

# Virtual Mentor

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## HEALTH LAW

### **Reproductive Tissue Transplants Defy Legal and Ethical Categorization**

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Since its inception in the early part of the twentieth century, organ transplantation has posed ethical and regulatory challenges. How should we allocate a limited supply of life-saving resources? Who should decide? Who should be allowed to donate organs—the living, the dead, prisoners, patients with communicable disease? Organizations like United Network for Organ Sharing (UNOS) and laws like the National Organ Transplant Act (NOTA) provide some guidance, but recent technological advancements in reproductive medicine are creating new dilemmas. The transplantation of reproductive organs (including ovaries, testes, and uteruses) challenges our notion of the very purpose of organ transplantation, its goals, and its outcomes.

#### **The Current State of Reproductive Tissue Transplant**

The most successful reproductive tissue transplants to date are ovarian tissue transplants. In 2004, a woman with non-Hodgkins lymphoma, whose ovarian tissue had been removed and frozen before she underwent chemotherapy, became pregnant and gave birth after receiving a transplant of her own ovarian tissue [1]. Ovarian tissue transplants between monozygotic twins and nonidentical sisters have succeeded, making it more probable that transplants from nonrelated donors will someday be possible [2, 3]. The procedure also appears to treat infertility over the long term—one woman gave birth to two children as a result of an ovary transplant, becoming pregnant without assistance in 2007 and through IVF in 2010 [4].

Fertility after testicle transplant was proven possible in 2001, when a man in remission for cancer fathered a child after transplant [5]. Uterus transplant is the least-developed technology, still mainly in the animal phases of research, with some success in mice, dogs, and pigs [6]. A failed attempt in a human occurred in 2002 in Saudi Arabia, but plans are in place to attempt a mother-daughter transplant in Sweden sometime in the spring of 2012 [7, 8].

Reproductive tissue and organ transplants vary in difficulty and demand, depending on the type. All enable greater involvement in and control over reproduction for a wide variety of groups with disease-related or congenital infertility. Testicle transplant receives less attention, both because sperm cryopreserve better than eggs and because male-factor infertility can more easily be resolved with less invasive techniques (like artificial insemination) than female-factor infertilities [9]. However, testicle and other transplants are key in regions where gamete donation (or, in the case of uterus transplant, gestational surrogacy) is illegal.

## **New Regulatory Challenges Raised by Reproductive Tissue Transplants**

While reproductive tissue transplants open a variety of possibilities for the future of infertility treatment, they also pose significant challenges for those regulating the practice of organ transplant.

*Applicable laws.* Reproductive tissue transplant is unusual in that it embodies elements of both assisted reproductive technology (ART) and organ transplantation, two fields that are treated differently under the law. Organs are regulated by federal rules, mainly the Uniform Anatomical Gift Act (UAGA) and National Organ Transplant Act (NOTA), whereas ART is regulated by the states, whose rules vary widely in their scope, context, and existence. Because reproductive tissue transplant has characteristics of both, it's unclear which rules should apply, and neither body of regulations applies perfectly.

Current organ regulations, for example, do not take into account new concerns raised by reproductive tissue donation, namely the genetic aspect of the donation. That is, while other organ transplants affect only the health and body of the recipient, reproductive tissue transplants affect the offspring of the recipient, as well as the donor and donor's family because of their genetic relationship to the recipient's offspring. Another example is payment. Payment for organ donation is strictly prohibited but payment for donating eggs and sperm is a burgeoning market—will an egg donor be paid if she donates for IVF but not for transplant? How reproductive tissue transplants will be treated depends a great deal on how legislatures classify these procedures in the current legal terrain.

*Informed consent.* Regulatory classification also has an impact on informed consent to donate organs. To the extent that any of these donations rely on deceased donors, if the UAGA applies, it permits the next of kin to donate organs on behalf of the deceased donor [10]. However, gamete donations raise more significant issues than livers or kidneys because of their ability to create genetic offspring, thus touching upon important legal rights to reproduce (or not). These are decisions that (despite countless hours of badgering at the Thanksgiving table) we typically do not leave to our parents or next-of-kin. Some may question whether deceased individuals have a right to control reproduction, a complex and unsettled legal and ethical question that some states have tackled in posthumous conception cases (where family members have asked to use deceased individuals' gametes to reproduce) [11].

*Allocation criteria.* United Network for Organ Sharing (UNOS) plays the primary role in determining who will receive organs and in what order for all solid organ transplantation in this country [12]. This method of distribution prioritizes recipients based on three factors: sickest-first, prognosis, and first-come, first-served [13]. Reproductive tissue transplants are not life-saving interventions, so the sickest-first criterion does not apply. If a "greatest need" criterion is applied, would that mean those with the most incurable forms of infertility, those who do not already have children, those closest to reaching the end of their reproductive years, or those who

have expended the greatest resources trying to become pregnant would be prioritized for the transplant?

Prognosis is also difficult to qualify. Reproductive tissue transplants are unlike other organ transplants because they are intended to achieve the short-term result of reproduction and then be removed to avoid the lifelong need for immunosuppression, unlike a liver or a kidney which ideally remains in place until the end of the recipient's life. Medical criteria used to determine organ candidacy, including psychosocial criteria, have thus focused on who can best sustain the organ for the longest period of time [14]. In reproductive tissue transplant, in contrast, the aim for everyone is the same—to maintain the organ long enough to reproduce. In this context, what criteria determine who has a better prognosis?

### **The Changing Goals of Transplantation**

Possibly the most significant difference between reproductive tissue transplants and other organs is reflected in the changing goals of transplantation. Organ transplant has already progressed from being a life-saving procedure to being a quality-of-life intervention. In December 2011, the Department of Health and Human Services proposed rules that would include a broader array of transplants under the purview of the current Organ Procurement and Transplantation Network (the group which regulates UNOS) [15]. The new rule adds mainly “vascularized composite allotransplantation” (or the transplant of multiple tissues and a functional unit), which mainly includes hand and face transplants, to the list of regulated organs. This new proposal shows both an evolving acceptance of these new goals of transplant and a desire to regulate them [16, 17].

Reproductive tissue transplants, however, present even newer issues than hand and face transplants because they are intended not only for quality-of-life improvement but the creation of life as well. This has led scholars to ask when a dangerous and expensive procedure should be permitted [18, 19]. It raises larger societal questions about how we wish to allocate health resources, what the boundaries of medicine and transplant medicine in particular are, and how far we will go in terms of research and individual risk in the pursuit of having children.

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