

# Ethical and medico-legal remarks on uterus transplantation: may it solve uterine factor infertility?

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**Abstract.** – Uterus transplantation was firstly tested with animal trials sixty-five years ago. Despite several successful attempts in human subjects, the different procedures still lay at the experimental stage, in need of further studies and investigations before they can be considered as standard clinical practices. Uterus transplant cannot be regarded as a life-saving procedure, but rather a method to restore woman ability to procreate, when lost, thus improving her quality of life. Uterus transplant is a complex surgical procedure and presents significant health threats. Medical staff should therefore always obtain informed consent from patients, emphasizing such risks. Before that, women undergoing uterine transplants should be thoroughly informed about the hazards inherent to the procedure and especially about the dangers of immunosuppressant drugs, administered after the surgery which may injure the fetus, eventually formed in the restored organ and even lead to its death, thus nullifying the purpose of the transplant itself. Therefore, the risk-benefit ratio of uterus transplantation needs to be carefully assessed and described.

## Key Words

Uterus transplantation, Infertility, Risk-benefit ratio, Informed consent.

## Introduction

Infertility can be considered as a medico-social issue and a disability<sup>1</sup>. Among its social causes, there is the prospective mother's advanced age, drug or alcohol abuse, smoking, adverse working conditions and finally pollution<sup>2</sup>. On the other hand, unfavorable medical conditions include a lack of uterus following its surgical removal (hysterectomy) or Rokitansky-Kuster-Hauser

syndrome (Müllerian agenesis), a rare congenital malformation that carries varying degrees of vaginal or uterine hypoplasia, making the uterus unfit for pregnancy<sup>3</sup>. Nowadays, females who cannot achieve a natural pregnancy, but still wish to have offspring bearing their genetic background can appeal to surrogacy<sup>4</sup>, and medically assisted procreation techniques make such option viable<sup>5,6</sup>. These practices consist in “borrowing” or “renting” the womb of another woman, who agrees to have implanted into her uterus an embryo which was formed in vitro via gametes from a couple with infertility problems. Surrogacy unleashes multiple ethical controversies, and it is outlawed in many countries, including Italy<sup>7</sup>, because it is perceived as damaging the dignity of motherhood, and turns babies into “tradable commodities”, often resulting in negotiations and litigations.

In this review, the authors aimed to briefly outline the history and development of uterus transplantation, from the first tests in animal model sixty-five years ago to the attempts and some successes in human subjects, ethical considerations and what is required for the different procedures, many of them still at the experimental stage, before they can be considered as standard clinical practices.

## *Historical Background of Uterus Transplantation: Research Trials on Animals and Human Subjects*

The first animal trials concerning uterus transplantation started around 1950, whereas the first attempt on a human female took place about 40 years ago, in the same Cape Town hospital

where Cristian Barnard performed the first heart transplant: the outcome was disastrous.

In 2000, the first transplant of the new century took place and demonstrated that such surgery was technically possible. In that specific case, the pregnancy had to be terminated because of arising vascular issues<sup>8,9</sup>. Nonetheless, medical staff expressed a positive judgment on the surgery itself, thus laying the groundwork for further improvement in surgical techniques. In 2008, the ethical committee of International Federation of Gynecology and Obstetrics (FIGO) issued a report that classified uterus transplants as unethical, due to a lack of data about its safety and effectiveness<sup>10</sup>. Nonetheless, human clinical trials have continued, with many of them carried out in Turkey, where surgeons used organs from deceased donors and attained pregnancies, which eventually ended in miscarriages<sup>11</sup>.

In 2012, the Ethical Committee at Gothenburg's University Hospital (Sweden) green-lighted ten uterine transplants from living donors. The first one was executed in September 2012, and a year later patient underwent immunosuppressive drug therapy and eventual in-vitro fertilization, in an attempt to achieve pregnancy. Two pregnancies were ultimately carried to term, after which the transplanted uterus was removed in order to discontinue immunosuppressive drug therapy<sup>12,13</sup>.

Another similar attempt was made in Cleveland, United States, on 24<sup>th</sup> February 2016. The recipient was a 26-year-old female included in a research trial totaling 10 transplants, whereas the uterus came from a 30-year-old deceased donor. The surgery led to an unfavorable outcome, and the transplanted uterus had to be removed 12 days later, due to complications<sup>14</sup>. In the wake of the successful attempts in Sweden, the same year, specialists at the a French "Agence Nationale de Sécurité du Médicament authorized a series of trials on eight women transplanted with uterus from donors declared to be brain-dead. Doctors are set to wait for a complete stabilization of the transplanted organs before attempting to achieve pregnancy through in vitro fertilization. The first childbirth is scheduled to take place by the end of 2018, according to the specialists<sup>15,16</sup>.

In Italy, the Ethical Committee of the Italian National Institute of Health has approved a womb transplant protocol at the Umberto I Hospital in Rome<sup>17</sup>. In the United Kingdom, the Health Research Authority has authorized ten uterus transplants<sup>18</sup>.

Generally speaking, since the year 2000, thirteen uterine transplants have been carried out in different medical institutions worldwide. A total of four children were born, and one woman even bore a second child in October 2015. Although such few but successful results have been attained be encouraging, the FIGO has not yet revised its assessment on uterus transplants non-ethics, which was released in 2008.

### ***Uterus Transplant: Risk-benefit Analysis***

Almost twenty years later, uterine transplant falls within the field of clinical as well as therapeutic research, since women who undergo it hope for an opportunity to get pregnant, thus benefiting from the procedure on a personal level. This kind of transplant requires surgical practices still in the process of being improved, such as anastomosis (i.e., the procedure through which blood vessels and arteries can be connected), in addition to more consolidated ones. Unlike other organs, which have larger veins capable of transporting large amounts of blood, the uterus has very thin vessels, which are difficult to re-connect.

Moreover, a uterine transplant offers only minimal chances to attain pregnancy. On the other hand, it implies substantial risks, which make necessary a long and thorough experimental phase starting with animal trials. The latest version of the Italian Code of Medical Ethics<sup>19,20</sup> recommends doctors to refrain from diagnostic and therapeutic procedures that might be viewed as clinically unwarranted and ethically questionable, and from those who cannot reasonably provide tangible benefits to the patient's health and quality of life (art. 16, Code of Medical Ethics). However, the remarkable rate of progress in medical transplantation techniques and biomedical engineering will hopefully improve uterine transplants as well, which anyway impact a fairly small amount of patients and poses multiple scientific and medical issues.

### ***Ethical Issues: The Montreal Criteria***

Uterine transplantation is a complex procedure that gives rise to multiple medical, ethical and legal inquiries due to the risks posed to both donors and recipients.

For all those reasons, in 2012, Lefkowitz et al<sup>21</sup> have released a set of arguments both for and against uterus transplantation (Utx), known as "the Montreal criteria", which have been updated the following year<sup>22</sup>. The revised Montreal

criteria for the ethical feasibility of uterine transplantation involve recipients, donors and medical staff, and have to be met as a whole, for a uterus transplant to be considered ethically viable.

Such criteria break down as follows:

### 1. The recipient

- a Genetic female of reproductive age with no medical contraindications to transplantation;
- b Presence of documented congenital or acquired uterine factor infertility (UFI) that failed all current gold standard and conservative therapies;
- c
- c1 A personal or legal contraindication to surrogacy and adoption measures and desire to have a child;
- c2 Uterus transplantation (UTx) sought only as a measure to experience gestation, with an understanding of the limitations provided by the UTx in this respect;
- d The decision to undergo UTx is not deemed as irrational by expert psychological evaluation, and no psychological comorbidity that interferes with diagnostic workup or treatment is present;
- e No frank unsuitability for motherhood;
- f Likely to take anti-rejection medication and follow-up with the treating team in a responsible manner, and
- g Responsible enough to consent, informed enough to make a responsible decision.

### 2. The donor

- a A female of reproductive age with no medical contraindications to donation;
- b
- b1 Repeatedly attested to her conclusion of parity;
- b2 Signed an advanced directive for post-mortem organ donation;
- c No history of uterine damage or disease,
- d Responsibility to consent, informed enough to make a responsible decision, and not under coercion.

### 3. The health care team

- a Part of an institution that meets Moore's third criterion<sup>23</sup>, as it pertains to institutional stability;
- b Able to provide adequate informed consent to both parties regarding risks, potential sequelae, and chances of success and failure,
- c No conflict of interest independently or with either party;
- d The duty to preserve anonymity if the donor or recipient do not explicitly waive this right".

### ***Uterus Transplant: Characteristics and Complications***

Transplantology has made giant steps from the viewpoint of surgical techniques and control of organ rejection, and in this concern uterine transplantation has a unique peculiarity, aimed at preserving the functionality of the uterus in relation to the pregnancy and the birth of healthy babies. Uterine transplantation does not fall within the category of scientific research, but rather therapeutic one, since women who undergo it aim to gain the ability to get pregnant, benefiting in this way of the possible positive outcome of such experimental procedure.

Several complications can arise after transplantation, which are the same that may potentially arise in any surgery such as postoperative bleeding, possible infections that may lead to severe illness up to death or to the removal of the transplanted organ<sup>24</sup>. Immunosuppressants, which have to be necessarily taken after transplant make treatment of infections and tissue recovery more complex, due to the weakening of the immune system they cause. Moreover, general medical complications may manifest themselves (pulmonary embolism, myocardial infarction, atrial fibrillation, pleural effusion, etc.). The point is that in case of uterus transplantation, immunosuppressive therapy has to be continued during the whole pregnancy and until birth, when the allograft uterus is removed. For that reason, the complications that this therapy may cause for fetal development have to be evidenced and reported. Unfortunately, the only available information on the safety of new drugs during pregnancy and lactation at the moment is from experimental and preclinical animal studies and from human case reports<sup>25</sup>.

Uterine transplantation is peculiar due to the fact that the uterus is not a life-sustaining organ (such as heart, liver or kidney), but it is just an "instrumental organ" with the only function to give back to an infertile woman the ability to become pregnant. In general terms, if an organ transplant should be considered ethically acceptable when it enables the patient to go on living (heart transplant is emblematic in this regard), those transplants that are not life-saving, but merely aimed at restoring lost organ functions, are much more controversial in ethical nature, especially when they entail significant risk or have a relatively low possibility of success<sup>17</sup>. An example is that of hand transplants. It is well documented that several patients who underwent

such surgery have later demanded to have the transplanted hand removed, not because of histocompatibility, but due to psychological issues arising from the perception of the transplanted hand as something not belonging to one's own body<sup>26</sup>.

### **Ethical and Medico-legal Issues**

Major ethical issues related to uterine transplant are: a) the validity of consent to explantation (particularly from a living donor) and implantation, owing to the dangerous nature of such procedures, b) the use of organs from deceased rather than living donors, c) the collection and equal distribution of organs, which are of limited supply, but at the same time of high demand<sup>27</sup>.

Research has shown that transplants have better chances of success if the organ comes from a donor related to the recipient, and in case of uterus possibly sisters or mothers. It is worth specifying that organ donations between kins are an altruistic act, thus justifiable as such. The fact that psychological dependency may develop between donor and recipient has not to be overlooked. Such an outcome, however, may arise in all cases of transplants *inter vivos*. Uterine transplants have better chances of success if the organ comes from a living donor. However, serious ethical issues come to the fore, namely an organ donation without a real therapeutic need. The uterus is a single, non-vital organ, nevertheless, the donor is affected in her physical integrity. Misgivings come from the intrinsic nature of such a procedure: it is not meant to be life-saving, as would be the case with kidney or liver transplants, but it only serves the purpose of achieving motherhood. When it comes to uterine transplant and its high complexity, the woman health is in severe danger, and the likelihood of organ rejection and fetal death is high, which nullifies the very purpose of the surgery itself<sup>28</sup>. One more reason for skepticism is the need to remove the organ from a deceased donor. The shortage of available organs is well known; hence, it is questionable that they should be used for non-therapeutic interventions. Currently, uterine transplants have extremely low chances of success; it is then hardly justifiable to massively invest in such possibility, blocking the limited financial resources towards procedures with higher success rates.

A great deal of misgivings arise in the phase following organ explantation, that is when the actual transplant takes place, being such a surgical procedure still experimental. The recipient, as is the case in any other transplant, will have

to undergo immunosuppressive drug therapy to prevent organ rejection which, in addition to exposing the patient to the risk of diseases (e.g., hypertension, diabetes, cataracts, osteoporosis), is highly harmful to the fetus. Therefore, the wish to have an offspring may be nullified by anti-rejection therapies, which are mandatory for any transplant and can greatly harm the possibly conceived fetus. To avoid immunosuppressive therapy for life, two follow-up procedures are necessary: cesarean section and hysterectomy. It is also worth noting that the uterus is not a "static" organ such as a kidney or liver, which keep the same size once implanted in the recipient. During pregnancy, in fact, the uterus increases in size and width, and in case of thrombosis, it should be removed in order to save the mother's life, thus terminating the pregnancy. In addition to all that, there are many technical difficulties, mostly associated with the intricate reattachment of veins and arteries<sup>9</sup>.

Uterine transplantation is hazardous from a psychological standpoint as well: possible organ rejection would only add to the sense of anguish and frustration already afflicting women due to their inability to have a pregnancy.

Such considerations are true for transplants from both deceased and live donors. Besides, in the latter cases, it should be kept in mind that uterine explantation is an extremely risky and a long surgical procedure.

### **Legal Regulation of Organ Transplants**

Uterus transplant needs to be assessed from a legal perspective as well. Every country regulates transplants in different ways, but the Italian framework is here detailed.

Italian law draws a distinction between transplants from deceased donors and those *inter vivos*. Law n. 91, 1999 regulates the former, whereas transplants from live donors may be carried out in compliance with Ministerial decree n.116, from 16<sup>th</sup> April 2010 (Regulation of transplantation activities from live donors)<sup>29</sup>. Art. 5 of the Italian Civil Code sets forth the principle according to which "any actions on one's own body when causing permanent damage to physical integrity or when violating law, public order or decency are prohibited". Italian lawmakers have enacted several laws that constitute exceptions to the above-mentioned principle, namely law 458, from 1967, which deals with kidney transplants, law n. 483, from 1999, regulating partial liver explantation, law n. 219 from 2005,

which addresses transfusion-related activities and the national production of hemoderivatives, by repealing previous law n. 107 from 1990 on blood transfusions. Yet, medical and scientific advancements have made possible some transplants that are not yet regulated, uterus transplantation being one of those. How should legal scholars approach the issue of still unregulated transplants, among which uterine transplant?

Uterus donation represents an act of “disposal of one’s body for the benefit of the recipient, which is aimed at gaining an advantage for a woman other than the donor. In order for such an act to be deemed legal, it must not compromise the woman donor’s physical and functional integrity. Based on such a principle, uterine transplants are lawful only when the donors are menopausal women, who have no longer the ability to procreate, and would therefore be unaffected in their physical integrity by the loss of their uterus. On the contrary, lays the choice of a woman in fertile age, but close to menopause, who has already born children. In such an instance, the donor could still have children in the future while donating her uterus for transplant would then deprive her of any future prospect to have more children. In our view, uterus transplantation should be deemed lawful in such hypothetical case, irrespective of its being a non-vital organ. However, each instance ought to be weighed on a case-by-case basis, thoroughly assessing the motivations behind the prospective donor’s choice to have her womb removed, and the recipient’s decision to undergo such a hazardous procedure, with a highly uncertain outcome.

### ***Informed Consent***

Law decree n. 116, from 16<sup>th</sup> April 2010, lays out *a set of regulations targeted to the organ transplant-related activities from live donors*<sup>30</sup>. Article 2 codifies the institution of expert committees due to handle all those issues stemming from living donor transplants. The committee is tasked with “verifying that both recipients and prospective donors have acted in compliance with informed consent principles, which consent must be free and thorough, and have received all possible information pertaining to their clinical case, the risk factors involved and the actual odds of success with transplants from deceased or living donors, in terms of survival rates for both organs and patients themselves”.

The issue of obtaining informed consent in uterine transplant cases is particularly sensitive in nature. Women who place themselves on the

waiting list for such surgery should be fully aware of the often lengthy wait that it requires. In Italy, organs must come from deceased donors, with immunological compatibility. When a woman is put on the waiting list, it is quite difficult to predict how long it might take before the actual surgery can be performed. In fact, since the organ to be transplanted comes from a deceased donor and must be compatible with the prospective recipient, it is just impossible to schedule the surgery, which might be performed at any time. Such a degree of uncertainty entails significant emotional and psychological strain, which the recipient has to be made aware of.

Medical staff should inform patients that any future successful pregnancy, granted that there even is one, will be carried to term with a cesarean section. Therefore, the patient will have to undergo three different surgical operations: uterus transplant, cesarean section and uterus removal, not to mention artificial insemination, which is itself an invasive kind of procedure. Doctors should make it absolutely clear to their patients that such medical procedures may give rise to complications, and explain exactly what kinds of unwanted side-effects might come into being. Patients ought to be informed as to the immunosuppressive drugs until the transplanted womb can be removed. Such immunosuppressants could damage some organs, kidneys for instance, increase the likelihood to develop cancer and turn out to be harmful to the fetus as well.

Lastly, in order to avoid possible disappointment in patients, women should be made aware that the transplanted womb will not convey the feeling of contraction, neither will they perceive the fetus pressing against the inner walls; women will be able to make a thoroughly informed decision on whether to accept the surgical risks and the immunosuppressive drug therapy.

The acceptability of an ill-defined, unidentified risk constitutes an ethical issue, since uterus transplantation entails hazards for both the mother and the embryo which is implanted into her womb<sup>30</sup>.

### **Conclusions**

Women diagnosed with uterine factor infertility can fulfill their wish to have a child through surrogacy, which is nonetheless illegal in many countries. Uterus transplantation, however, can be a sustainable alternative for women who wish

to achieve motherhood. Uterine transplant is still an experimental procedure; as a general principle, such transplants designed to make childbirth possible is ethically acceptable. Yet, there are correlated issues that must be weighed carefully before an uterine transplant can become a routine surgical practice. It is therefore paramount to carefully evaluate the risk-benefit ratios and reflect whether the longing for motherhood may warrant an acceptance of the hazards inherent in the procedure, for both the mother and the fetus.

### Authors contributions

All the authors made substantial contributions to conception and design of the manuscript. They have been involved in revising the manuscript critically for important content and all of them have given final approval to the version to be published.

### Conflict of Interest

The authors declare no conflicts of interest.

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