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Gametes or organs? How should we legally classify ovaries used for transplantation in the USA?

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Abstract

Ovarian tissue transplantation is an experimental procedure that can be used to treat both infertility and premature menopause. Working within the current legal framework in the USA, I examine whether ovarian tissue should be legally treated like gametes or organs in the case of ovarian tissue transplantation between two women. One option is to base classification upon its intended use: ovarian tissue used to treat infertility would be classified like gametes, and ovarian tissue used to treat premature menopause would be classified like organs. In the end, however, I argue that this approach will not work because it engenders too many legal, cultural and logistical concerns and that, at least for the near future, we should treat ovarian tissue like gametes.

In 2004, at age 30, Joy Lagos was diagnosed with non-Hodgkins lymphoma. She survived thanks to a bone-marrow transplant from her older sister. However, cancer treatment left her infertile and in menopause.[1] To treat both these conditions, she got another transplant from her sister: an ovary. Whereas bone marrow is listed as one of the 10 human (including fetal) organs under regulation by the United States National Organ Transplantation Act (NOTA), the ovary is not.[2] Also not included as organs regulated by NOTA are human gametes. NOTA prohibits the sale of organs, but gametes (as well as embryos, though I limit myself to gametes because they, like ovaries contain genetic material from only one person) are legally and even socially viewed as objects that can be purchased. That the sale of gametes is legally permitted (but the sale of other organs and tissues is not) is well known, as exemplified by mass media stories of couples paying top dollar for Ivy League or supermodel gametes.[3] The USA is one of the few western countries that allows gametes to be purchased; other western countries typically regulate them like organs, though donors are sometimes compensated for their inconvenience.[4]

Given this dichotomy between the legal treatment of gametes and the legal treatment of organs, the question then arises: how should we legally classify ovaries, as they can be used to treat both reproductive and non-reproductive conditions? Working within the current legal framework, my goal in this paper is to examine how to legally categorise ovarian tissue transferred from one woman to another. I begin by contextualising ovarian tissue transplantation (OTT) within the field of oncofertility. Next I explain why women suffering from premature menopause may find OTT more appealing than hormonal therapy. I then explore categorising ovarian tissue based on its intended use (ie, what condition the transplant is being used to treat), which is often how medical treatments are classified for legal and insurance purposes. In the end, however, I argue that this approach will not work because it engenders too many legal, cultural and logistical concerns and that, at least for the near future, we should treat ovarian tissue like gametes.

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OVARIAN TISSUE TRANSPLANTATION

The interdisciplinary field of oncofertility—the joining of oncology and reproductive medicine—recently emerged to find ways of preserving the fertility of cancer patients like Lagos.[5–7] Sperm banking, which is the main form of fertility preservation technology for men, is well-established, easy and inexpensive. In contrast, most technologies for women are experimental, invasive and expensive. The only established one is embryo banking, which is often not a palatable option for women without male partners. Embryo banking even has risks for partnered women should their partner change his mind about fatherhood and try to prevent implantation. Egg freezing is gaining popularity thanks to vitrification, a new freezing technique. However, this type of fertility preservation technology is still considered experimental and unreliable by many.[8]

OTT, which is also considered experimental,[9] has recently gained attention in the medical realm[10] and the popular press.[11, 12] OTT involves transferring a piece of ovary into a woman's body with the goal of restoring ovarian function and, for women hoping to become pregnant, initiating ovulation. As with other types of assisted reproductive technologies, women can use either their biological material or donor material. Indeed, the transferred piece of ovarian tissue can either be from another woman—allograft (tissue from a non-identical person) or isograft (tissue from an identical twin)—or from the woman herself—autograft. The ovarian tissue is usually grafted onto a woman's ovary (or near the uterus or uterine tube) so that the woman can conceive through vaginal intercourse or artificial insemination. However, it can also be placed elsewhere in the body (the arm and stomach are two common places[13, 14] and mature eggs will be removed to use for in vitro fertilisation.

OTT has some significant advantages over other types of reproductive technologies. First, surgery to remove a piece of ovarian tissue can happen immediately after a woman is diagnosed with cancer, whereas harvesting eggs typically takes 2–3 weeks depending on where a woman is in her cycle.[8, 15] Some newly diagnosed cancer patients need to begin treatment immediately, thereby precluding egg freezing. Second, the drugs used to hyper-stimulate the ovaries in order to produce a large number of eggs for freezing/creating embryos can have negative side effects, such as moodiness, bloating, kidney disease and even death.[16] Furthermore, women with breast cancer often cannot use the drugs to hyper-stimulate because many breast tumours contain oestrogen receptor positive cells.[15] Yet, OTT has disadvantages both for the donor and the recipient. The donor may experience difficulty achieving pregnancy, premature ovarian failure and menopause at a younger age than the general population.[15, 17] I will discuss disadvantages for recipients in the next section.

When cancer patients choose OTT as a form of preservation, they have a piece of their ovary or their entire ovary removed and frozen for later use. Not all women, however, are able to predict future infertility and take action against it. Women who develop premature menopause may not realise the disease has rendered them infertile until it is too late to harvest their eggs or ovarian tissue. Additionally, some studies show that healthcare providers do not always discuss fertility preservation technologies with cancer patients, which results in many patients not knowing about them and thus not using them.[18] This is precisely what happened with Lagos. In her experience, 'no one is concerned with preserving your fertility when you are diagnosed with cancer'.[19] Women like Lagos who do not freeze their ovarian tissue before infertility have to rely on donor tissue for OTT if they decide to use this treatment post-cancer.

OTT FOR PREMATURE MENOPAUSE

Currently the standard treatment for premature menopause is hormonal drugs,[20, 21] which has a variety of advantages including: they are long-lasting, can be easily stopped, are not invasive and can be dispensed in a precise dosage. However, OTTi has also been used to alleviate the symptoms of menopause. In fact, using OTT to treat surgical menopause can be traced back to Robert Morris as early as 1895.[22] Even today, symptom management of premature menopause has led some women to OTT. For example, in a 2000 article, prominent physicians Kutluk Oktay and Guvenc Karlikaya describe the case of 29-year-old woman who requested autograft of her frozen ovarian tissue due to 'persistent menopausal symptoms.'[13] Oktay and Karlikaya believe OTT 'offers a new alternative for women who face ovarian failure due to surgery, chemotherapy or radiation therapy.'[13]

Despite these physicians' optimism, it is doubtful that OTT will be used as a primary treatment method for premature menopause because it has some significant disadvantages: it typically only works for a few years,[23] stopping this treatment is more complex (involving either surgery or medication), surgery is invasive and carries various risks, and it is difficult to control the level of hormones. But arguably the biggest disadvantage to OTT is that, like other organ transplants, it would require immunosuppressant drugs, which can have serious side effects both for the recipient and a developing fetus.[24, 25] Doctors have successfully performed OTT for over a dozen women. However, immunosuppressant drugs were not necessary for these women because they each received ovarian tissue from their identical twin sister[17] or from their non-identical human leucocyte antigen compatible sister.[26, 27]

Even though OTT suffers from the aforementioned problems, some women with premature menopause who do not have frozen eggs, embryos or ovarian tissue have chosen it as a way to both treat their menopausal symptoms and achieve pregnancy even though more established methods are available (eg, hormonal therapy for premature menopause and egg donation for infertility). Here I return to Lagos's story to explore two reasons related to the alleviation of menopausal symptoms that may factor into why OTT was an attractive option for women in these circumstances.

First, some women may be hesitant to use hormone replacement therapy (HRT) because of the reports that long-term oestrogen therapy can lead to cardiovascular complications and breast cancer in post-menopausal women.[28] Lagos's husband, Rodrigo (and presumably Lagos herself) shares such concerns. In their joint blog, he writes: 'There have been recent studies that suggest HRT leads to a higher incident of cancer in women'.[29] Yet, these reports were for post-menopausal women and most medical experts agree they do not apply to women with premature menopause.[30] Hormonal therapy in women with premature menopause is seen as safe until they reach menopausal age, as using it returns hormonal levels to what is normal for premen-opausal women, whereas giving hormones to postmenopausal women increases their hormonal levels above what they would naturally be at that age.[30] However, like Lagos, women with premature menopause may not realise that HRT is safe for them.

Second, having functional ovaries is very important to many women. Jean Elson interviewed women who had undergone gynaecological surgeries and found there to be a 'hormonal hierarchy' in which retaining both ovaries had the highest value and removal of both had the lowest. Most women believed their ovaries to be essential to womanhood, mainly due to the popular notion that sex hormones are the determinants of sexual difference between women and men.[31] Many women described a 'symbolic value of knowing that their bodies were still

[i]From this point forward, whenever I am discussing OTT I am only referring to allograft or isograft, not autograft.

"working" like those of other ("normal") ovulating women.' Lagos echoes this sentiment, saying she 'just wanted to feel like a woman again'.[29] Furthermore, her husband explained her preference for an ovary transplant: '[HRT] does help lots, but will never match her own body producing exactly what she needs'. These statements suggest Lagos' adherence to the 'hormonal hierarchy', believing that an ovary will restore her femininity in a way HRT cannot. While most women use established treatments for premature menopause, these two reasons (among others, such as conceiving 'naturally' and possible lower price) shed light on why OTT may be an attractive option for some women.

INTENTION AND CLASSIFICATION OF OVARIAN TISSUE

Given that OTT can be used as treatment for two different conditions, should the intended outcome of OTT play a role in how we legally classify ovarian tissue? Specifically, should we treat OTT more like organ donation if the patient is having this procedure to treat premature menopause and treat OTT more like gamete donation if for infertility treatment?

If we answer yes to these questions, then the determining factor in how to classify OTT is the reason or motivation—not just the patient's, but also the healthcare providers'—for the procedure. Put differently, this deontological approach makes the intent of the treatment the basis for its classification. As other cases in medicine show, when a treatment has a dual function, the patient's (and healthcare providers') reason for its use—that is, the condition it aims to treat—often plays a role in how it is categorised legally and/or for insurance coverage.

One example is genital surgery. The legality of a particular genital surgery is dependent upon the reason it is performed. For example, removing part of the clitoris as a way to 'normalise' an intersex child's genitals is legal, whereas removing part of the clitoris as part of female genital cutting for religious or cultural tradition is illegal. Federal law bans genital mutilation, permitting exceptions only if it is done in the midst of a birthing or if 'necessary to the health of the person on whom it is performed'.[32] As with OTT, genital surgery can be used to treat two different types of conditions—a 'real' medical condition (intersex) and a social condition (cultural understandings of womanhood). Presumably both OTT and genital surgery are considered more socially acceptable for treatment of a medical, rather than social, condition. Yet, as other scholars have pointed out, cultural factors strongly influence which conditions are, or are not, classified as medical.[33, 34]

Applying this deontological approach to the case of OTT leads to logistical concerns. As in these other cases, how do we know what the true reason is for the treatment? Individuals may claim the reason is X even though it is really Y because X is legal and/or covered by insurance. One way to differentiate between the reasons for using OTT could be the placement of the ovarian tissue within the body: women who use OTT for reproductive reasons would have the tissue grafted to their uterine tubes, allowing them to conceive through heterosexual intercourse or artificial insemination, whereas women who use OTT for treatment of premature failure would have the ovarian tissue transferred to a place, such as her arm or abdomen, where it is not possible for them to 'naturally' conceive. If this approach were implemented, it might make sense that there would be two ways of accessing ovarian tissue: United Network for Organ Sharing (UNOS) could be responsible for allocating ovarian tissue to be used for treatment of premature menopause and infertility clinics could be permitted to use and sell ovarian tissue for reproductive use.

However, there are some problems with using intention to determine the placement of the tissue. One major concern is that placing the tissue somewhere other than by the uterine tubes does not preclude a woman from using it to have a biological child. A woman could take fertility drugs, causing ovarian hyperstimulatation, have the eggs from the ovarian

tissue retrieved and used in IVF. Such a procedure has already proved successful.[35, 36] If a recipient has the donor's biological child, does the donor have any legal recourse? While classifying OTT differently depending upon intention is problematic, so too is treating OTT the same regardless of intention. Would it be legal to sell and bequeath ovarian tissue like it is with gametes? What organisation(s) (eg, UNOS or private clinics) would be responsible for allocating ovarian tissue? Under what, if any, circumstances, would insurance companies cover OTT? Would a donor have the right to put limitations on how the tissue can be used because she does not want the recipient to have her biological child? In short, both using and ignoring intention when classifying OTT run in to complex moral and logistical concerns. How then should we understand using OTT to treat different conditions?

WHY WE SHOULD LEGALLY TREAT OVARIAN TISSUE LIKE GAMETES

We should take a pragmatic approach that acknowledges the current social context in which OTT occurs. For the near future, I recommend that ovarian tissue be treated like gametes. While I am not completely comfortable with this recommendation, I think it is the best option given the constraints of our legal system, the improbability that UNOS will add ovarian tissue to its list of organs, and, most importantly, the uniqueness of OTT in its potential to lead to pregnancy. Again, I am not making any normative claims about the current legal framework that dichotomises organs and gametes. Working within this framework, I conclude that ovarian tissue should be aligned with gametes rather than organs. I recognise that this leads to concerns about the sale of ovarian tissue (eg, price, access, limitations, etc). However, due to space constraints, I am not going to address these concerns here.

On a logistical level, there are legal constraints that make classifying ovarian tissue like gametes the better, and maybe the only feasible, option. To begin, I doubt the USA will start regulating the transfer of gametes as it does for organs. The current approach to gametes is too entrenched and some may worry that regulation would encroach upon reproductive liberties. Until the USA does start regulating reproductive technology, we are stuck with the dichotomy of selling gametes and donating organs. Although I think it would be good for bioethicists (among others) to push for more regulation of reproductive technology, OTT, an experimental technology that very few women have undergone and many people have never heard of, is not the strongest starting point for such arguments.

Even if OTT were to become an established procedure, it seems plausible that UNOS would not add ovaries to their list of regulated organs. First, OTT is likely to be limited to an extremely small population (pairs of identical twins and human leucocyte antigen compatible sisters in which one is fertile and the other is not) because of the reasons I outlined earlier, especially the need to take immunosuppressant drugs. It consequently may not seem worthwhile to invest the time and effort for such a small population, particularly a population that, at least so far, prefers private donations within immediate families (it is worth pointing out that keeping OTT within families may reinforce women's role as reproductive gift givers).[37] Second, although the medical community classifies infertility as a disease, a public perception that infertility is merely a frustrated social desire persists.[38–41] This perception seems to be changing, as evidenced by the public support and pressure that has led 15 states to require insurance companies cover infertility treatment.[42–44] However, that reproductive healthcare continues to remain marginalised,[45, 46] in part because it is so politically charged, may make the government and UNOS reluctant to include OTT.

The strongest reason we should treat ovarian tissue like gametes is that, unlike other types of transplant, it can lead to pregnancy—a socially and ethically significant difference. The potential to create a new life is significant because new life often engenders new

relationships and legal responsibilities. Whereas organ donors, both living and cadaveric, can remain anonymous, gamete donors typically cannot, at least not fully anonymous. Gamete donors are generally required to provide personal information on a variety of topics, physical characteristics family medical history, religion, personal achievements and personality traits. Potential recipients (and fertility centres) are usually the only ones who have access to this personal information. However, it is becoming more common in western countries for donor information to be made available to donor offspring upon request. For example, the UK's Human Fertilisation and Embryology Act of 1990 grants donor offspring, once they reach 18, access certain information about their biological parent(s).[47] There is concern that allowing offspring information about their biological parent(s) would discourage anonymous donations,[48] as some donors do not want potential offspring to know their identity, let alone seek a relationship. In addition to an interpersonal relationship, some donors do not want a legal relationship with potential offspring (ie, one in which they would have to assume financial and/or social responsibility for their biological children). Given the lack of uniform law on reproductive technologies in the USA, especially regarding what criteria are used to determine who a child's legal parent(s) are, it is understandable that donors would not want their identity known or made available to be known.

Yet there is a bigger concern with transplantations that can lead to pregnancy than anonymity and it gets at the heart of why ovarian tissue should be classified with gametes rather than organs. OTT is intrinsically tied to a basic human right: the right to or not to reproduce.[49] An OTT recipient becoming pregnant with her donor's biological child without the donor's permission is a violation of the donor's reproductive rights. As Alexander Capron argues, '[b]ecoming a parent should involve the freedom to choose both whether and with whom.'[50] The donor has both of these freedoms violated. It is as if she is forced to reproduce against her will and then not control who raises her future child. Similar situations that have arisen due to gamete mix-ups in infertility clinics have been met with moral outrage.[51–53]

Assuming that the organ donation process was handled ethically, it is difficult to imagine a case outside of OTT where organ recipients 'use' their new organs in a way that violates the donors' rights. Part of the reason for this is due to 'the [prevailing] idea that organs are simply mechanical entities whose worth is entirely without symbolic or affective meaning.'[54] When our organs are functioning properly, we often assume that they do not play much of a role in our identity, though we may recognise that some organs (eg, the hands and face) carry more symbolic weight than others.[55] The mind/body dualism implicit in the common understanding of organs as 'tools' underpins this disconnect between our identity and our organs.[56, 57]

In contrast, ovaries are quite significant not just for our gendered identity (as previously discussed), but for our identity more broadly. In our individual-focused culture, where genetic determinism runs strong, many people have a sense of ownership of their genetic material, which often extends to their genetic children. This is reflected in how laws treat gametes and embryos as property, courts frequently prioritise genetic relationships over social ones when deciding child custody suits, and people usually use the words 'biological' and 'own' synonymously when discussing adopted versus genetically-related children. The beliefs that our identity is intertwined with, or dependent upon, our genes and that reproduction is an intensely personal and private matter are two main reasons why an organ recipient having the biological child of the donor without the donor's consent is so troubling.

Given the concerns that arise if the recipient has the biological child of the donor against the donor's wishes and the fact that there is no easy way to regulate and prevent such pregnancies, it is possible to obviate these concerns by restricting the transfer of ovarian

tissue to infertility clinics. Distributing ovarian tissue through infertility clinics rather than UNOS makes it clear to both donors and recipients that pregnancy is a potential, and usually a desired, outcome of OTT. Even if NOTA were to decide to include the ovary among regulated organs, I think it is unlikely that women who sign organ donor cards would think that their ovaries might be among organs that could be donated. Caplan *et al* make a similar point in their article on uterus donation, stating 'Few, if any, American women ever thought that the uterus might be one of the organs considered for donation when they signed a donor card'.[58]

In short, classifying ovarian tissue like organs could lead to many logistical, legal and ethical concerns, many of which can be sidestepped by treating it like gametes. Although defaulting to the classification with fewer problems may not seem like the best way of determining how we should treat ovarian tissue, at this point in time I think it is the best option. Indeed, I have presented a pragmatic approach based on our current social context that avoids many, though not all, of the concerns that could arise by basing our classification of OTT on intention. While it is unlikely that OTT will become a mainstream treatment, exploring the philosophically interesting question of how to classify ovarian tissue is not just useful for current cases of OTT, but also for uncovering some of the theoretical foundations of how we understand and classify medical procedures. This discussion of ovarian tissue classification sets the stage for thinking about other reproductive technologies that show more promise. For example, scientists are currently working on in vitro follicle maturation (taking immature ovarian follicles and developing them into mature eggs). As this technology develops, we will need to consider how to classify follicles under our current legal framework in order to anticipate and provide strategies for addressing logistical, legal, and ethical concerns. Hopefully, the discussion here will provide a basis for such future considerations.

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