

## OBSTETRICS

# Fetal tissue research: an ongoing story of professionally responsible success

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## Introduction

Procuring fetal tissue for research and treatment has recently become politically controversial in the United States.<sup>1,2</sup> The result has been to obscure professional responsibility in this matter, which has been a disservice to the medical community and the patients who can and do benefit from resulting medical advances. In this commentary we explain why the use of fetal tissue for research and treatment should not be controversial but, instead, viewed as a professionally responsible success story.

## A brief history of fetal tissue research and treatment

The 1954 Nobel Prize in Physiology or Medicine was awarded to John Enders, Thomas Weller, and Frederick Robbins for the discovery of the ability of poliomyelitis viruses to grow in cultures of various types of tissue. Although great progress had been made in fighting bacterial infections in the prior decades, viruses were difficult to cultivate. Preventive or therapeutic agents were therefore mostly unattainable. Although animal models are informative for many diseases, viruses are often species specific, so nonhuman studies were often not informative. As early as the 1930s, Olitsky et al<sup>3</sup> had attempted to grow poliovirus in cultures of chick, mouse, monkey, and human embryo cells. Only the human brain tissue from embryos that were the product of induced abortion was successful as a host. This line of research was continued by Enders et al<sup>4</sup> who found that the virus could be grown in cells from numerous embryonic tissue types in addition to neurons. Ultimately, these advances in human embryo-derived viral culture advanced the field and led to the ability to cultivate varicella, measles, and numerous other viruses. This research was instrumental in the ability to produce viruses to study and develop vaccines. Without such research, the polio vaccine and other vaccines may not have been developed or may have been delayed by decades.<sup>5</sup>

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Although the teratogenicity of congenital rubella was known since the 1940s,<sup>6,7</sup> progress in understanding the disease and developing vaccines only came later, when research was undertaken on embryonic and fetal tissue from patients who opted for termination because of acquisition of rubella in pregnancy. The tissue from those aborted embryos and fetuses was used both to purify virus and to understand viral host reactions.<sup>8</sup> Research using cadaveric fetal tissue led to the development of the rubella vaccine and the subsequent elimination of congenital rubella in the Americas, thereby decreasing the need for induced abortion due to congenital rubella.

More recently, fetal tissue became a cornerstone of some of the most promising therapies for Parkinson disease and other difficult-to-treat adult conditions. More than 100 patients with Parkinson disease have received cells transplanted from the midbrain of aborted embryos.<sup>9-12</sup> Initial studies indicated that the patients most likely to benefit were young, had early-stage disease, and had large numbers of cells of fetal origin integrated. Those studies were used to help design a new trial of 150 patients in Europe. Although there is hope that pluripotent stem cells may provide an alternative in the future, “right now the fetal cell is the gold standard we need to match.”<sup>12</sup>

Cadaveric fetal tissue benefits scientific research across many fields, including physicians and scientists who may not even realize its contribution to their work. The HEK293 cell line originated from the kidney cells of an aborted embryo.<sup>13</sup> Due to the ease of transfection, and the subsequent ease of production and purification of human proteins, they have become ubiquitous in research. A PubMed search for “HEK293” reveals >28,000 articles. Studies in the *American Journal of Obstetrics and Gynecology* in areas as diverse as preeclampsia, fetal drug exposure, and placental gene transfer also utilized this cell line.<sup>14-16</sup> The cell line can be purchased from repositories. Protein production can also be outsourced to companies that maintain these cell lines and will transfect and purify the protein of interest. These cells have been used in the development and production of therapeutics.<sup>17</sup>

## Induced abortion before viability is legally permissible in the United States<sup>18</sup>

Induced abortion before viability authorized by the pregnant woman's informed consent is permissible in professional obstetric ethics.<sup>19</sup> It is well understood that the informed consent process should convey evidence-based information about the medically reasonable alternatives for managing a preivable pregnancy, the biopsychosocial benefits and risks of each alternative, and the disposition of the fetal cadaver.<sup>20</sup>

Discussion of procurement of tissues or organs from the fetal cadaver, which may or may not be intact, is not part of the informed consent process for induced abortion. Indeed, concern that the benefit of research may encourage women to choose induced abortion led to the 1988 fetal tissue transplantation panel to recommend that tissue donation not be addressed until after the decision to terminate.<sup>1</sup> In fact, the oversight of fetal tissue research is carried out in the same way as other human subjects research. The Department of Health and Human Services has clear rules:

45CFR 46.204 (i): "Individuals who use fetal tissue in their research will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy, and (j) "individuals engaged in the research will have no part in determining the viability of a neonate."<sup>21</sup>

Attestation that the researchers will adhere to these guidelines is part of the prospective review process for obtaining permission to do such research. In fact, the practice of procuring fetal tissue for research with consent is consistent with professional responsibility<sup>18</sup> as the patient has a right to assert her value-based preference. Deidentified tissue from surgical procedures is used routinely in research without consent. By obtaining consent for use of fetal tissue in research we are adding additional protections. This is a level of respect for women that is not required in other spheres of medicine.

Once a patient has independently made her informed decision to authorize induced abortion, it is reasonable to present her with the opportunity to consider authorizing procurement of tissues and organs from the fetal cadaver for purposes of research and treatment. Those who agree may do so from diverse motivations. Some women may find value in the knowledge that donating organs and tissues may benefit other patients from research and treatment using such tissues. This is an expression of a common motivation for participation in research of all kinds: altruism. This is analogous to the value that parents find in donating organs and tissues after a child has been determined to be dead. There is no evidence that the potential for societal benefit causes patients to choose termination of pregnancy or that research on fetal tissue causes abortion. Any claims to the contrary are pure speculation. Moreover, neither the woman nor her physician derives financial benefit from authorizing procurement of fetal tissues, thus removing incentives to act on financial self-interest that could bias the decision-making process.

### **The justice-based obligation to tolerate what one judges to be morally impermissible**

Even though induced abortion is permissible both in law and professional obstetric ethics,<sup>20</sup> some regard induced abortion to be ethically impermissible, usually on theological grounds. Those who do not share this moral conviction are nonetheless obligated to respect the fact that those with such moral convictions are sincere. Individuals who regard induced abortion to be morally impermissible but live in a society in which it is legally available sometimes regard themselves as

having to tolerate what is ethically intolerable or even evil. This belief should also be respected. These beliefs, however, are not the whole of ethical reflection on how to live with mutual respect in a morally pluralistic society. As has been argued in the case of human embryonic stem cell research, the ethical issue that needs to be addressed is not the morality of abortion but whether this ethical burden of tolerating what one sincerely believes to be morally impermissible should be regarded as unacceptable to those who have to bear this burden.<sup>22</sup>

This ethical issue should be addressed using the justice-based concept of exploitation. Fairness in society requires the prevention of exploitation, ie, circumstances in which one group is unduly burdened, another group benefits, and the burdened group does not have the opportunity to experience these benefits. Justice requires that burdens be distributed so that those who are burdened have the opportunity for offsetting benefit. As no one is compelled to have an induced abortion or to authorize procurement of cadaveric fetal tissue, individuals who have theological objections to induced abortion can decline to take part. While some may object to living in a society that requires them to tolerate cadaveric fetal tissue being used in research, this burden is offset by the benefit to society in the form of improved clinical care for millions of patients and the advancement of biomedical research with the potential for such benefit. In fact, those who object to what they judge to be the evil of induced abortion, and their children, benefit from fetal tissue research. Because they experience significant offsetting clinical benefit, they should not be considered exploited. That is, one can be morally burdened by procurement and use of cadaveric fetal tissue and not be exploited. The objection that some are unacceptably morally burdened in this way is therefore not determinative because, in the absence of exploitation, there is a justice-based obligation to tolerate what one considers to be morally impermissible.

### **Conclusion**

The procurement of cadaveric fetal tissue for research and treatment is legally permitted and regulated and is supported by professional responsibility in obstetrics and gynecology. Those who object on the grounds that induced abortion is ethically impermissible for theological reasons deserve recognition of and respect for the seriousness of their moral convictions. However, these individuals are not exploited by the procurement and clinical and research use of cadaveric fetal issue. Such procurement is therefore supported by the ethical principle of justice. The success story of cadaveric fetal tissue research and treatment should continue unhindered, to fulfill professional responsibility to current and future patients. ■

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