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ETHICAL AND LEGAL ISSUES IN REPRODUCTIVE HEALTH

Legal and ethical issues of uterus transplantation

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ABSTRACT

The clinically detailed report of a successful uterus transplantation and live birth in Sweden, in which a family friend donated her uterus, provides a basis for expanded practice. Family members and friends can serve as living donors without offending legal or ethical prohibitions of paid organ donation, even though family members and friends often engage in reciprocal gift exchanges. Donations from living unrelated sources are more problematic, and there is a need to monitor donors' genuine altruism and motivation. Donation by deceased women—i.e. cadaveric donation—raises issues of uterus suitability for transplantation, and how death is diagnosed. Organs' suitability for donation is often achieved by ventilation to maintain cardiac function for blood circulation, but laws and cultures could deem that a heartbeat indicates donors' live status. Issues could arise concerning ownership and control of organs between recovery from donors and implantation into recipients, and on removal following childbirth, that require legal resolution.

1. Introduction

The extensive clinical detail that the medical team under Mats Brännström at Sahlgrenska University Hospital, Gothenburg, Sweden, has provided of the birth of a healthy neonate delivered slightly prematurely following his mother's receipt of a transplanted uterus "opens up the possibility to treat the many young women with uterine factor infertility worldwide" [1] (p. 615). Uterine factor infertility can be congenital (absence of the uterus at birth [Rokitansky syndrome]), disease related, or iatrogenic (e.g. through hysterectomy). In the UK, more than 12 000 women of childbearing age are thought to have absolute uterine factor infertility [1] (p. 607), and estimates suggest that 9.5 million of the 62 million women of reproductive age in the USA have some form of uterine factor infertility [2].

The mother of the neonate was one of nine women the regional ethics board of the University of Gothenburg had approved to enter a clinical trial of uterus transplantation. This approval was built on more than a decade of research using several animal species, ranging from rodents to non-human primates. The mother had been aged 35 years at time of transplantation and was affected by congenital absence of a uterus. The uterus donor was aged 61 years, and had delivered two children of her own. She was unrelated to the recipient, but was a close family friend.

Conception was by in vitro fertilization (IVF) of her own ovum, to verify that she and her partner were fertile, and the cryopreserved embryo was transferred approximately 1 year after transplantation. The pregnancy was normal, but after slightly less than 32 weeks, she was admitted to the hospital's obstetrics division because of pre-eclampsia. At 16 hours after admission, a cesarean delivery was undertaken and a male neonate weighing 1775 g was delivered. The mother was in good condition the day after delivery, and the newborn's first postnatal week was uneventful, showing him to be normal for gestational age, and requiring only phototherapy and room air [1] (p. 613). He was discharged in good health from the neonatal unit 16 days after birth, and weighed 2040 g 21 days after delivery.

Two of the nine women in the Swedish trial had their transplanted uteruses removed because of complications, but the others received IVF embryos, and two were expected to give birth towards the end of 2015. All women in the study would be given another of their IVF embryos to attempt a second pregnancy [3]. In the UK, Richard Smith—a consultant gynecologist at the Queen Charlotte's and Chelsea Hospital, London—will lead a uterus transplantation team after ethical approval was given for clinical trials involving ten transplants from brain-dead women [4]. However, £500 000 needs to be raised before any operations can proceed, and it is uncertain whether the UK National Health Service would actually fund the procedures if the trial is completed successfully [4].

Clinical concerns and related ethical consultations [5] tend to focus on transplant recipients and their intended neonates rather than on the uterus donors, but several legal and ethical concerns are raised by such donation. Recipients must obviously provide informed voluntary consent, but special legal and ethical concerns are raised by uterus donations directed to specific recipients from live donors related or known to the recipients, live altruistic donations to no specified recipients, and post-mortem (cadaveric) organ recoveries for transplantation.

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2. Live related donors

For purposes of the present discussion, close family friends related by neither genetic nor marriage ties are deemed "relatives" and members of the family as extended by mutual empathy. The preference in the Swedish clinical trial was for uterus donors to be relatives. As the team observed [1] (p. 614): "In the present study, the live donor was a close family friend of the recipient, by contrast with the other donors of our study cohort who were all family members. Our patient's first choice of donor was her mother, but blood group incompatibility prevented her from taking part in the study."

Candidate donors must be suitable in many ways other than blood group compatibility. In the social context, they must be women who accept that they will be unable to bear any further children of their own. However, it is desirable that they have successfully carried pregnancies in the past, as evidence that their uteruses would be functional. Clinically, they must be free of pathologic disorders of the uterus, especially any that might be related to precancerous disorders. Additionally, lifestyle choices such as smoking or drug/alcohol misuse could disqualify candidates.

Removal of a live woman's uterus for transplantation requires highly invasive, complex, hazardous procedures that present a full range of irreducible levels of risk, especially to delicate organs, tissues, and pathways of body fluids, even in skilled hands. The dedication of women to subject themselves to such risks so that others might bear children could appear to exceed commonplace altruism and be laudable at the highest level. Accordingly, it could appear churlish in law or ethics to raise issues of donors' motivations. The gratification of seeing one's sacrifice result in a loved, formerly infertile family member or close friend nursing her newborn is no doubt immeasurable, but laws and ethics could be compelled to take an unsentimental view.

An ethical concern is that, in tight-knit personal relationships, individuals could feel under familial or social pressure to act against their own interests or preferences for the benefit of others close to them, taking risks or making sacrifices they would not for more distant acquaintances. Their consent to donate does not offend the legal principle that consent be freely given, because pressure comes not from medical or comparable personnel, but from donors' social environments, from which healthcare professionals are not obliged to isolate them [6]. If service providers consider that prospective donors are really reluctant to undertake the risks and discomforts of donation, however, they might be able to assess them as unsuitable to donate on psychological health grounds, remembering that "health" is a state of physical, mental, and social well-being [7]. The claim of devoted mothers that "there is nothing they would not do" for their children, and their hopes to have their grandchildren, could require that they be objectively counselled about risks to themselves of uterus donation so that they can make a realistic assessment of competing real risks of donation and prospective benefits.

Laws might not only permit altruistic donation, but also require that donation be only altruistic. There is widespread legal prohibition of commercially rewarded organ donation, for fear sometimes amounting to disgust that human organs or body parts, from living or cadaveric donors, could become market commodities. Giving part of one's body for payment has been analogized to prostitution. Legal prohibition of payments leaves patients requiring transplantable organs dependent on altruistic donors, such as family members. For instance, before public blood transfusion services were established, patients needing to draw on health facilities' blood banks commonly had to be able to replenish the bank through donations from others (usually family members). Participants in the Swedish clinical study acted in this tradition by looking first to family members to donate transplantable uteruses if they were suitable.

Reliance on close family members and friends for donation presents the potentially confounding issue that networks of family members and friends often maintain reciprocal relationships of gift exchange, although outside the impersonal barter of exchange, usually of money, for goods or services in trade and commerce. The obvious hope of a mother's exchange of the gift of her uterus to her daughter is for the reciprocal gift of a grandchild. However, gifts could be given in more material forms, which could raise legal concerns of payment, perhaps in kind rather than money. That is, the exchange of intra-family gifts could include an element of excessive generosity that could be construed as payment.

The practice of reciprocating donation of body material such as an organ with a comparatively modest gift has been described as "rewarded gifting" [8]. When this occurs between strangers and is prearranged, it could be legally and perhaps ethically suspect as commodification of the material, and commerce. When a family member donates an organ such as her uterus to another, however, and a reciprocal gift of a relatively trivial nature is spontaneously given to the donor as an expression of gratitude, by or on behalf of the recipient, this may be considered different from a commercial transaction. Accordingly, a token gift in appreciation of a woman's donation of her uterus for transplantation to a relative should not offend legal or ethical rules that condemn commercial trading in human organs. The issue of substantive or proportionate gifts or exchanges is more acute when gifts are made, or offered, between strangers.

3. Live unrelated donors

Living individuals could be inspired to make genuinely altruistic donations of tissues or organs to others, including unidentified others. In assisted reproduction, for instance, men provide their sperm without reward, women can similarly provide their ova (particularly those that on superovulation prove surplus to their own needs), and couples can donate surplus embryos. Sharing of ova in return for reduced IVF fees raises issues of payment in kind, although such arrangements are allowed in the UK [9]. Philosophical arguments have been made that altruistic donation to unspecified individuals can be a source of gratification to donors [10]. When people in public life or celebrities require organs to survive, strangers could offer a directed altruistic donation, and families could publicize an attractive family member's need to induce such a donation. This has been questioned on ethical grounds for seeking unfair priority on a waiting list, but presenting an individual in need as a more appealing recipient than others could be defended [11].

Priority on an organ transplantation waiting list is important for life-endangering conditions but, although WHO describes infertility as a disease [12], it is not of this menace. Outside a family relationship or close friendship, the willingness of a woman to undertake the hazards of non-therapeutic removal of her uterus to promote an unrelated woman's childbearing raises questions of her motivation. In the UK, the Nuffield Council on Bioethics has noted that [13] (para 2:24): "Domestic legislation within the UK, EU [European Union] Directives and Council of Europe [14] instruments all recognise, in various forms, the need for particular protection of living donors, especially as regards living organ donors. In the UK, the HTA [Human Tissue Authority] regulates all living organ donations, with the aim of ensuring that the consent provided by the living donor is fully informed and that there is no evidence of coercion, duress or reward.… Donors are only accepted after detailed medical and psychosocial assessment.… Where a person is offering to donate an organ to a stranger, rather than to a relative or friend, approval must first be sought from a panel of at least three members of the HTA."

Donation compelled by coercion or duress is clearly unlawful and unethical, but donation induced by reward is more internationally contentious, whether for life-preserving organ transplantation or to provide fertility. Almost all donors are allowed to recover expenses that they reasonably incur in making their donations, including recovery of lost wages, but profiteering is controversial. The Nuffield Council observed that "attitudes to the role of payment in the donation of bodily