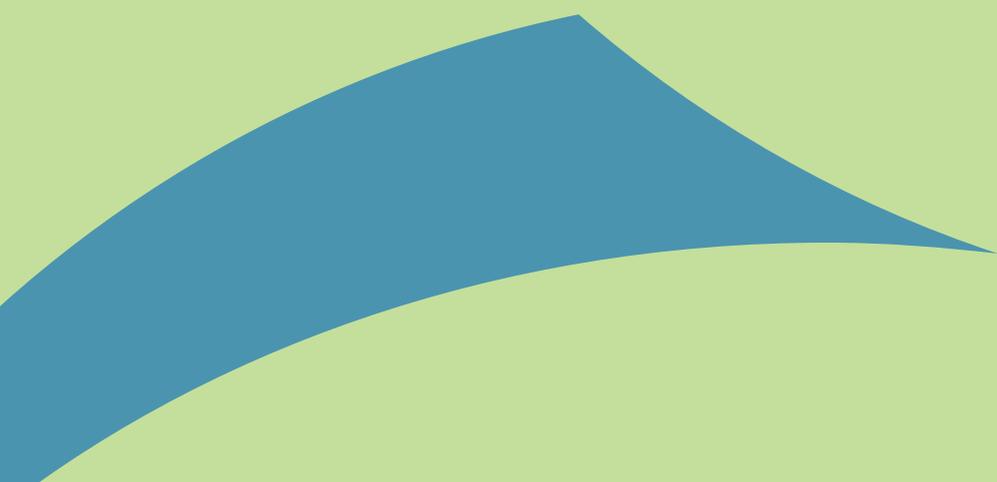
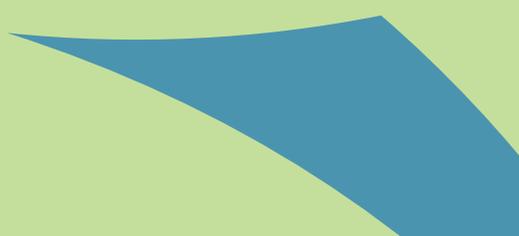


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**National Advisory Commission on
Biomedical Ethics NCE**

Uterus transplantation Procedure – ethical considerations

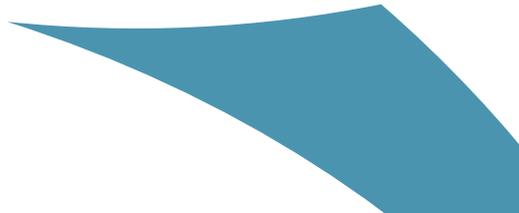
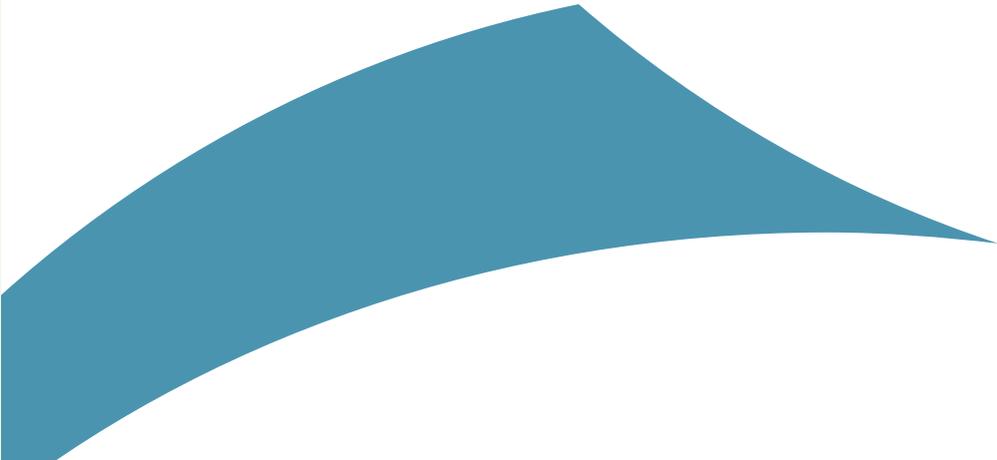
Opinion no. 29/2018
Bern, 23 March 2018

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Introduction

Uterus transplantation is a medical procedure currently being investigated and developed. First attempted unsuccessfully in Saudi Arabia in the early 2000s (Fageeh et al. 2002), it has since been carried out – without complete success¹ – in various countries, including Turkey (Erman Akar et al. 2013; Ozkan et al. 2013), China (Wei et al. 2017), the US (Flyckt et al. 2016; Testa et al. 2017) and Brazil (Soares et al. 2016). The effectiveness of the approach was demonstrated in Sweden in 2014, with the first live birth (Brännström et al. 2014; Brännström et al. 2015). So far, around 40 uterus transplantations involving living or deceased donors have been undertaken in various countries (Petrini et al. 2017; Brännström et al. 2018; Kisu et al. 2018), with 11 live births reported overall (8 in Sweden, 2 in the US and 1 in Brazil). It should be noted that, to date, with one exception, all the women who have given birth following this procedure had received a living-donor uterus transplant; the woman who had received the uterus of a deceased donor gave birth to her child in Brazil in December 2017 (Saúde 2017; Globo 2017).²

In Switzerland, the public has become aware of uterus transplantation through the media, particularly in connection with plans to conduct the procedure at Zurich University Hospital (Bröhm 2016; Lüthi 2016; Niederer 2016; Straumann 2016; Reichmuth 2016).

Even at this early stage, the National Advisory Commission on Biomedical Ethics (NCE) considers it appropriate to express its views on the ethical and legal issues raised by this procedure. However, since uterus transplantation is still in its infancy, the Commission's Opinion is, of necessity, preliminary, and it may need to be adapted to take new findings into account. It should be underlined that uterus transplantation combines, in an unprecedented manner, elements of medically assisted reproduction and organ transplantation (Büchler & Schlumpf 2017). It thus blurs the boundaries between these two distinct areas of ethico-legal discussion and regulation. In addition, it is currently the only type of transplantation which is temporary (Petrini et al. 2017; Arora & Blake 2015; Catsanos, Rogers & Lotz 2013), as the transplanted organ is intended to be removed after having made pregnancy and childbirth possible.

Uterus transplantation falls within the scope of the Transplantation Act and of the Reproductive Medicine Act. If the procedure forms part of a research project, the Human Research Act is also applicable. These various legal constraints thus need to be taken into consideration.

In the following sections, the NCE examines, firstly, the practical aspects of uterus transplantation (the medical indications, in Section 1, and the various steps involved, in Section 2). It then considers the ethical issues associated with the procedure, undertaking firstly an ethical assessment (Section 3) and then an overall evaluation (Section 4). The conclusions reached by the Commission on this basis are presented in Section 5.

1) Complete success of uterus transplantation is defined by three criteria: (1) a favourable surgical outcome – with a viable graft by 3 months; (2) graft function by 1 year, with several months of regular menstruation; (3) a successful pregnancy resulting in a healthy live birth (Brännström et al. 2018).

2) As of March 2018, based on scientific publications. There are no scientific publications on the case of the child born after deceased-donor uterus transplantation.

1. Medical indications

The uterus transplantation procedure was developed to enable a woman to carry and give birth to a child – essentially her own biological child – despite the presence of anatomical or pathological conditions preventing her from doing so. It is this prospect which inspires researchers and patients interested in the procedure, such as those who participated in the initial experiments abroad.

There are various reasons why a woman cannot become pregnant due to an absent or dysfunctional uterus (absolute uterine factor infertility). The list of diseases or disorders giving rise to such a situation is not irrevocably fixed, if only because methods of treating these conditions are constantly evolving. There are thus some conditions – for example, types of cancer – which used to be treated by measures involving removal of the patient's uterus (hysterectomy) and which can now be managed without resort to such radical interventions. At present, conditions associated with an absent or dysfunctional uterus are, for example, Mayer-Rokitansky-Küster-Hauser syndrome³ (MRKH), severe Asherman's syndrome⁴, or serious uterine malformations; conditions whose treatment may involve hysterectomy include uncontrolled postpartum bleeding and cervical or endometrial cancer.

According to the International Federation of Gynecology and Obstetrics, around 1 in 500 women of childbearing age are affected by absolute uterine factor infertility (FIGO 2009). No specific statistics are available for Switzerland concerning the number of women belonging to one or other of the two groups mentioned above (absent or dysfunctional uterus); likewise, there are no estimates of the proportion of women in each group who are of childbearing age and wish to have their own biological child. Even though it is not possible to provide clear and reliable figures, it may be assumed that some women with absolute uterine factor infertility in Switzerland would be candidates for the procedure of uterus transplantation.

3) This anomaly, affecting around 1 in 4000–10000 women, involves malformations of the urogenital system, with different degrees of severity; in general, the uterus and vagina are absent, and sometimes a kidney is also missing. The ovaries, however, develop normally and are functional.

4) This is characterised by dense adhesions (scarring) inside the uterine cavity and endometrial dysfunction, generally as a result of intrauterine procedures (e.g. curettage) or severe inflammation of the endometrium.

2. Steps involved in the uterus transplantation procedure

The procedure of uterus transplantation for reproductive purposes encompasses various stages and can extend over a period of several years.

In the first phase of the procedure, it is necessary to confirm that the woman concerned has an adequate number of eggs which can be retrieved for in vitro fertilisation treatment (IVF). If this is the case, the woman undergoes ovarian stimulation to permit the retrieval of sufficient eggs, which are then fertilised by the sperm. The resulting embryos are further developed in vitro and finally frozen. In the absence of (sufficient) eggs, the procedure could not be pursued at present, since egg donation is prohibited in Switzerland. In addition, the medical team would have to ensure that the couple meets the legal requirements for assisted reproduction.

Transplantation takes place in the second phase of the procedure. In order to ensure that sufficient embryos are available to establish a pregnancy, IVF has to be carried out before, not after, transplantation, since the procedure impairs ovarian vascularisation and the ovarian reserve is usually diminished as a result. In addition, because the transplanted uterus is not innervated and the Fallopian tubes are absent, natural pregnancy is not possible following (successful) uterus transplantation.

This second phase of the procedure begins with uterus retrieval from a living – or even deceased – donor. Both types of procedure have been carried out abroad; with one exception, all the births ($n = 10/11$) reported to date worldwide have taken place after living-donor uterus transplantation; only in a single case has deceased-donor uterus transplantation led to the birth of a child. In Switzerland, only retrieval from deceased donors is envisaged at this point (on this question, see Section 4.3). The donor would have to consent, prior to death, to the removal of her uterus; if her wishes have not been expressed, her relatives may decide on her behalf (Transplantation Act, Art. 8), as is the case for any other organ. As the organ is removed *post mortem*, the procedure does not involve any surgical risks for the donor. From a medical perspective, uterus retrieval does not pose particular technical challenges. The choice of donor is, however, important; the chances of a successful pregnancy are expected to be higher if the uterus is retrieved from a donor who, prior to her death, was in good health and, in particular, did not have any uterine disorders or other medical contraindications. The donor should match the recipient as closely as possible (both anatomically and in terms of tissue type).

Immediately after retrieval, the uterus has to be transplanted to the recipient, who would have to have consented to the procedure. If the procedure is conducted within the framework of a research project, the more stringent requirements of the Human Research Act (HRA) would have to be respected (see Section 3 below). She must have received comprehensive oral and written information, been able to ask questions and decided freely. It should be noted that the information given to the recipient would have to emphasise the absence of uterine sensations (due to the fact that the transplanted organ is denervated) and the impossibility of a natural (vaginal) birth. If the woman has given valid consent – which may be revoked at any time – the transplantation can take place.

Currently, transplant surgery of this kind takes around 4–6 hours (Castellón et al. 2017). It is regarded as a delicate operation. The main risks for the recipient are complications of surgery (bleeding, infection, septicaemia, fistulae, injury to other organs) or anaesthesia, thrombosis/embolism, graft rejection and

adverse effects of immunosuppressant (anti-rejection) drugs. The recipient must take this medication immediately and continue to do so as long as the transplanted uterus remains in the body. However, rejection reactions are likely to occur due to the well-developed immune mechanism of the uterus (Kisu et al. 2018). While mild rejections can be treated with medication, a hysterectomy is necessary in more severe cases.

The third phase is a waiting period. This period makes it possible to verify that the new organ is well tolerated and functional. The length of the waiting period has been determined for the time being on the basis of preliminary findings; experts estimate that the appropriate period is between 9 and 18 months.

In the fourth phase, the embryo transfer takes place. The procedure is the same as for other IVF patients, as uterus transplantation does not require any special measures or precautions. For this new phase, the couple's consent would again need to be given. Each partner may change his or her mind. No reliable and/or published medical evidence is available to indicate whether the chances of success (i.e. successful implantation) are the same as or lower than in other cases of IVF treatment.

The fifth phase is that of pregnancy. This calls for particular monitoring, since vascularisation of the uterus is reduced after transplantation. As the transplanted organ is not connected to the pelvic nerves, the recipient will feel fetal movements less well and will not experience contractions; for this reason, caesarean delivery is essential.

In addition, women with MRKH syndrome often only have one kidney (MRKH type 1) and may have other skeletal or cardiac malformations (MRKH type 2). Accordingly, these patients, who make up a specific group, more frequently develop pre-eclampsia or are at risk for other pregnancy-related complications.

The sixth phase is removal of the uterus. Unless the woman wishes to have another child, the transplanted uterus, no longer serving any function, needs to be removed on account of the ongoing risks (immunosuppressant medication, subsequent rejection, etc.). The main risks associated with a procedure of this kind are complications of surgery (bleeding, infection, injury to other organs) or of anaesthesia and thrombosis/embolism. Once the uterus has been removed, immunosuppressant medication can be discontinued. However, the patient will still require regular medical and psychological follow-up (Brännström et al 2018). Even after the six phases of uterus transplantation and removal, potential consequences for the patient can still not be ruled out. Possible risks include abdominal wall hernia, adhesions, urethral strictures and problems relating to pelvic floor innervation, with pelvic organ prolapse or incontinence; also to be considered are potential long term effects of immunosuppressants, such as malignancies, renal insufficiency or diabetes (Brännström et al. 2018).

3. Legal framework and ethical assessment

Having outlined the various phases of the procedure and the associated risks, we now turn to an ethical assessment of the procedure as a whole. To cover the six phases described above, we use the term “procedure” or “uterus transplantation procedure”, rather than “uterus transplantation” – a term which strictly speaking only applies to one of these phases.

In general terms, the question arises of how this procedure is best to be considered from an ethical and legal viewpoint. In particular, it needs to be established whether the procedure would have to be conducted within the framework of a research project. If that is the case, it would require authorisation from the cantonal or regional ethics committee responsible (Human Research Act/HRA, Art. 45) and authorisation from the Federal Office of Public Health (Transplantation Act, Art. 36). With regard to the regulation of human research, the Federal Council has emphasised, with particular reference to the Declaration of Helsinki, that “treatments involving uncertainties as to the risk-benefit profile should, as far as possible, be carried out in the form of a research project – not only for the protection of the patients concerned, but also in the interests of medicine, since valid findings can thus be obtained on the effects of the treatment in question” (Conseil fédéral 2015, p. 8; cf. Swiss Academy of Medical Sciences 2015, p. 13).

In the Human Research Act (Art. 3 let. a), research is defined as the “method-driven search for generalisable knowledge”. This means that a research plan designed to answer a scientific question is required for the conduct of a uterus transplantation procedure. In order to have a basis for comparison, data on a number of patients must be prospectively collected and analysed. Moreover, since the procedure of deceased-donor uterus transplantation has so far only been successfully carried out once worldwide, it would be of considerable scientific and medical value to conduct a rigorous and systematic investigation serving either to explain the difficulties encountered in this type of procedure, or to establish what methods or new techniques could increase its success rate.

On this basis, the NCE considers the uterus transplantation procedure to be, at present, an experimental procedure (and not a standard treatment), which should be investigated within the framework of a research project. Naturally, the existence of a research project does not exclude therapeutic benefits for participants, but – like the corresponding risks – these need to be evaluated differently than in the case of procedures not undertaken in a research context. In the case of research, an appropriate risk-benefit ratio is a legal requirement.⁵ The benefits and risks which need to be taken into account are those which concern the participant(s) and the future child. The woman’s consent – even if it may be closely linked to her perception of a direct benefit – is not sufficient for the risk-benefit ratio to be considered favourable. Evaluation of the risk-benefit ratio is an ethical enterprise, which is often based on scant and preliminary knowledge; accordingly, the result of the assessment is often uncertain from an objective point of view. In addition, the law requires research projects to address a scientifically relevant topic and to meet the requirements concerning scientific quality and integrity.

5) Art. 12 para 2 HRA: “The likely risks and burdens for the participants must not be disproportionate to the expected benefits of the research project.”

From a broader ethical perspective, it also needs to be asked whether a research project is reasonable from a social viewpoint. In particular, in the case of complex and costly research projects, the question arises whether, in view of the benefits to be delivered by the project for society in general, the resources required represent an appropriate investment.

The NCE maintains that the debate must focus on the following aspects: the health of the child, the development of scientific knowledge and the protection of third parties.

3.1. Ethical issues at the individual level

The NCE began by identifying the potential benefits and risks or possible disadvantages of the procedure for the donor, the recipient and the future child.

As uterus transplantation is not a life-sustaining procedure and does not offer improved survival (FIGO 2009), the way in which the risks are accepted or weighed against the benefits is different for this procedure than for most other organ transplants – while bearing in mind that transplantation medicine pursues various goals and not merely patients' survival.

a) Firstly, the question arises of what potential benefits are offered by research projects involving uterus transplantation with the aim of establishing a pregnancy. The procedure can enable women with an absent or dysfunctional uterus to become pregnant with a child that is genetically their own. The desire for children is a fundamental aspect of personal development and reproductive autonomy, which – as elements of personal freedom and private life – are constitutionally protected. While it is true that the women concerned could also realise their desire for children in ways other than via this procedure – specifically, by means of adoption or surrogacy – these alternatives are not equivalent insofar as they do not give rise to a child carried by the mother herself. In addition, in the case of adoption, the child is not genetically related to the adoptive mother. Moreover, the option of surrogacy only exists theoretically, as it is prohibited in Switzerland. Thus – apart from the desired gains in scientific and medical knowledge – the potential benefits offered by research projects involving uterus transplantation lie in the development of a method whereby certain women can realise their desire to have a child that is genetically and biologically their own.

b) The recipient participating in a uterus transplantation procedure is exposed to health risks which are not negligible. These risks are, in brief, (potentially serious) complications of surgery or anaesthesia, thrombosis/embolism, graft rejection and adverse effects of immunosuppressant drugs, which may occur during the procedure but can also persist for a long time thereafter. The likelihood that the recipient's health risks will materialise also depends to a certain extent on her general state of health. In the current state of knowledge, these risks are difficult to minimise.

c) The procedure can potentially have a serious adverse impact on the recipient's psychological well-being, creating anxiety, fear and long-term stress. In itself, IVF treatment involves non-negligible stress, to which are added the stress of significant surgical risks, adverse effects of immunosuppressant medication, the Damoclean sword of graft rejection during the long period of waiting and pregnancy, uncertainty as to whether or not pregnancy will be achieved, etc.

d) In order to participate in a uterus transplantation procedure, the woman must provide voluntary informed consent (for certain phases, the couple's consent is required). Informed consent presupposes that one has received full, clear and reliable information. The fact that the woman has to make a decision on the basis of scant information is not exclusive to this procedure – it is also encountered in other experimental research. In the case of the uterus transplantation procedure, however, this circumstance weighs heavily, since not only the woman but also the future child is exposed to risks. Investigators and cantonal or regional ethics committees must ensure that the woman does not have an incorrect view of the chances of success or mistakenly believe the procedure to be better established than it is in fact – the problem known as “therapeutic misconception” (Petrini et al. 2017; Woessner, Blake & Arora 2015). Consent must thus meet the specific requirements for a subject participating in a research project (Caplan et al. 2007).

The patient and her partner must be aware that consent will be required several times, for the various phases of the procedure. At each stage, one or both of them may change their mind. It is therefore important to include the partner in the decision-making process. The risk of the partner refusing to consent to embryo implantation is of course minimal, but it does exist. In this case, the woman will have undergone burdensome procedures in vain. The same risk exists if the partner dies prior to implantation, or if he loses capacity.

e) The complexity of the surgical procedure (removal of the uterus), requiring an operation of around 10–13 hours, entails considerable risks for a living donor (cf. Section 4.3).⁶

f) The risks for the future child are considerable. There is a markedly increased risk of prematurity, low birth weight and malformations (Kanzaki et al. 2016; Nagy et al. 2003). Prematurity and low birth weight are known risks for the development of somatic and mental disorders in later life (Story & Chappell 2017; Anderson & Cacola 2017). In the case of prematurity, there may be complications due to immaturity of organs (eyes, intestines, lungs, brain, etc.) that cause long-term disabilities (Sanchez-Joya et al. 2017; Luyckx 2017; Lee 2017). The more premature the birth, the lower the infant's chances of having a healthy life. The additional problem of low birth weight can have long-term consequences, such as metabolic disorders (diabetes, hypercholesterolaemia, obesity, metabolic syndrome, etc.) and cardiovascular disease (e.g. high blood pressure, heart attack) (Barker 1995; Phillips 1998; Hummer, Lehner & Pruckner 2014; Thanh et al. 2015). Also reported in the literature are long-term effects in infants exposed to immunosuppressants (Padgett & Seelig 2002; Scott, Branch & Holman 2002).

It is known that 9 of the 11 children born to date after uterus transplantation were born prematurely and with a low birth weight. Today they are between 0 and 3 years old. The development of the 8 children who are the fruits of the Swedish group's scientific efforts will be subject to long-term follow-up thanks to a registry. The published studies (Brännström et al. 2018; Testa et al. 2018) indicate that these 8 children and the first of the 2 born in the US are in (relatively) good health (reference is made to “healthy babies”). It remains to be seen how their state of health will develop in the long term. Today, it is not yet possible to assess whether or not the physical and psychological development of these children is

6) In 2017, a Chinese team using robot-assisted surgery managed to reduce the length of the procedure to 6 hours (Kisu et al. 2018).

“normal”. Even in the best case (with careful observation via registries), reliable information on their long-term health status will not be available for some years to come.

3.2. Ethical issues at the social level

a) It is difficult to estimate the number of women with an absent or dysfunctional uterus who wish to undergo a uterus transplantation procedure and meet the inclusion criteria. For this reason, it is unclear whether the number of cases in Switzerland would be sufficiently large to ensure adequate surgical expertise.

b) For society, there is a risk of financial resources being used in a questionable manner. The costs of uterus transplantation alone, without those of IVF treatment, could exceed CHF 100000 per case. This does not include the costs of potential medical complications for the mother and the future child. Considering the lack of adequate medical research in various areas such as rare diseases or childhood diseases, it may well be asked whether research in the field of uterus transplantation represents an appropriate use of the taxpayer’s money.

The high costs associated with the uterus transplantation procedure would presumably not be covered by mandatory health insurance. The procedure would thus in all probability be reserved for the well-off. From the viewpoint of distributional justice, it would appear to be problematic if methods that are developed with taxpayer funding subsequently benefit only a small number of affluent people.

c) Lastly, it should be emphasised that an expansion of the options available to women affected by infertility does not necessarily entail a concomitant expansion of their decision-making freedom or autonomy. Indeed, given the growing treatment options, these women could feel (psychologically or socially) obliged to have recourse to them.

4. Overall evaluation

In Switzerland, the uterus transplantation procedure is subject not only to the Transplantation Act but also – insofar as it involves research – to the Human Research Act, as well as to the Reproductive Medicine Act.

4.1. Health of the child

Consideration must be given to the risks identified which the procedure poses for any child in a general manner. Here, in the view of the NCE, the risks for the future child are significant: There is a significantly increased risk of the child being born prematurely or with low birth weight or malformations. Information on medium- and long-term health effects is lacking. Great caution should therefore be exercised. However, since the 8 children born in Sweden and the first child born in the US appear to be in (relatively) good health, it is conceivable that, despite the still-experimental nature of the procedure and the risks which must be taken into account, further research could be conducted in order to expand and consolidate existing knowledge.

4.2. Development of scientific knowledge

The development of new medical procedures almost always takes place within a context of uncertainty. When the various techniques of (organ, tissue or cell) transplantation were developed, the failure rates were, initially, high, as were the risks for the research participants (death, adverse effects). The same is true of the early development of assisted reproduction techniques (ART): they were not always successful, and the risks for the participants were considerable. Likewise, the long term health of children born with the aid of the first ART was not known for many years. In all these cases, science and researchers made a “bet” that the techniques would work and were worth attempting. This is often how medical science progresses. Numerous medical advances, doubtless including ART, have been made thanks to the resolute optimism of researchers, sometimes with unsatisfactory results for the patients in whom new methods were tested.

At any rate, before a new procedure comes to be accepted as standard in medicine, a certain amount of trial and error is required. In the early stages, little is known about the risk-benefit ratio. It is even possible that the potential benefits and risks of the procedure are assessed as equal.

Since the development of new medical procedures necessarily involves uncertainties and risks, precautionary measures must be observed to protect those involved. Thus, sound preclinical findings must be available before tests can be conducted in human subjects (this entails mastery of the techniques via animal experimentation, for example, the establishment of rigorous protocols, the existence of appropriate infrastructure, etc.). The first experiments in humans must involve a very small number of participants so as to gain an initial idea of the risk-benefit ratio without jeopardising the health of too many people.

4.3. Protection of third parties

The advantages put forward for the use of a deceased donor are the lack of surgical or psychological risks for the donor, as well as the much shorter operation time – 90 minutes as opposed to 10–13 hours (or 6 hours; Kisu et al. 2018) in the case of a living donor (Lavoué et al. 2017; Petrini et al. 2017; Brännström et al. 2018); however, this procedure involves a higher risk of rejection (Lavoué et al. 2017). The

scientific findings on deceased-donor uterus transplantation published in reputable journals are still, at this stage in the development of the technique, very rudimentary. The feasibility of this approach is demonstrated by the case of a child born after deceased-donor uterus transplantation in Brazil in 2017; however, no scientific publications are available as yet on this case. For these reasons, the NCE believes that the cases where the procedure has been undertaken with living and deceased donors should be more closely investigated, and that, in the case of deceased donors, even greater caution should be exercised, so as to protect the patients who might participate in such research and the children who could be born with their health potentially at risk.

So far, almost all uterus transplantation procedures resulting in a birth have involved living donors ($n = 10/11$). The latter have to accept not only the definitive loss of the organ but also significant physical and psychological burdens and considerable surgical risks (e.g. internal injuries) due to the long and complex surgery. In addition, there are risks of emotional duress: “[R]elated donors would potentially face emotional pressures akin to those experienced by related kidney donors” (Catsanos, Rogers & Lotz 2013) and risks related to a disturbance of self-image: “A uterus cannot be regenerated, and although the clinical significance of living without a uterus is minor, there are emotional and practical consequences to uterus donation; loss of gender identity and effects on sexuality are among the consequences described” (Lefkowitz, Edwards & Balayla 2012, 2013).

4.4. Equitable use of resources

Given its still-experimental nature, this procedure is not currently reimbursed by health insurers. The following problems thus arise: equitable access to the uterus transplantation procedure (since only those able to pay for it out of their own pocket could benefit from it), the limited utility of the procedure (the number of potential candidates has yet to be determined), and the reasonable use of resources in the area of public health (the uterus transplantation procedure does not appear to be a priority).

4.5. Other arguments

Three arguments are sometimes invoked to justify potentially risky research. Here, we explain why these are rejected by the NCE.

Firstly, it is sometimes argued that, if the research is not done in Switzerland, it will be done elsewhere – in particular, in jurisdictions with different or less stringent regulations. The NCE has already had occasion (Opinion no. 22/2013, Section 1.6) to observe that this argument in itself cannot lead to the lowering of standards designed to protect participants (women and children).

A second argument, somewhat similar, is formulated as follows: it is unjust for a country to refuse to take part in research in the experimental phase and subsequently benefit from it when it has been adopted as a standard procedure. It is unjustifiable to want other countries and other people abroad to take the risks, while the benefits are then reaped by everyone, or at least by those living in wealthy countries such as Switzerland. Once again, the NCE takes the view that the primacy of research participants’ individual interests requires greatest importance be accorded to their protection.

A third argument, still following the same line of reasoning, revolves around the risk that patients who are denied access to the procedure in Switzerland will turn to centres abroad where it is available. Once again it is argued that it would be better to offer women in Switzerland a procedure accompanied by appropriate safeguards, rather than “forcing” them to go abroad. It is indeed often better to oversee in Switzerland a procedure which an individual is determined to undergo, rather than simply prohibiting it in the knowledge that the individual will have recourse to it abroad – at his or her own risk. However, this applies primarily in the event that the risks are borne primarily by the patients or those involved in the research project. The argument loses much of its force when the risks affect not only the patient, but also third parties – in this case, the child whose birth is sought. If the risks to which the latter is exposed are deemed to be too high, in particular, if one believes that the child’s health will be seriously compromised at birth and in the long term, then it is justified to strictly regulate a procedure in Switzerland, even if these regulations remain ineffective abroad.

5. Conclusions

The NCE does not rule out the possibility that, in the future, the uterus transplantation procedure may become a medical procedure whose risks are well defined and acceptable, while also offering a considerable success rate. In that case, for a certain number of women in Switzerland who are affected by absolute uterine factor infertility, it will represent a medical option for childbearing. Researchers' enthusiasm will have advanced science for the benefit of the individuals concerned.

At present, however, the procedure is at an experimental stage. Its physical and psychological consequences for those concerned should not be underestimated. In particular, we are not yet able to assess the medium- and long-term risks for the health of the child. If the procedure is to become part of the practice of medically assisted reproduction and future patients are to benefit from it, research will be required. For each research project, the overall risk-benefit ratio – in the light of the scientific knowledge available when the decision is taken – is required to be favourable, more particularly with regard to the physical and mental health of the donor and recipient, as well as the health of children born as a result of the procedure. This assessment is not fixed for all time – it must evolve as new knowledge becomes available.

The development of uterus transplantation as a (future) treatment option must be pursued with great caution, within the framework of research projects which include follow-up, with appropriate preparation and only at centres offering a multidisciplinary team with links to other centres at the international level.

Ultimately, it is a matter for the competent cantonal or regional ethics committee and the Federal Office of Public Health (FOPH) to assess whether a specific research project on the uterus transplantation procedure meets the ethical, legal and scientific requirements of the Human Research Act.

However, reservations exist with regard to research on uterus transplantation from the perspective of social ethics:

Firstly, the potential benefits of research on uterus transplantation are relatively low compared with other fields of medical research, e.g. concerning life-threatening rare diseases or dementia. Thus, if research on the procedure is (partly) financed by public funding, the question arises whether this is an appropriate use of limited healthcare resources.

Secondly – should the procedure prove to be medically safe and effective – it will presumably only be available to couples who can afford it.

This document was unanimously approved by the National Advisory Commission on Biomedical Ethics on 23 March 2018.

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