**Uterine transplantation: Legal and regulatory implications in England**

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**Abstract**

Uterus transplantation (UTx) is fast evolving from an experimental to a clinical procedure, combining solid organ transplantation with assisted reproductive technology. The commencement of the first human uterus transplant trial in the United Kingdom leads us toexamine and reflect upon the legal and regulatory aspects closely intertwined with UTx from the process of donation to potential implications on fertility treatment and the birth of the resultant child. As the world’s first ephemeral transplant, the possibility of organ restitution requires consideration and is discussed herein.

**Tweetable abstract**

Uterine transplantation warrants a closer look at the legal frameworks on fertility treatment and transplantation in England.

**Key words:** Transplantation; uterus; IVF; organ donation; consent; regulation; law.

**INTRODUCTION**

The last two decades have resulted in the evolution of uterine transplantation (UTx) as a novel method of reproduction. UTx, alongside IVF, presents a transformative option for treating women who are unable to gestate such as those with absolute uterine factor infertility (AUFI) which affects approximately 1 in 500 women of reproductive age worldwide. UTx has ushered in a new clinical arena in the field of transplantation and assisted reproduction. Since the first livebirth following UTx in 2014, women with AUFI may now have an alternative option to adoption and surrogacy in starting a family.1 To date there have been over 70 UTx procedures and 24 live births achieved, with detailed outcomes from 17 births reported in the literature.2 This has confirmed UTx as a fast developing medically feasible option.

Whilst surrogacy allows for biological offspring, it remains forbidden by the law in many countries, or carries restrictions because of ethical or religious views. In the United Kingdom (UK) surrogacy is legal, but commercial surrogacy remains prohibited resulting in a shortage of surrogates.3 It is also a legally uncertain route to acquiring parenthood, in that the law defines the legal mother as the woman who gestates and gives birth to the child.4 Furthermore, surrogacy arrangements are not legal binding and not enforceable in the event the surrogate changes her mind after birth.5

Adoption can offer legal parenthood, but it does not enable biological relatedness. It is also a challenging route to follow, with many initial assessments and vetting of prospective parents, long waiting periods and no guarantee of being matched with a child.6

The only therapeutic option which anatomically and physiologically restores the fertility of women with AUFI and allows for biological, legal and social parenthood is UTx. While UTx is not associated with the legal restrictions associated with surrogacy, there are important legal and regulatory aspects that require consideration when commencing a UTx programme. Due to the requirement of IVF and embryo cryopreservation pre-procedure, UTx combines assisted reproduction technology (ART) with a transplantation procedure, and thus represents a ‘new level of collaboration between the two’.7 This alone may generate regulatory difficulties, since the two fields are regulated differently in many jurisdictions, such as the UK and America.

A deceased donor (DD) UTx research programme has commenced in England via the ‘Investigation Study into Transplantation of the Uterus (INSITU)’ trial albeit on pause at the time of writing due to the Covid-19 pandemic. This, along with the exponential rise in the number of successful cases worldwide provokes consideration of the legal issues as UTx transcends from a research concept to a clinical procedure.8 The legal framework surrounding any medical procedure plays an important role in its successful incorporation into practice. Additionally, development of legal protocols is key for UTx to fit seamlessly with other organ transplants.

The aim of this manuscript is to examine and reflect upon the legal and regulatory aspects closely intertwined with UTx in England. It will focus on the process of donation to potential implications on fertility treatment as well as the birth of the resultant child.

1. **Regulation of Uterus Transplantation: square pegs into round holes**

UTx is a procedure combining both ART and organ transplantation. In all the research trials to date, conception occurred via implantation of embryos harvested and stored pre-transplant and implanted once the transplanted uterus was *in situ*. Thus, when the procedure takes place in England it will necessitate creation of embryos via IVF. It is therefore anticipated that the procedure will be subject to the regulatory frameworks of both the Human Fertilisation and Embryology (HFE) Act 1990, the Human Tissue (HT) Act 2004 and Human Organ (Deemed Consent) Act 2019. If this procedure becomes a clinical treatment, as it will come under dual regulation, it is important that attention is given to how the procedure can be safeguarded, so as to avoid anomalies of a woman with AUFI seeking to procreate via a UTx and having IVF, only to be later refused access to the UTx procedure. However, should it become possible to allow for natural conception within a UTx setting (although not feasible with the current surgical method), the transplant procedure would presumably fall entirely outside the ambit of regulation designed to govern fertility treatment and the HFE Act /Human Fertilisation and Embryology Authority (HFEA). At present, whilst reproduction via UTx necessitates both a transplant and IVF, both regulatory frameworks apply. As the law governing the latter and access to IVF is well documented, the focus of this paper is on the law and regulations that would govern UTx.9

**Uterus Transplantation**

In England, if UTx is to be regulated in the same manner as other organ transplants, it would fall under the HT Act 2004 and Human Organ (Deemed Consent) Act 2019, depending on whether the uterus is sourced from a live or deceased donor. The Human Tissue Authority (HTA) is the statutory authority that regulates the removal, storage, use and disposal of human bodies, organs and tissues for a number of scheduled purposes, including transplantation. The rules that would govern UTx will vary depending on whether the uterus is sourced from a living or deceased donor (DD).10 At present clinical research teams around the world are proceeding using both.

1. **Deceased Donation**

While the majority of UTx cases to date have involved living donors (LD), the subsequent achievement of livebirths following donation after brainstem death donors has proven the feasibility of UTx using DD’s.11,12,13,14

The National Health Service (NHS) organ donor register has over 25 million people registered.15 In May 2020, following the passing of the Organ Donation (Deemed Consent) Act (2019), organ donation law in England changed to an ‘opt out’ system whereby adults are presumed to consent to be an organ or tissue donor by default, unless a decision to opt out has been recorded otherwise.16 As with other rare or novel transplants such as limb and face, donation of the uterus is not included in the opt out strategy and as such, explicit consent is required from the family, close friend or nominated representative of the DD. However, there are challenges associated with making a proxy decision at such an unstable and emotional period.17,18 Previously, studies have shown the donation of organs that have not formerly been considered by the deceased individual often result in the grieving family deciding not to proceed. This is reaffirmed by previous studies highlighting prior knowledge of the patients' wishes increases the donor family’s willingness to donate.19,20

Importantly, the legal position underpinning organ donation is that the state does not own the human body, such individuals that are entitled to determine how their bodily material is used and the donation of organs is considered a ‘gift’. Thus, legally valid consent is only relevant if no decision to the contrary has been recorded or expressed by the donor or any qualifying individuals linked to the DD. As such, the donor family will still be approached in all cases and their decision would override the presumed consent associated with the opt out policy.

The principle of consent with regards to the removal of human tissue and organs was made legally binding in 2004 with the introduction of the HT Act 2004.10 This was following the inquiry that looked in part, at organ retention in Bristol and Liverpool.21,22 In these cases, organs of the deceased had been retained without knowledge, or explicit consent from the next of kin.22 Prior to this, the HT Act (1961) was unsatisfactorily centred on the lack of objection from families, rather than explicit consent with regards to separated biological materials. The HTA was established by the HT Act 2004, to regulate the removal, storage and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. The HTA must give approval for organ and bone marrow donations from living people. It was during the non-consensual removal of human ‘tissue’ that a closer inspection of the difference in the use of terms ‘human tissue’ and ‘organ’ was performed.

1. **Living Donation**

The HT Act 2004 requires the HTA to approve all transplants from LD’s (whether or not the donor is related to the recipient). Thus, doctors embarking on UTx in England must first refer the case to the HTA, who will then scrutinise the donation to ensure the donor has given free consent. Careful pre-operative interview of the LD is performed, including a psychological assessment to ensure she has securely completed her family and clearly understands donation of her uterus will subject her to terminal gestational infertility. Once the clinical team have deemed the donor medically and psychologically fit to proceed, an independent assessor (IA) is involved to ensure the requirements of the HT Act 2004 are met, and to protect the interests of the donor, particularly in ascertaining no reward or coercion has been sought or offered. The HTA base their approval of the case on the report provided by the IA.

**Non-directed / altruistic donors**

Altruistic donation has been considered and pursued successfully in America with the first live birth from UTx involving an altruistic donor who had already given birth to 2 children.24,25,26

Altruistic donation would be lawful in England and the same rules apply to non-directed LD- it is permitted provided there is appropriate consent and the donation is made by an adult with capacity, free from duress, coercion and there has been no payment.

Whilst there are no age restrictions imposed for LDs, there may be concerns surrounding young women who have not yet had children who wish to donate their uteri. Mc Queen has noted how sterilisation requests made by young, child-free adults are frequently denied by doctors, despite being legally available to individuals over the age of 18.27 Successful UTx trials to date have been with uteri that have proven the ability to sustain gestation, thus it may well be that donors must display parity prior to donation. Informed consent within the context of a decision for hysterectomy for LDs of any age should include balanced information and supportive exploration of the woman's values, goals and life plans.28

**The legal status of the Uterus**

The legal status of the retrieved uterus remains a debated topic. Whilst ownership is not an issue for recipients of DD organs, it does require consideration for LD UTx. Being the world’s first ephemeral transplant, the uterus is exclusive as a transplanted organ in its temporary requirement up until one or two live births are achieved. Beyond this unless a second child is desired, the organ is no longer required and is removed. The possibility of the LD changing her mind after retrieval and requesting the uterus back (organ restitution), perhaps even once it has served its required ‘purpose’, is one which needs consideration from a legal standpoint. The ethics surrounding the issue of organ restitution have been addressed previously.29,30

For UTx, there exists the notion of whether donation of such an organ is a ‘loan for use’ contract. Human tissue has been recognised as being the subject of property rights by legal scholars in the UK and USA.31,32,33 Physical detachment of biological material from a human body transforms the material into ‘things’ which are capable of being the subject of property rights.34 If applied, property law would assume the uterus as the ‘property’ of the donor which has been tendered into the possession of the recipient upon implantation and thus the right to ownership rests with the recipient. However, given its temporary therapeutic purpose, the question arises as to whether the uterus is analogous to an implantable medical device for example, where ownership once extracted rests with the surgical team.35 The HT Act 2004 does not address the legal requirements concerning the removal of materials from living persons, which is governed by common law.

While organ restitution exists as a theoretical possibility for the uterus and as a more probable prospect for the kidney and the heart, a multitude of medical difficulties would prevent safe and efficient re-transplantation.36,37,38,39,40 This is secondary to deterioration of the organ as a result of surgical implications. Also, the uterine functional ability to carry a further pregnancy would be questionable as empirical data on this is lacking in the field of UTx.

English law does not currently address organ restitution. Possibly because it has not been considered a serious issue in the past owing to the permanent nature of all other organ transplants performed to date. Although the HTA has clear guidance on the LD’s right to withdraw consent prior to the transplant, it does not mention the withdrawal of consent following transplantation. The donor is consented on how they wish to proceed in the event the organ is not implanted into the intended recipient. She is then given four options: for the organ to be transplanted into an alternative recipient on the waiting list or a directed donation, donation to research, disposal, or reimplantation into the donor.41 Given the HTA states donors have a ‘right to withdraw consent at any time *before* the removal of transplantable material’, one may deduce the right of ownership is not maintained to the same standard once the uterus is extracted. The decision to proceed with the transplant in the recipient rests with the medical team. No property rights are attached to removed organs as body parts are not presently recognised under property law.42 Once transplanted, the uterus as any such organ, would require explicit consent from the recipient before removal. With organ restitution, the original recipient would now be treated as a donor under law, thus the same organ donation policies would apply.

1. Recipients

**What are the legal implications if the recipient refuses to have a hysterectomy following UTx?**

From the outset a UTx is intended to be a temporary transplantation which is removed once child bearing is completed. Whilst patients may consent at the outset, given the potential this organ holds to enable gestation of life, symbolic value may be attached to the organ and problems may arise if post-transplant a woman refuses to consent to its removal. This could arise in a number of ways, consider the following:

R has a uterus transplanted and successfully gestates two children and completes her family. However, the uterus has consolidated a maternal identity and now makes her feel complete. She would like to keep the organ and refuses to consent to a hysterectomy. She understands the risks of long-term anti-rejection medication and is willing to run those risks.

R has a uterus transplanted but she fails to successfully gestate. After four failed miscarriages the medical term recommend removal of the uterus. R refuses.

R has a UTx and during the resultant pregnancy problems develop. In the sixth month of pregnancy (week 24 of gestation) her body has begun to reject the uterus. The medical team recommend its removal. Continuance of the pregnancy is a threat to her life and that of the fetus. R is aware that if she has a c-section whilst her baby is on the cusps of viability, it may not survive and there is a high chance of disability. She refuses to consent to a c-section until she is at least 8 months pregnant, when the chances of survival for her baby are better.

In all the above hypothetical scenarios, the law is clear, assuming the recipient is an adult patient with capacity, she has the right to consent, or in this context to refuse the recommended treatment.43 She thus has a right to refuse a hysterectomy and this is the case even if refusal may result in her death. If pregnant, the recipient is still entitled to refuse consent to an early c- section and a hysterectomy, even if this refusal may harm or cause the death of the fetus. Following a series of cases involving pregnant women, the law is now clear that providing a woman is competent, she can decline any treatment which may save the life of herself, or her fetus.44,45,46,47 Since a fetus has no actionable legal interests until birth, the pregnant mother’s wishes must prevail.48,49 To act otherwise would be an affront to her bodily autonomy and give rise to legal action.50

The converse is also true. A recipient may have a UTx and an IVF embryo successfully implanted, a change in personal circumstances may mean she no longer wishes to continue the pregnancy. She may seek a termination and for the uterus to be removed. Legally she is entitled to do this, provided of course she comes within the defences provides under The Abortion Act 1967 as amended by The HFE Act 1990. Whilst this is unlikely given the emotional and physical toil involved in a UTx and IVF, it is important that teams embarking on UTx are aware of the legal position should this transpire.

If a recipient later refuses a hysterectomy, immunosuppressant drugs will be needed to maintain the transplant, the question then arises whether there is an obligation to continue such medication when the patient is insisting on retaining the organ against medical advice. Whilst a competent patient has a right to refuse treatment, the corollary does not, however, follow, at least as a general proposition. As noted by Lord Phillips MR in *Burke (on the application of) v General Medical Council & Ors* [2005] EWCA Civ 1003: ‘autonomy and the right of self-determination do not entitle the patient to insist on receiving a particular medical treatment regardless of the nature of the treatment. Insofar as a doctor has a legal obligation to provide treatment this cannot be founded simply upon the fact that the patient demands it.51 Whether such treatment should continue or not depends on whether it is regarded as in the interests of the patient from a clinical viewpoint.

1. **Vascular composite allograft (VCA) versus a Solid Organ Transplant**

The HTA defines an ‘organ’ as “a differentiated and vital part of the human body, formed by different tissues” and one which “maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy”.52 The definition of “composite tissue” and hence vascular composite allograft (VCA) used by the HTA is a “construct containing multiple structures that may include skin, bone, muscles….that is recovered from a donor as an anatomical or structural unit, without altering its relevant characteristics”. Examples given are the face, hand and leg. The launch of the term ‘VCA transplant’ was initiated with the first successful hand transplant in 1998 and continued to be used for the first face transplant in 2005.53,54 The move to the VCA label for novel transplants displayed recognition of them being more like organs than tissue constructs. The success of VCA transplants as not just reconstructive, but restorative tissues with differing utility, demands an individualised approach to their labelling as a VCA versus a solid organ transplant (SOT).

The functional potential of the human uterus meets the HTA criteria for an organ with it being a vascularised construct consisting of a structured arrangement of tissues and capable of functioning independently of the body (in addition to maintaining a pregnancy). This is proven by the successes of extracorporeal perfusion platforms. 55,56,57 The uterus is therefore more like a traditional SOT yet the transplant community continues to refer to the uterus as a VCA, which has implications for its legal jurisprudence as detailed in this review. 58,59,60 Recognition of the uterus as a SOT will also drive the development of individualised clinical and service policies and robust training programmes.61

Moreover, the standardised scoring system for rejection in a VCA, the Banff VCA system utilises skin as the primary indicator of rejection, whereas in UTx, rejection is based on cervical biopsies.62,63,64 Therefore, caution must be exercised in the implementation of the Banff schema into clinical practice within the UTx setting. A more applicable classification based on cervical biopsies has been suggested by Molne et al.65

1. **How is a new organ licensed by the HTA?**

In England, the HTA is the licensing authority for VCAs.10 The clinical pathway is controlled by the National Health Service Organ Transplant Service (NHSBT) founded upon the NHSBT (Establishment and Constitution) Order 2005.

Although VCAs share a common goal of restorative and life enhancing abilities, they consist of a diverse group of organs with distinct variations in function. The uterus in both its ability and purpose to carry the recipient’s reproductive material and amalgamate donor and host utility to form a separate being needs to be considered differently to a ‘limb’, which is referred to as a VCA. As UTx transitions from an experimental to a clinical procedure, policies in parallel to other SOT’s must be considered for its incorporation into practise. This includes the allocation of DD uterus’ which importantly may need to factor the ageing recipient, in addition to regulatory policies on living UTx donors. Furthermore, by recognising the uterus as a SOT, it can assimilate to the same consent policy for organ donation after death. Especially, as unlike VCA transplants such as the face or limbs, there is no physical disfigurement on procurement of the uterus, which involves the same laparotomy incision as made for the procurement of other organs.

1. **Legal implications of the resultant offspring of a UTx**

The legal implications of a child born from a donor uterus also necessitates consideration. At present, the HFEA does not define the legalities for uterus donors. Given the recipients right of ownership towards the uterus, following donation and subsequent successful fertility treatment, the child to whom she gave birth legally belongs to her if parallels are drawn with surrogacy law. Thus, UTx bypasses the legal challenges encountered with surrogacy and adoption. The donor would have no legal rights over any resulting child.4

The DNA of the offspring of UTx recipients will resemble the recipient parents assuming no donor gametes were used. Studies are lacking on whether in the context of UTx there are traces of the uterus donor’s DNA in the resultant child. The concept of the uterine endometrium having a reprogramming effect on the embryo has long been suggested.66 Evidence suggests the endometrial fluid serves as the ‘uterine milk’ nurturing the embryo.67,68 Micro-RNA molecules within the endometrial fluid have been found to be incorporated into the embryo resulting in modification of the embryonic transcriptome.69 This notion of the ability to impart some genetic material to the offspring needs addressing scientifically, primarily to draw clear distinctions for the recipient parents and the donor.

**Conclusion**

As England’s first trial on UTx is underway (albeit postponed), the potential legal implications of a novel organ transplant warrant consideration. UTx represents a combination of a transplant procedure and ART which needs closer inspection under law given the different governing legislation. As the world’s first ephemeral transplant, the possibility of organ restitution for LD UTx exists and requires further consideration under law. Legalities for living uterus donors implicating them with the resultant child also need to be addressed.

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None declared. Completed disclosure of interest forms are available to view online as supporting information.

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### SV and BPJ conceived the idea. SV wrote the manuscript. SS, MF, AA, GT, LJ and JRS provided expertise and helped revise the final draft.

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