusions may also pose risks to the mother and may cause premature [birth](#). Additionally, families must receive proper counseling on their options. Those faced with the diagnosis of bilateral renal agenesis also have pregnancy termination and expectant management with palliative care, as well as experimental interventions, to consider.

"It is important that expectant parents considering an intervention do so by enrolling in a formal clinical trial," says Jeremy Sugarman, a professor of bioethics and medicine at the Johns Hopkins University School of Medicine and the deputy director for medicine of the university's Berman Institute of Bioethics. "This way the decisions and experiences of the families, patients, and physicians can be captured so we can find out if the intervention is safe and effective."

The bottom line, says Sugarman, is the need for long-term multicenter research involving those who choose serial amnioinfusions and those who do not, so that physicians can properly inform and counsel families about treatment options and likely outcomes for their fetuses.

**More information:** Jeremy Sugarman et al. Ethical Considerations Concerning Amnioinfusions for Treating Fetal Bilateral Renal Agenesis, *Obstetrics & Gynecology* (2017). [DOI:](#)

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