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Uterus Transplantation: A Future Issue for the French Legislator?

Antoine Bérar \mid ORCID 0000-0002-6583-2882 Department of Legal & Forensic Medicine, Rennes University Hospital, F-35000 Rennes, France Faculty of Medicine, University of Rennes, F-35000 Rennes, France Corresponding author antoine.berar@chu-rennes.fr

Laetitia Marcucci

Faculty of Medicine, University of Rennes, F-35000 Rennes, France Atlantic Centre of Philosophy (CAPHI), University of Rennes, F-35000 Rennes, France laetitia.marcucci@univ-rennes.fr

Renaud Bouvet

Department of Legal & Forensic Medicine, Rennes University Hospital, F-35000 Rennes, France
Faculty of Medicine, University of Rennes, F-35000 Rennes, France
Institute of Public Law and Political Science (IDPSP), University of Rennes, F-35000 Rennes, France
renaud.bouvet@chu-rennes.fr

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Abstract

Uterus transplantation (UT) is a surgical procedure that seeks to correct absolute uterine infertility. As such, it is coupled with assisted reproductive technologies (ART). Currently performed as an investigational procedure in France, this technique could be subject to a legal framework in the future. Given its specificities, the French legislator

will need to state their position on several matters. Regarding the donor, they will need to determine whether the benefits for the infertile woman justify exposure of a living person to the risks of the removal procedure. If necessary, they will have full freedom to set the criteria for selecting the living donor based on age, the existence or not of past pregnancies or the nature of the donor-recipient relationship. On the other side, the conditions for becoming a recipient should be consistent with the existing rules for ART. Other considerations could include age and past pregnancies again. Lastly, the legislator will also need to address the possible desire for UT without the endpoint of pregnancy.

Keywords

donor selection – infertility – organ transplantation – presumed consent – reproduction – uterus

1 Introduction

Uterus transplantation (UT) is a surgical procedure in which a uterus derived from one person is implanted in a different person. It allows women with uterine factor infertility to give birth, an outcome not possible with the main alternatives, adoption and surrogacy—the latter being prohibited in several countries, including France. As such, UT has been systematically coupled with assisted reproductive technologies (ART), given that spontaneous pregnancies remain impossible after the transplantation. In vitro fertilisation is usually carried out before the transplantation, and the embryos obtained are transferred at least several months after the transplantation. The uterus is removed after one or two successful pregnancies to limit the side effects of immunosuppressive treatment, which is required to prevent the body from rejecting the uterus for as long as it remains in place.

The first UT attempts in recent history took place in 2000 in Saudi Arabia then in 2011 in Turkey. The first live birth following UT occurred in 2014, in Sweden; in this case, the uterus had been obtained from a living donor. Another first followed in 2017, in Brazil, when a woman gave birth with a uterus that had been removed from a deceased donor. In France, Foch Hospital in Suresnes, Limoges University Hospital and Rennes University Hospital are currently the only institutions to have obtained authorisation to perform UTs, as

¹ M. Carbonnel and J.-M. Ayoubi, '[Uterine transplantation: a treatment for absolute uterine infertility]', *La Revue Du Praticien* 73 (2023) 471–476.

an investigational procedure.² The first births occurred in 2021 and 2023, to a woman who had undergone UT at Foch Hospital in 2019.³

It is highly likely that society will eventually push for UT to move out of the research domain and become part of standard health care. Transplantation procedures are already regulated in France, as are ART. Since the Caillavet Law of 22 December 1976, transplantation law has rested on three pillars: presumed consent, by which organs can be removed from any deceased person provided that they did not express refusal during their lifetime; non-remuneration of donations; anonymity.4 Transplantation from a living donor, primarily targeted at people waiting for a kidney or liver, has been authorised since the first bioethics law of 29 July 1994.5 Nevertheless demand for organs continues to outstrip supply, even though the pool of potential donors has been progressively expanded: initially limited to close family members (parents, children, brothers and sisters of the recipient) and, in emergency situations, the spouse, it now includes nearly all close relatives and loved ones: the spouse even outside of emergencies, grandparents, uncles and aunts, cousins, step-parents, as well as "any person who can demonstrate a close and stable emotional relationship of at least two years with the recipient". 6 The law of 7 July 2011 also authorised cross-over transplantations between two donor—recipient pairs when there is immunological incompatibility within each pair.⁷

ARTs encompass "clinical and laboratory practices for in vitro conception, preservation of gametes, germinal tissues and embryos, embryo transfer and artificial insemination". ART legislation was structured by the first bioethics laws of 1994, which only authorised ART for couples formed by a man and a woman, but changed considerably with the law of 2 August 2021, which made ART accessible to same-sex couples and to single women. Which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably which are considerably which are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with the law of 2 August 2021, which made are considerably with

² A. Favre-Inhofer, M. Carbonnel, A. Revaux, A. Rafii, L. Karpel, R. Frydman and J.-M. Ayoubi, '[Uterus transplantation: state of knowledge and ethical reflection]', *La Revue Du Praticien* 68 (2018) 657–663.

³ Supra note 1.

⁴ Law no. 76-1181 of 22 December 1976 on organ removal.

Law no. 94-654 of 29 July 1994 on the donation and use of elements and products of the human body, on medically assisted procreation and on prenatal diagnosis.

⁶ Law no. 2011-814 of 7 July 2011 on bioethics.

⁷ Ibid.

⁸ Article 2141-1 of the Public Health Code (CSP).

⁹ Law no. 94-653 of 29 July 1994 on respect of the human body and law no. 94-654 of 29 July 1994 on the donation and use of elements and products of the human body, on medically assisted procreation and on prenatal diagnosis.

¹⁰ Law no. 2021-1017 of 2 August 2021 on bioethics.

From the point of view of both transplantation and ART, UT is a singular procedure. It differs from usual transplantation procedures in its endpoint, procreation, and its temporary nature. In addition, it is the only organ transplantation within the sexual domain. ART legislation assumes that the person who wants to become pregnant is necessarily of female biological sex, yet UT will surely be possible, technically speaking, in biological males. In view of these particularities, it is not certain that UT will fit into the existing legal framework. Without wishing to underplay the importance of issues relating to UT-born individuals, notably the delicate matter of lifting anonymity if said individuals want to know their "uterine" origins, " it appears to us that the main legal issues arising from UT concern the potential donor and the potential recipient. Hence below we assess positive law in relation to several aspects that will no doubt arise when the legal framework for UT is being devised, limiting ourselves to those aspects concerning the donor and the recipient.

2 Donor-Related Legal Issues

2.1 Uterus Removal from a Living Person

Under current French law, organ removal from living people is mainly performed for kidneys and livers, whose removal—only one of the two kidneys or a fragment of liver—does not endanger the donor's life. Nevertheless there are risks for the donor, related to the explantation surgical procedure or to post-operative complications that can arise over the short or long term.

So then one might wonder whether it is legitimate to remove a uterus from a living person. UT does not help keep the recipient alive, as the absence of a uterus does not represent any kind of threat to its life. The donor is therefore exposed to risks that are not counterbalanced by the imperative of life-saving therapy. Nevertheless the donor's consent, freely provided after being informed of the risks, could be considered sufficient for authorising uterus donation, by virtue of the ethical principle of personal autonomy. Furthermore, the parallel between UT and other transplantations is strengthened by a more nuanced look at the medical necessity of kidney transplantation: this procedure improves quality of life and extends life expectancy in the long term, yet is not life-saving for the recipient in the short to medium term as he/she can be kept alive by dialysis. Transplantation from a living donor should therefore not be considered as inextricably linked to life-saving therapy.

¹¹ M. De Fallois, 'What Legal and Ethical Framework for Uterine Transplantation?' ['Quel Encadrement Juridique et Éthique Pour La Transplantation Utérine?'], *Revue droit & santé* 77 (2017) 319–331.

Moreover, a prohibition on living donors would make UT totally reliant on deceased donors, which would create problems related to the number and quality of available organs. French law has made organ procurement and transplantation a "national priority", notwithstanding specific types of organ. Ruling out uterus removal from living donors could be perceived as a renunciation of this ambition. Moreover, people waiting for a uterus would be subject to a legal framework less favourable than for people waiting for a liver or kidney.

Finally, from an ethical standpoint, organ removal from a deceased person is often presented as less problematic than removal from a living person.¹³ Risks for the living donor need, without a doubt, to be taken into account, yet other considerations make the matter more complex than it might seem at first glance. First, a living donor can give their express consent while a deceased donor's consent is—if the law remains unchanged in this regard—only presumed in the absence of a refusal expressed while alive. Yet, uterus donation can elicit reticence in some individuals, in view of its symbolic dimension or potential for pregnancy.14 Second, the recipient derives greater benefit if the uterus is from a living donor: the possibility of planning the procedure improves the quality of the organ (by reducing the duration of cold ischaemia) and gives more time for pre-transplantation assessment¹⁵; it also allows for greater immunological compatibility between the donor and the recipient, which translates into lower doses of immunosuppressive treatment after the transplant and hence a more favourable side effect profile.16 Of the first 81 published cases of UT, the technical success rate was 78% with living donors and 66% with deceased donors.17

¹² Article L. 1231-1 of the CSP.

¹³ National Advisory Ethics Council (Conseil Consultatif National d'Ethique), working group composed of Annick Alpérovitch, François Beaufils, Ali Benmakhlouf (Rapporteur), Sylvie Cazalot, Anne-Marie Dickelé, Frédérique Dreifuss-Netter, Roger-Pol Droit, Patrick Gaudray, Marie-Thérèse Hermange, Pierre Le Coz, Claude Matuchansky, Bertrand Weil (Rapporteur), Opinion no. 115, "Ethical questions surrounding the removal and donation of organs for transplantation" [Questions d'éthique relatives au prélèvement et au don d'organes à des fins de transplantation], 7/4/2011.

A.-B. Caire, 'Uterus transplants: For a prospective legal framework' ['La Greffe d'utérus : Pour Un Encadrement Juridique Prospectif'], Revue de droit sanitaire et social 2 (2017) 269–280.

V. Lavoué, C. Vigneau, S. Duros, K. Boudjema, J. Levêque, P. Piver, Y. Aubard and T. Gauthier, 'Which Donor for Uterus Transplants: Brain-Dead Donor or Living Donor? A Systematic Review', *Transplantation* 101 (2017) 267–273.

¹⁶ Ibid

¹⁷ Supra note 1.

If the principle of living uterus donors is authorised, it is then necessary to consider who can become a living uterus donor.

2.2 Defining the Living Donor Pool

2.2.1 Organ Removal from a Living Person in Positive Law

Leaving aside minors and adults under legal guardianship, for whom it does not seem judicious to modify the legal provisions currently in force that prohibit organ removal¹⁸, there is a need to consider the question of including certain categories of people within the pool of potential donors. Today, article L.1231-1 of the French Public Health Code (CSP) stipulates the following:

I—The removal of organs from a living person who donates them may only be carried out in the direct therapeutic interest of a recipient. The donor must be the father or mother of the recipient.

Notwithstanding the first section of this I, the following persons may be authorised to donate an organ in the direct therapeutic interest of a recipient: the recipient's spouse, brothers or sisters, sons or daughters, grandparents, uncles or aunts, first cousins and the spouse of the recipient's father or mother. The donor may also be any person who can provide proof of having lived with the recipient for at least two years, as well as any person who can provide proof of a close and stable emotional relationship with the recipient for at least two years.

2.2.2 Donation by the Mother

The choices made by the legislator in the past are premised on the idea that "the selflessness required to perform such an act without any compensation is primarily found among close family members or friends". ¹⁹ The rule is that the living donor is in priority the recipient's father or mother. However this rule could be challenged in the case of UTs, more on ethical grounds than legal ones.

Although the first woman worldwide to undergo UT had had a haemostatic hysterectomy at the age of 20, the majority of recipients are women born without a uterus—primarily as a result of Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome. Although mothers of such patients may consider uterus donation as a way to satisfy their desire to become a grandmother, they may also consider it a moral obligation that would fix their child's malformation, for

¹⁸ Article L. 1231-2 of the CSP.

¹⁹ State Council, study of 28 June 2018 on the revision of the bioethics law.

which they may feel responsible. ²⁰ Conversely, perception of the uterus as an organ in the sexual domain could act as a cultural block to intrafamilial donation—especially because the operation involves removal of part of the donor's vagina for anastomosis with the recipient's one. In fact, some psychologists assert that sexual relations after the transplantation could be experienced as a form of incest, ²¹ as the recipient could feel that she is sharing the same body with the donor—even though the donation is not of the same essence as sharing. One might also dread the donor's interference in the upbringing of a child born this way. ²² Finally, there is also the symbolic charge associated with transplant of an organ from which the recipient herself came. In relation to uterus donation, it would be useful to reaffirm and possibly clarify the distinctions and borders between donation, transmission and sharing. The ethical, moral, psychological and societal implications should be debated. In view of the above, the legislator will ultimately have to decide whether the rule prioritising parents for organ removal should be maintained for UT.

2.2.3 Donation by a Daughter and Age Limits

The law authorises by way of derogation the daughters of recipients to donate an organ. With regard to UT, situations in which the daughters of patients could be donors would be expected to be very rare. First, the woman desiring to become a mother would have to have had one or more children before undergoing a hysterectomy (haemostatic hysterectomy, for cancer, etc.) or established a legal parent-child relationship via adoption or surrogacy. Second, the law currently prohibits organ removal from minors, and the daughters of recipients are not expected to have reached the age of majority when UT is being contemplated for the mother. Although this type of situation is expected to be extremely rare, it is not impossible that it will arise one day.

According to the trilogy demonstrated by Marcel Mauss, ²³ "giving", "receiving", "returning", which is based on the reciprocity of relationships of exchange, the recipient of a gift contracts a debt towards the giver: the received gift disposes, even morally obliges the recipient, to "return" what they received by means of a counter-gift, real or symbolic, to the giver or more broadly to

^{20 &#}x27;The mother who donated her uterus to her daughter explains her actions' [*La mère qui a fait don de son utérus à sa fille explique sa démarche'], www.20minutes.fr (18 February 2021), available online at https://www.20minutes.fr/sante/2980379-20210218-greffeuterus-toujours-dit-si-pouvais-faire-ferais-dit-mere-donne-uterus-fille.

²¹ R. Henrion and J. Milliez, Uterine transplantation. A report by the National Academy of Medicine [La transplantation utérine. Rapport de l'Académie nationale de médecine.] (23 June 2015).

²² Ibid

²³ M. Mauss, Essay on gifts [Essai sur le don] (1925) (Puf, coll. Quadrige, Paris, 2007).

society. In the context of a mother-daughter relationship between the donor and recipient, a debt prior to the gift of a uterus, within the scope of intergenerational transmission, may be felt in psychological and moral terms, towards the parent who brought you into this world and/or raised you and more broadly towards the previous generation. This issue, which addresses the daughter's freedom to consent to a donation request from her mother, is common to all organ transplants.

Beyond the nature of the donor-recipient relationship, another issue affects UT more singularly: in the case of a uterus donation from a daughter, the recipient has already become a mother, in contrast to the majority of other people who receive a uterus, many of whom have had uterine aplasia from birth. The question then becomes whether to limit UT to women who have not had any children, or to allow it for those who are already mothers too. At first glance, authorising UT only in women who have not been able to have children may lead to higher societal acceptability of this innovative method, and could possibly help reduce the gap between supply and demand. Nevertheless in the long run it seems that nothing would justify the exclusion of women who have already had children and by extension of their daughters as potential donors.

However, the establishment of a minimum age for donors could de facto exclude daughter donors. In the current investigational field in France, the living donors eligible for UT must be aged 40 to 65 years, have had at least one child and have abandoned any future motherhood plans.²⁴ Although the exclusion of women who have never been pregnant can be justified with the argument that only uteri that have demonstrated their gestational functionality should be transplanted, the minimal age criterion could be interpreted as only a woman who had had at least one child can legitimately abandon her uterus. This tacit injunction to procreate contrasts with the ever-greater affirmation of the freedom to not procreate. This social change questions the pertinence of a minimum age condition for uterus donation. From a legal standpoint, it is worth noting that tubal ligation, a contraceptive method difficult to reverse, is authorised for every adult, i.e. without any age or past pregnancy conditions.²⁵ Logically, it follows that an age limit should not be applied to uterus donors. Nonetheless, it would be desirable that uterus donors be subject to the same conditions as women undergoing tubal ligation, notably the requirement for a minimum period of reflection, set at 4 months.

Opinion no. 2019.0043/AC/SEAP of 10 July 2019 of the college of the National Authority for Health evaluating the public health interest of the study "Uterine transplant from a living donor" [Greffe utérine à partir de donneur vivant].

²⁵ Article L. 2123-1 of the CSP.

2.2.4 Donation within a Female Couple

Currently, the law authorises organ donations from the recipient's spouse or any person who can provide proof of living with the recipient for at least two years. In the future, it is possible that a woman in a female couple will want her uterus transplanted to her partner—with this having no effect on the acquisition of parental status, which would be accorded to both the woman who gives birth and to the spouse with whom ART was requested.²⁶ This scenario raises issues about the endpoint of UT: should it be to allow the recipient to have a pregnancy and to give birth to her child or "only" to become a parent? If UT is considered a procedure intended to satisfy a desire for motherhood and not for pregnancy, then it is hard to conceive of it taking place within female couples, in view of the attendant risks. Yet, application of such a restriction would be difficult: how does one prevent cohabiting people (notably those who are not married with or in a civil partnership with the recipient) from becoming donors in their capacity as people with a "close and stable emotional relationship with the recipient" without discarding this criterion altogether? A radical solution would be to prohibit UT for women in a female couple if their partner is fertile (so, able to use ART), with the rationale of risk reduction. However such a solution, which would block access to UT for women in a couple with another person of the same sex, could be denounced as discrimination due to sexual orientation. The legislator may therefore be tempted to conceive of UT as a way of satisfying not only a desire for motherhood but also a desire for pregnancy. If they did, there would be no grounds for restricting the pool of donors when the recipient is a woman in a female couple.

2.2.5 Donation by a Person Unknown to the Recipient

Another potential option is authorising "altruistic" donors to donate their uterus to a person they do not know if they do not have or no longer have a motherhood plan. This donation might seem ethically more acceptable than donations of other organs, considering that the uterus loses its biological function in these potential donors, which is never the case for other transplantations (a kidney or a liver fragment is continually contributing to an individual's health up until the moment it is removed). However there would remain the ever-present risk of commodification of uterus donation, which would be contrary to the principle of non-ownership of the human body. Consequently the most probable option would seem to be alignment with legislation surrounding transplantation of other organs, by which people who cannot provide

²⁶ Article 342-11 of the Civil Code.

proof of a relationship with the recipient are excluded from the pool of potential donors.

Uterus donation by transgender men and by people whose uterus is removed for a pathology not affecting it (for example, a prolapse) might represent an exception to this principle. Transgender men sometimes seek a hysterectomy in order to make their body align with their gender—even though this procedure is not required to change their legal sex. Adding an altruistic dimension to this procedure, via donation of the explanted organ, seems at first sight to fit within the existing legal framework, which permits the reuse of organs removed during a surgical procedure carried out in the interests of the person, provided that he/she does not express refusal. However, the removal of a uterus for future implantation is technically different to standard hysterectomies and carries greater risks, given that it involves removal of more tissue to ensure that uterine vessels are sufficiently long. The matter of whether to authorise these donations should therefore include a debate on whether it is acceptable to expose the donor to these additional risks.

3 Recipient-related Legal Issues

3.1 Uterus Transplantation on the Frontier of Legislation on Assisted Reproductive Technologies

3.1.1 Recipient Selection

In contrast to what the law says about organ donors, the CSP does not lay down criteria about who can be a recipient. The decree of 6 November 1996, in its latest version, only stipulates that "any patient whose health status requires an organ transplant is defined as a potential recipient" and that "registration of a potential recipient [on the national transplantation waiting list] is done by an authorised medico-surgical team." Undoubtedly the law's silence and the concision of the decree are necessary: medical considerations should suffice for any recipient, and greater specificity would only serve to discriminate against potential beneficiaries on the basis of non-medical criteria. The

²⁷ Supra note 21.

²⁸ Article L. 1235-2 of the CSP.

²⁹ Carbonnel and Ayoubi, op. cit.; Mats Brännström, Caiza A Wranning and Albert Altchek, 'Experimental Uterus Transplantation' (2010) 16 Human Reproduction Update 329.

³⁰ Decree of 6 November 1996 ratifying the rules for distributing and allocating organs removed from a deceased person for transplantation [Arrêté du 6 novembre 1996 portant homologation des règles de répartition et d'attribution des greffons prélevés sur une personne décédée en vue de transplantation d'organes].

duration of alcohol abstinence required before authorisation of a liver transplant is, for example, left entirely at the discretion of doctors.

It would seem that for the legislator, recipient selection, which is delegated to the medical profession, is a purely medical matter and not concerned with the organisation of life in society, which would justify its involvement. Yet, on a societal level, UT is without a doubt not as neutral as other organ transplantations. Its endpoint is the birth of a child, not merely to correct an absent or failing organ. It aims to make the recipient a mother. This singularity highlights one of the societal issues raised by UT: who, according to society, can be a mother? In fact, this issue has already been tackled by French law: it has been around since the advent of ART, which required that the law specify which groups of people could benefit. Today, the CSP stipulates that ART is open to all couples formed by a living man and woman or by two living women, and to all unmarried women, subject to an age condition: oocyte removal for ART can only be done to the age of 43 years.31 This criterion could be transposed to women wanting to undergo a UT. It is close to the criterion "woman of reproductive age" which is among the ethical feasibility criteria for UT, the so-called Montréal criteria—which also, in common with French law, do not require that the recipient be in a couple. 32 In all cases, the rules for UT should fit in with the rules for ART, given that it would be meaningless to allow women to undergo UT for gestational purposes, while at the same time denying them access to ART.

3.1.2 UT in a Transgender Woman or a Man

UT also brings with it new possibilities, not accessible via ART, liable to generate debate on aspects other than the recipient's age. Notably, it would probably make a pregnancy possible in a transgender woman or in a man. Although this scenario presents anatomical difficulties (creating uterine vascularisation *de novo* and implanting the uterus in a non-female pelvis) and hormonal difficulties, these are not considered insurmountable by the scientific community. ³³ On a societal level, it is not impossible that UT in a transgender woman be considered more acceptable than in a man. Legally, the two situations should also be distinguished under ART law.

³¹ Article R. 2141-36 of the CSP.

A. Lefkowitz, M. Edwards and J. Balayla, 'Ethical Considerations in the Era of the Uterine Transplant: An Update of the Montreal Criteria for the Ethical Feasibility of Uterine Transplantation', *Fertility and Sterility* 100 (2013) 924–926.

³³ Ibid.

Since 2016, French law has authorised transgender people to change their legal sex without any requirements for medical/surgical treatment.³⁴ Therefore, a transgender woman who has changed her legal sex and who undergoes a UT could have access to ART, either as a single woman or as part of a couple.³⁵ Donation of oocytes by her partner (partner-assisted reproduction) would be impossible, as this technique is prohibited by French law under the principle of anonymity of donations, but the pregnancy could follow an anonymous oocyte donation and self-preservation of sperm (there are no legal provisions against the same person providing the sperm and hosting the embryo), or a double gamete donation. Thus, ART law would not be an obstacle to a pregnancy after UT in a transgender woman.

Conversely, single men are excluded from accessing ART, including those born women who still have full gestational capacity. Similarly for a man in a couple with another man: the CSP limits ART to couples that are formed by a man and a woman or by two women. The constitutionality of this restriction was referred as a high priority (question prioritaire de Constitutionalité) to the French Constitutional Council. The latter pronounced that the principle of equality was not breached if the legislator applied a different treatment to different situations, or they derogated from equality for reasons of general interest. Hence it did not consider that excluding single men or men in a couple with another man from accessing ART was unconstitutional. Consequently, a man who undergoes UT while he is single or in a couple with another man would be legally unable to become pregnant owing to lack of access to ART.

The final case is that of men in a couple with another woman. There are no legal provisions against the transfer of an embryo to the body of a man, given that the CSP systematically refers to a "couple" when ART is carried out in this context: "A couple or an unmarried woman who meet the conditions stipulated in article L. 2141-2 can host an embryo." Only regulatory (sub-legislative) provisions stipulate that the woman must carry the child. 39 It is not impossible that the legislator would want to clarify the law and limit pregnancy to women by giving an *ad hoc* definition of the person who can undergo UT, including a direct and exclusive reference to women.

Law no. 2016-1547 of 18 November 2016 on modernising justice in the 21st century [Loi n° 2016-1547 du 18 novembre 2016 de modernisation de la justice du XXI e siècle].

³⁵ Law no. 2021-1017 of 2 August 2021 on bioethics.

³⁶ Article L. 2141-2 of the CSP.

³⁷ Constitutional Council, 8 July 2022, no. 2022-1003 QPC.

³⁸ Article L. 2141-6 of the CSP.

³⁹ Article R. 2141-38 of the CSP.

Once implanted, the uterus is not intended to remain in place *ad vitam aeternam*: the UT will eventually be followed by explantation of the uterus.

3.2 Explantation of the Uterus

3.2.1 Refusal to Undergo Explantation

UT requires that the recipient take immunosuppressive treatment from the moment of the transplantation and for the entire post-transplantation period. This treatment has a certain number of side effects including a higher risk of infection and cancer. The infection risk is maximal in the first six months after the transplantation, ⁴⁰ even though it persists in the long term, while the cancer risk increases over time. For these reasons, a limit is placed on the duration of time the implanted uterus remains in place; for example, it may be removed after the birth of one or two healthy babies or after five years. ⁴¹ The explantation requires another surgical procedure, whose risks are greatly offset by the reduction in the impact of immunosuppressive treatment.

Eventually the question will arise of the consequences of a refusal to undergo uterus explantation once the pregnancy plan(s) has/have been completed or after a certain period of time has elapsed. This issue is unique to UT: explantation is not performed after transplantation of other organs for as long as the transplanted organ is functioning correctly. One could argue that the only person affected is the transplanted person exposed to the risks. However, such an argument overlooks the fact that French law sometimes goes to great lengths to protect individuals from risks only they are exposed to; and it also overlooks the consequences of this refusal for society as a whole: immunosuppressive treatments and their complications have a cost, borne by Social Security, which over time exceeds that of the explantation procedure.

Underlying the refusal is the question of the scope of the consent given at the time of transplantation: should it necessarily include consent for the explantation? In fact, even if it did, the issue would remain given that the CSP stipulates that consent "can be withdrawn at any time". ⁴² French law considers consent to be a "subjective right", regarded as a fundamental freedom by the State Council and recognised by supranational law via the Oviedo convention. ⁴³ The fact that consent was previously given has no bearing on the duty

⁴⁰ Supra note 1.

⁴¹ Supra note 21.

⁴² Article L. 1111-4 of the CSP.

Article 5 of The Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine [Convention pour la protection des Droits de l'Homme et de la dignité de l'être humain à l'égard des applications de la biologie et de la médecine: Convention sur les Droits de l'Homme et la biomédecine].

of healthcare professionals to respect, in such a situation, the refusal to undergo the procedure. Any other course of action would breach the principle of inviolability of the human body. ⁴⁴ Generally speaking, a patient's medical journey frequently consists of several procedures and the correctly informed patient is free to accept or refuse any one of them, even if the medical process is already underway and regardless of the consequences.

Penalising the refusal is not envisageable either. Apart from the ethical implications of such a scenario—which would possibly mean penalising a recipient who is refusing explantation whereas no pregnancy has been successful, the law would consider a penalty as a way of forcing consent, which should always be freely given. 45

3.2.2 Absence of Explantation: UT without a Pregnancy Endpoint Explantation of the uterus would make little sense if UT was intended to correct the absence of a uterus per se, whether congenital or subsequent to a hysterectomy. In some people, this absence could have a negative effect on their perception of their body and cause distress.⁴⁶ The fact that some of these women would want to undergo a UT without a pregnancy endpoint might meet with disapproval on the principle that the procedure would mean prolonged exposure to immunosuppressive treatment and would affect the supply of organs. It nevertheless seems difficult to conceive of a legal solution that could completely prevent this eventuality. Excluding single women from UT to ensure that only women in a couple could access it would create an asymmetry with the law on ART, available to single women, and would offer absolutely no guarantee that a pregnancy plan would ensue. Even if it were possible to oblige the recipient to use ART once the uterus has been transplanted, this solution would be tantamount to penalising every woman who had undergone a UT with the sincere aim of procreating but changed her mind after the UT (for example, after a separation). Perhaps the best way for the legislator to hinder UT requests without a pregnancy endpoint, and hence to regulate the recruitment of uterus recipients, would be to require that the recipient had previously begun a course of ART.

Let us suppose that a debate was launched on the appropriateness of authorising UT for a non-gestational indication. We could note that such an indication is not cosmetic surgery, given that the endpoint of the procedure is not a changed appearance, nor is it sex reassignment surgery, given that the uterus can be transplanted independently of any desire to change sex. Legally

⁴⁴ Article 16-1 of the Civil Code.

⁴⁵ Article L. 1111-4 of the CSP.

⁴⁶ *Supra* note 32.

speaking, UT without a reproductive endpoint could not be regarded as anything but transplantation. As such, a difficulty appears: currently transplantation procedures are premised on the existence of a therapeutic benefit for the receiver. 47 However, we note that therapeutic benefit is not medical benefit, as is apparent from the amendment made to article 16-3 of the Civil Code in 1999, 48 substituting the notion of "medical necessity" for that of "therapeutic necessity" enabling violation of the integrity of the human body. Medical activities constitute a much larger set than therapeutic activities, which are "actions or practices intended to heal".49 UT without a reproductive endpoint would be impossible under existing law, unless it was considered to meet a therapeutic need, namely relieving psychological distress. In this regard, although UT without a reproductive endpoint is not sex reassignment surgery, a parallel can still be drawn: in sex reassignment surgery, the surgical procedure is not performed for a physical anomaly but, here too, for psychological distress, in this case not due to a missing organ but the feeling of belonging to the opposite sex. This did not prevent the Court of Cassation from considering, in 1992, that a medico-surgical treatment had been carried out on a transgender person "for a therapeutic purpose".50 Therefore, UT without a reproductive endpoint does not seem incompatible with the "therapeutic benefit" required for transplantation.

In sum: although the legislator has in the past delegated the selection of organ recipients to the medical profession, it seems quite unlikely that they would adopt the same attitude for UT, a technique with a societal dimension as significant as the medical one. It is in the interests of both the people requesting UT and the medical teams, which would still be entrusted with identifying situations of absolute uterine factor infertility, that the legislator specifies a certain number of criteria for accessing this innovation. There are few options at their disposal if they wish to oppose UT without a gestational endpoint. In the case of UT with a gestational endpoint, the legislator would need to make sure that the rules for the transplantation procedure are consistent with those they laid down in the past for ART. In this regard, they would have to take into account that existing ART rules exclude access for single men and men in a couple with another man.

⁴⁷ Articles L. 1231-1 and L. 1232-1 of the CSP.

⁴⁸ Law no. 99-641 of 27 July 1999 creating universal medical coverage [Loi n° 99-641 du 27 juillet 1999 portant création d'une couverture maladie universelle].

C. Leprince, 'Transsexualism, contemporary evolution of ideas and of the law' [*Le transsexualisme, évolution contemporaine des idées et du droit'*], *Revue Juridique de l'Ouest* 21 (2008) 132–182.

⁵⁰ Cass. Ass. Plén., 11 Dec 1992, pourvoi no. 91-11900, Bull. civ. 1992 A.P. no. 13 p. 27.

