Introduction
International Legal and Ethical Perspectives on Uterus Transplantation

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The first birth following uterus transplantation (UTx) hit the headlines in 2014. Born in October 2014 as part of a clinical trial at Sahlgrenska University Hospital in Sweden, the baby, known as Vincent (from the Latin, 'to conquer'), was conceived after his mother received a uterus donated by a family friend in 2013. While the first to be born, Vincent was not the last, and a further nine births have now occurred as part of the Swedish trial followed by dozens more from trials across the globe. Ten years on, and as the procedure is finessed and exported around the globe, it is time to reflect on the development of UTx and its future as a treatment for infertility caused by an absent or non-functional uterus. We therefore present here a collection of different legal and ethical perspectives on the challenges posed by UTx contributed to by experts from across the globe.

This edited collection is for anyone with an interest in the legal and ethical issues that uterine transplantation raises. Due to the unique nature of UTx, many different legal and ethical questions arise. We appreciate that not everyone will be familiar with UTx so here we provide readers with an introduction to UTx including a brief history of its development, and a summary of the process of UTx (from initial enquiry through to removal). We then move on to summarise the sections of the edited collection and the subjects of the individual chapters in more depth as well as some of the overarching questions they raise.

1. UTx: A Brief Introduction and History

UTx is a novel and innovative procedure that combines the two medical specialities of organ transplantation and assisted reproduction. Unlike most common organ transplants (such as kidney, liver, lung, and heart), UTx is not a lifesaving procedure. Instead, it is a transplant which is undertaken with the aim of increasing the quality of the lives of those who seek it. In this sense, it is akin to other novel forms of organ transplant (like hand, face, and penis). However, in contrast to these other novel transplants, the uterus is transplanted for the sole purpose of reproduction. Consequently, it is the only transplant currently performed that is intended to be temporary: to be removed after a recipient has completed their family. The reproductive function and ephemeral nature of this novel transplant departs significantly from the traditional aims and limits of transplantation and as a result pushes the boundaries of this area of medicine leading to numerous thorny legal and ethical questions regarding how to appropriately balance important values in medicine such as respect for patient autonomy against principles of beneficence and non-maleficence, and specifically weigh the physical and psychological harms and risks of UTx for donors, recipients and offspring against the anticipated quality of life benefits arising from this elective transplant. Questions of appropriate consent, allocation, and funding of UTx, amongst others, also arise.

While the first successful attempt at UTx took place in the 2010's, UTx was actually first attempted in 1931, 80 years prior.[1] Sadly, but perhaps inevitably, given that effective immunosuppression medications were not developed until much later,[2] the recipient (the Danish artist Lili Elbe) died as a result of complications arising from rejection shortly after the transplant.[3] Indeed, scientific research into the prospect of UTx only really began in the 1960's with studies by Eraslan et al exploring the prospect of the transplantation of the uterus and oviducts in canine models with the procedure originally proposed as a treatment for tubal factor infertility.[4] However, after the first birth from IVF in 1978, research exploring the prospect of uterus and

[1] Amani Sampson and others, 'Reimagining Uterus Transplantation' (*Journal of Medical Ethics Blog*, 5 March 2019)<https://blogs.bmj.com/medical-ethics/2019/03/05/reimagining-uterus-transplantation/> accessed 1 January 2024
[2] Jean Colaneri, 'An overview of transplant immunosuppression--history, principles, and current practices in kidney transplantation' (2014) 41(6) Nephrology Nursing Journal 549
[3] Amani Sampson and others (n1)
[4] Sadan Eraslan, Robert J Hamernik, and James D Hardy, 'Replantation of the uterus and ovaries in dogs with successful pregnancy' (1966) 92(1) Archives of Surgery 9

ovary transplantation as a treatment for tubal factor infertility was largely abandoned.[5] In the late 1990's interest in uterus transplantation was renewed as clinicians noted its potential to assist women with absolute uterine factor infertility (AUFI) in their goals to gestate and give birth to their own children.[6] AUFI is a form of infertility which affects approximately one in every 500 women worldwide of childbearing age and is an umbrella term covering infertility problems in individuals who either lack a uterus as a result of congenital abnormality (such as Mayer Rokitansky Küster Hauser Syndrome) or a previous hysterectomy, or who, due to physiological or anatomical abnormalities, are unable to conceive or sustain gestation.[7] Research activities in animal models were then recommenced in Sweden by a team led by Dr Mats Brännström, and in the UK by a team led by Mr Richard Smith and Dr Giuseppe Del Priore.[8]

The first modern attempt at UTx was performed in Saudi Arabia on 6th April 2000 on a 26-year-old woman who had previously lost her uterus due to post-partum haemorrhage.[9] The uterus was subsequently removed 99 days later due to acute vascular thrombosis.[10] This attempt has been widely criticised as having not been "preceded by proper research studies and team preparations".[11] It wasn't until 2011 that another attempt at UTx took place, this time in Turkey.[12] This one-off procedure finally resulted in a live birth nine years after the transplant.[13] No further uterus transplants in humans took place until the commencement of the first clinical trial, in Gothenburg, Sweden.[14] Since this first clinical trial, UTx trials have spread across the globe, demonstrating the increasing interest in, expertise regarding, and accessibility of UTx.

As of October 2023 UTx trials which have reported at least one birth are as follows (dates in brackets show the year of the first transplant): Turkey (2011)[15]; Sweden (2013)[16]; China (2015)[17]; Dallas, Texas USA (2016)[18]; Brazil (2016)[19]; Cleveland, USA (2016)[20]; Czech Republic (2016)[21]; Germany (2017)[22]; Pennsylvania (2017)[23]; India (2017)[24]; Serbia (2017)[25]; Lebanon (2018)[26]; Alabama, USA (2023)[27] and Australia (2023).[28] Research groups based in the following countries have all performed at least one uterus

[5] Luis Arturo ruvalcaba Castellon and others, 'The history behind successful uterine transplantation in humans' (2017) 21(2) JBRA Assisted Reproduction 126, 127
[6] Mats Brännström, 'The Swedish uterus transplantation project: the story behind the Swedish uterus transplantation project' (2015) 94(7) Acta Obsetrica Gynaecologica Scandinavica 675, 676
[7] Liza Johannesson and others, 'The future of human uterus transplantation' (2014) 10(4) Women's Health 455.
[8] International Society of Uterus Transplantation, 'History, vision and mission of ISUTx' (*The Transplantation Society*, 2019) <https://tts.org/isutx-about/isutx-about-history-vision-mission> accessed 1 January 2024
[9] Wafa Fageeh and others, 'Case report: Transplantation of the human uterus' (2002) 76 International Journal of Gynecology and Obstetrics 245
[10] Wafa Fageeh and others, (n9) 245
[11] Mats Brännström, 'Introduction: Uterus transplantation' in Mats Brännström (ed), *Uterus Transplantation* (Springer, 2020) 1, 3.
[12] Omer Ozkan and others, 'Birth of a healthy baby 9 years after a surgically successful deceased donor uterus transplant' (2022) 275(5) Annals of Surgery 825
[13] Omer Ozkan and others, (n12) 825
[14] Mats Brännström and others, 'Livebirth after uterus transplantation' (2015) 385(9968) The Lancet 607
[15] Omer Ozkan and others, (n12) 825
[16] Mats Brännström and others, (n14) 607
[17] Yanhong Huang and others, 'Report of the first live birth after uterus transplantation in People's Republic of China' (2020) 114(5) Fertility and Sterility 1108
[18] Giuliano Testa and others, 'The evolution of transplantation from saving lives to fertility treatment: DUETS (Dallas UtErus Transplant Study)' (2020) 272(3) Annals of Surgery 411
[19] Dani Ejzenberg and others, 'Livebirth after uterus transplantation from a deceased donor in a recipient with uterine infertility' (2018) 392 (10165) The Lancet 2697
[20] Rebecca Flyckt and others, 'Deceased donor uterine transplantation' (2017) 107(3) Fertility and Sterility e13
[21] Jiri Fronek and others, 'Human Uterus Transplantation from Living and Deceased Donors: The Interim Results of the First 10 Cases of the Czech Trial' (2021) 10(4) J Clin Med 586
[22] S. Y. Brucker and others, 'Selecting living donors for uterus transplantation: lessons learned from two transplantations resulting in menstrual functionality and another attempt, aborted after organ retrieval' (2018) 297(3) Arch Gynecol Obstet 675
[23] Liza Johannesson and others, 'The first five years of uterus transplant in the US: A report from the United States Uterus Transplant Consortium' (2022) 157(9) JAMA Surgery 790
[24] Shailesh Puntambekar and others, 'Novel Anastomotic Technique for Uterine Transplant Using Utero-ovarian Veins for Venous Drainage and Internal Iliac Arteries for Perfusion in Two Laparoscopically Harvested Uteri' (2019) 26(4) Journal of Minimally Invasive Gynaecology 628
[25] Mary Kekatos, 'Woman, 38, gives birth to baby boy after receiving a uterus transplant from her twin sister' (*Mail Online*, 28 June 2018) <https://www.dailymail.co.uk/health/article-5897867/Woman-38-gives-birth-baby-boy-receiving-uterus-transplant-twin-sister.html> accessed 1 January 2024
[26] Randa Akouri and others, 'First live birth after uterus transplantation in the Middle East' (2020) 25 Middle East Fertility Society Journal 1
[27] Savannah Koplon, 'UAB's first uterus transplant recipient delivers healthy baby' (*The University of Alabama at Birmingham*, 24 July 2023) < https://www.uab.edu/news/health/item/13684-uab-s-first-uterus-transplant-recipient-delivers-healthy-baby> accessed 1 January 2024
[28] Maddy Massy-Westrop, 'Kirsty has given birth to a baby boy. A year ago she didn't have a uterus' (UNSW, 18 December 2023) <https://www.unsw.edu.au/news/2023/12/kirsty-has-given-birth-to-a-baby-boy--a-year-ago--she-didnt-have> accessed 1 January 2024

transplant, but no births have been reported: Saudi Arabia (2000)[29]; Italy (2020)[30]; and the United Kingdom (2023).[31] Teams based in Belgium[32] and Spain[33] are currently recruiting for participants in clinical trials, while groups based in France,[34] Japan,[35] and The Netherlands[36] have expressed an interest in performing uterus transplants in the future. Indeed, while the majority of transplant centres are still offering UTx *only* as part of research trials, groups based at Baylor University (Dallas, Texas) and The University of Alabama (Birmingham, Alabama) have now started to offer the procedure in the clinic.[37]

Since the first birth from UTx in 2014 more than 100 uterus transplants have now taken place worldwide with over 50 babies born. The field of UTx research has also made rapid advances, and innovation in the surgical techniques and protocols used is increasing. Proof of concept for transplants using both living (2014)[38] and deceased donor models (2017)[39] has been achieved, living donor retrieval surgeries *and* recipient transplant surgeries have both been performed using robotic assisted surgical techniques,[40] and work exploring the prospect of the development and use of bioengineered uteri is currently ongoing which could provide a solution to both concerns regarding the scarcity of uteri for transplant and significantly reduce the risks of UTx associated with immunosuppressive medications.[41] Indeed, while UTx is only currently available to cisgender women with AUFI, discussions are also ongoing regarding the clinical feasibility of performing UTx in transgender women.[42]

The International Society of Uterus Transplantation (ISUTx) was established in January 2016[43] with goals to: facilitate networking between scientists engaged in UTx research; advocate for patient rights; educate the public and medical professionals; share current knowledge and new discoveries; promote multidisciplinary and collaborative research regarding UTx; develop consensus and guidelines on UTx; and establish and maintain an international registry of UTx cases with follow-up of patients, children and donors.[44] In 2021 the ISUTx became the tenth official section of the Transplantation Society.[45] In 2020 the ISUTx established a web-based Registry, with the aim of 'worldwide completeness of UTx procedures with a mandatory submission of data from all active UTx centers'.[46] While not all UTx teams are currently contributing data to the Registry and the data inputted is limited to up three months post-transplant, the role of a Registry in this novel field of transplantation and reproductive medicine should not be underestimated. As we have stated in previous work:

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[29] Wafa Fageeh and others, (n9) 245
[30] Federica Umani Ronchi and Gabriele Napoletano, 'Uterus transplantation and the redefinition of core bioethics precepts' (2021) 92(5) Acta Biomedica e2021435
[31] Benjamin P Jones and others, 'Living donor uterus transplant in the UK: A case report' 2023 (online first) BJOG <https://obgyn.onlinelibrary.wiley.com/doi/full/10.1111/1471-0528.17639> accessed 1 January 2024
[32] *Uterus Transplantation From a Multi-organ Donor,* Identifier NCT03252795 (National Library of Medicine, 2013) <https://clinicaltrials.gov/ct2/show/NCT03252795> accessed 1 January 2024
[33] *Uterus Transplantation Procedure from a Live Donor*, Identifier NCT04314869 (National Library of Medicine, 2020) <https://clinicaltrials.gov/study/NCT04314869> accessed 1 January 2024
[34] *Feasibility Study of Uterine Transplantation From Living Donors in Terms of Efficacy and Safety in Patients With Mayer-Rokitansky-Küster-Hauser Syndrome (MRKH)*, Identifier NCT03689842 (National Library of Medicine, 2017) <https://clinicaltrials.gov/study/NCT03689842> accessed 1 January 2024
[35] Iori Kisu and others, 'Keio Uterus Transplantation Research: From Basic Research toward Future Clinical Application' (2022) 71(2) Keio Journal of Medicine 33, 39
[36] HE Peters and Others, 'Feasibility study for performing uterus transplantation in the Netherlands' (2020) 2 Human Reproduction Open <https://academic.oup.com/hropen/article/2020/2/hoz032/5686151> accessed 1 January 2024
[37] See: Adam Pope, 'UAB establishes uterus transplant program' (*The University of Alabama at Birmingham*, 19 October 2020) <https://www.uab.edu/news/health/item/11630-uab-establishes-uterus-transplant-program> accessed 1 January 2024; Baylor Scott and White, 'Uterus transplant' (*Baylor Scott and White*, 2023) < https://www.bswhealth.com/treatments-and-procedures/uterus-transplant> accessed 1 January 2024
[38] Mats Brännström and others, (n14) 607
[39] Dani Ejzenberg and others (n19) 2697
[40] Mats Brännström and others, 'Uterus transplantation: from research, through human trials and into the future' (2023) 29(5) Human Reproduction Update 521
[41] Arvind Manikantan Padma, Mats Brännström, and Mats Hellström, 'Uterus bioengineering as a future alternative to uterus transplantation' (2022) 49(3) Clinical and Experimental Obstetrics and Gynecology 1
[42] Benjamin P. Jones and others 'Uterine transplantation in Transgender Women' (2019) 126(2) BJOG: An International Journal of Obstetrics and Gynaecology 152
[43] International Society of Uterus Transplantation, (n8)
[44] International Society of Uterus Transplantation, (n8)
[45] Mats Brännström and others, 'Registry of the international society of uterus transplantation: First report' (2023) 107(1) *Transplantation* 10
[46] Mats Brännström and others, (n45) 11

> As the number of cases performed increases so too does the volume of potential data that may be gathered in both the short and long term to inform the development, practice, and regulation of UTx…. There is: (i) a need to establish the goals and purposes of the IRUTx from the outset in order to determine the required datasets that will ensure its longevity; (ii) a need for clear governance and oversight, transparency and openness; (iii) a need for clear procedures to obtain initial and ongoing consent of participants, with the development of an interactive consent model; and (iv) a need for compliance by all parties with GDPR.[47]

2. UTx: A complicated and lengthy process…

While UTx itself is an isolated procedure, it occurs as part of a long and arduous process (for all involved parties whether they are researcher funders, clinicians, recipients, or donors) that begins with initial enquiries from prospective recipients and ends with the removal of the transplanted uterus via hysterectomy ideally after the birth of one or two healthy children but sometimes, and regretfully, much sooner due to medical complications or transplantation failure. To grasp the ethical questions that UTx raises, and the legal and regulatory questions and challenges it poses, familiarity with this process is required. While parts of the order of the process (and aspects of individual steps) will differ from team to team and depending upon whether UTx takes place as part of a research trial or in the clinic, we summarise the process below:

1. **Enquiry**: Potential recipients (and their partners where applicable) contact medical teams to enquire about UTx.

2. **Determinations of Suitability and Counselling**: Medical teams select amongst potential recipients using pre-determined selection criteria. These criteria differ from team to team but generally include *both* medical and social criteria which are informed by national regulations (where such regulations exist), and professional guidelines regarding the provision of fertility treatments. Potential recipients who meet selection criteria will undergo both physical and psychological assessments to determine suitability and will be provided with counselling and psychological support to help them make an informed decision regarding whether to proceed with UTx or to pursue alternative means to family formation such as adoption and surrogacy (where legally permitted).

3. **In Vitro Fertilisation (IVF):** IVF is required to enable conception in UTx recipients as current UTx procedures do not attach the recipient's fallopian tubes to the transplanted uterus. If accepted for treatment, potential recipients and their partners will undergo in vitro fertilisation (IVF) before UTx if they do not already have enough high-quality embryos in storage. The numbers of embryos required differ dependent on the research team; the process involves egg retrieval, sperm retrieval, fertilisation, and storage. In the UK, for example, a minimum of 10 embryos are required.[48] Dependent on the research trial requirements and the regulatory environment, recipients may or may not be permitted to use donated gametes if their infertility is multifactorial.

4. **Waiting for transplant:** The uterus for transplant will be procured from a living or a deceased donor. Most transplants to date have been performed with living donors, and most commonly have been directed and related donations between friends or family members (primarily mothers and sisters) but non-directed living and deceased donor transplants have also been performed. For living donation, both related and unrelated donors must undergo psychological

[47] Natasha Hammond-Browning and Nicola Jane Williams, Developing an International Registry for Uterus Transplantation (IRUTx): Promises and Challenges (2020) 35(12) Human Reproduction 2643

[48] Natasha Hammond-Browning, 'UK criteria for uterus transplantation: a review' (2019) 126(11) BJOG: An International Journal of Obstetrics and Gynaecology 1320, 1321

and physical testing to ensure suitability to act as a donor and counselling to ensure informed consent to donation. Recipient wait time for directed living donations will depend on the outcome of physical and psychological screening of potential donors, and the availability of the medical team. Waiting time for non-directed living and deceased donations will likely be longer due to the need to both find a suitable donor and obtain consent for the donation of this uncommon tissue.

5. **Uterus Retrieval:** After valid consent to donation is obtained and suitability is determined, the uterus for transplant is removed in a procedure similar to a total abdominal hysterectomy (but slightly more invasive than and of significantly longer duration than a 'standard' hysterectomy[49]) which can be performed using open or laparoscopic (including robot assisted) techniques.[50] Surgical duration is currently significant with data from the most recent report of the ISUTx registry showing that in the majority of registered cases living donor retrieval surgery took over 8 hours.[51] In the deceased donor context, the removal of the uterus occurs *after* removal of vital organs for transplant and the average duration is estimated to be around 2 hours.[52]

6. **Transplantation:** The donor uterus is transplanted into the recipient in a surgery with a normal duration of between 2-6 hours.[53]

7. **Surgical Recovery Period and Starting Immunosuppressive Medication:** Both the living donor and recipient must recover from the surgery to remove/transplant the uterus. Complications arising from donation so far observed in living donors include haemorrhage, ureteric injury, vaginal cuff dehiscence, buttock pain, and mental health related quality of life issues.[54] Common complications in recipients include arterial and venous thrombosis requiring immediate hysterectomy, infections, vaginal stricture, and organ rejection.[55] Recipients will need to start taking immunosuppressive medications immediately following transplant to avoid organ rejection and must continue with medications until transplant removal.

8. **Embryo Transfer:** 3-12 months post-transplant, and once menstruation has started, the recipient may begin to undergo embryo transfer procedures. According to data from the Registry of the International Society for Uterus Transplantation, in those who have achieved a live birth following UTx the total live birth rate per embryo transfer is 35.8%, and circa 27% of transplants had at the time of publication been removed from UTx patients prior to pregnancy and childbirth due to complications from either surgery or failed embryo transfers.[56]

9. **Pregnancy:** Should the transplant prove successful & embryo transfers result in pregnancy, uterus recipients should expect a highly monitored pregnancy,[57] and high rates of pregnancy complications (shown to be 47% in the ISUTx 2023 report).[58]

10. **Birth by Caesarean Section:** At this point in time, all births following UTx must take place via caesarean section due to the method of transplantation which does not allow for vaginal delivery.

11. **Surgical Recovery Period:** After birth, recipients who choose to retain the uterus for subsequent pregnancies (if this is medically supported) must recover prior to embarking on any further attempts at pregnancy. As with other caesarean sections, major risks include infection,

[49] Mats Brännström and others, (n45) 10
[50] Elliot G. Richards and others 'Uterus transplantation: state of the art in 2021' (2021) 38 Journal of Assisted Reproduction and Genetics 2251, 2253
[51] Mats Brännström and others, (n45) 15
[52] Sakineh Taherkhani, 'Differences between living and deceased donation in human uterus transplantation: A narrative review' (2023) 21 International Journal of Reproductive BioMedicine 193, 199.
[53] Mats Brännström and others, (n45) 12
[54] Elliot G. Richards and others (n50) 2253
[55] Elliot G. Richards and others, (n50) 2254-2255
[56] Mats Brännström and others, (n45) 16
[57] Mats Brännström and others, (n45) 16
[58] Mats Brännström and others, (n45) 16

excessive bleeding requiring blood transfusion, deep vein thrombosis, and ureteric injury, as well as increased risks in any subsequent pregnancy of abnormal attachment of the placenta to the uterine wall.[59]

12. **Subsequent Embryo Transfers and Pregnancy:** see steps 8 and 9, and if embryo supply has been exhausted see step 3.

13. **Removal of Transplanted Uterus:** Once a recipient has completed childbearing the uterus should be removed in order to reduce the long-term negative health effects associated with immunosuppression.

3. Summary of Chapters

As can be garnered from consideration of both the history of the development of UTx and its process, UTx is a procedure that raises numerous complex ethical, legal, and regulatory questions. Despite its potential benefits for those who have AUFI and who seek to experience both gestation and childbirth, UTx is no stranger to controversy and criticism. For, given the novel, temporary, and reproductive purpose for which it is performed, and the high risks and costs associated with the procedure for donors, recipients *and* children produced, it also raises fascinating questions regarding the proper aims and limits of medicine; the justifications which underpin the practice of living organ donation; tensions between core principles of biomedical ethics such as beneficence, non-maleficence, and respect for patient autonomy; how to balance the interests of individuals against those of society more generally where these conflict; and the proper objects of funding in socialised and insurance based medical systems. The answers to such questions will ultimately determine the regulation and future availability of UTx, its acceptance by the public, and indeed, whether, once it reaches clinical application, who will have access to this treatment. As editors of the collection, some of the ethical and regulatory questions raised by UTx that we consider to be most pressing, and which are explored either directly or indirectly in this collection include the following:

- Are the psychological benefits for uterus recipients sufficient to justify the performance of risky surgeries and procedures? Does the procedure move too far beyond the acceptable aims of medicine?
- How should we weigh a desire to gestate one's own offspring against a desire to become a social and/or genetic parent? Is *and should* gestation be viewed as valuable? And if so, how valuable?
- Does UTx perpetuate damaging pro-natalist and sexist stereotypes regarding the ideal of parenthood and the social acceptability of infertility?
- To what extent is UTx merely another instance of (ART) assisted reproductive technology or organ transplantation? Do these similarities and differences impact upon the ethical assessment of UTx?
- Despite the success of the first clinical trial in Sweden, was the move from animal to human UTx trials too quick?
- Are the selection criteria used in UTx trials justifiable?
- Is UTx an appropriate object for public funding in countries with socialised medical systems? Is there anything special about UTx which suggests that it should not be funded?
- What legal and ethical issues are raised if uterus transplants are provided to transgender women? How may these be resolved?
- Does UTx invoke any special concerns regarding the welfare of the children created?
- Should children created after UTx have a right to know the identity of uterus donors? Do uterus donors have any obligations to children created due to their donation?
- Does the existence of alternatives, such as adoption and surrogacy, cast doubt on the appropriateness of UTx?

[59] National Health Service, 'Risks: Caesarean section' (NHS, 4 January 2023) <https://www.nhs.uk/conditions/caesarean-section/risks/> accessed 2 January 2024

- How should donors for UTx be selected? Should living donors be utilized for UTx? Should increased risk deceased donors be considered for UTx?
- Are current legal and regulatory frameworks which govern organ donation and assisted reproduction fit for purpose in this context?
- Are participants able to give informed consent free of undue pressure?
- Does regulation require new interpretations or reform to account for this new medical procedure?

Here we present a range of different ethical and legal perspectives on UTx that address many of the questions that arise in this innovative and novel field of organ transplantation and reproductive medicine. Before proceeding, however, it should be noted that our goal in compiling this edited collection has not been to produce an exhaustive account of the legal and ethical questions that UTx raises. Instead, we have sought to explore, from the perspectives of a number of experts who have previously published research in this field, the questions, and concerns that *they consider to the most pressing* with the goal of shaping the direction of future discourse and policy on this topic.

The book is divided into two parts: Part I - Ethical Perspectives on Uterus Transplantation and Part II - Legal and Regulatory Perspectives on Uterus Transplantation. In the first part of the book contributors explore various ethical and philosophical questions related to the social contexts in which both desires for UTx arise and the procedure is developed (chapters 1-3), the donation of uteri for transplant (chapter 4), future advances in reproductive technology such as ectogenesis (chapter 5), allocation and selection criteria (chapter 6), the concept of 'need' and UTx (chapter 7), the welfare of the child (chapter 8), public funding and state support for UTx (chapters 8-10), and ethical data management and sharing in UTx research (chapter 11). In the second part of the book contributors explore the international legal context surrounding UTx. As UTx straddles the medical specialities of organ transplantation and assisted reproduction, the legal chapters consider the regulation (or, as is often the case, lack thereof) of these specialities, how they are applied to UTx within particular legal jurisdictions, and where applicable, suggestions for reform. Countries that have conducted clinical trials resulting in live births are first presented, Sweden, the United States, Lebanon (chapters 12-14), followed by the United Kingdom as an example of a country that has performed UTx but not yet had a birth (chapter 15), and finally Japan provides an example of a country that is interested in performing UTx but has not yet done so (chapter 16).

3.1. Part I – Ethical Perspectives on UTx

In chapter one of the collection "Public Provision of Uterus Transplantation: What Should Feminists Do if They Win?" Giulia Cavaliere explores the social norms and pressures that shape demand for UTx in women with AUFI and examines the permissibility of public provision of UTx in this context. Her approach within the chapter builds upon feminist theorist's work on procreation and seeks to take the procreative preferences of women with AUFI seriously while simultaneously engaging with and mitigating some of the negative externalities that may be produced as a result of such provision. Her main claim is that the question of whether UTx ought to be publicly funded should be approached in a way that engages with the norms that shape the demand for UTx but which also, and importantly, does not seek to restrict women's reproductive choices. To defend this claim, she first sketches her normative commitments and the approach that she thinks should be taken to examine the permissibility of UTx provision. She then moves on to canvass what this approach entails and considers and responds to potential criticisms of her view. This chapter constitutes a thoughtful and rich exploration of many of the concerns that have previously been raised in the academic literature regarding UTx which discuss the extent to which UTx may legitimate several problematic norms and values regarding femininity, motherhood, and womanhood, and thereby cause harms to women either generally or collectively.

In the second chapter of the collection: "Uterus Transplantation and Adoption in Empirical and Normative Context: The Question of Alternative Parenthood Modalities," Mianna Lotz, following on from previous work exploring alternatives to UTx, explores the normative context in which individuals

consider and make decisions regarding reproduction and parenthood. While Cavaliere's chapter focussed on the value of reproductive choice and opportunity despite concerns regarding norm legitimation and effects on practices such as adoption, Lotz uses the results of some recent empirical research she has conducted with young Australians to explore the extent to which individuals do (and should) consider adoption to constitute a meaningful (and normatively preferable) alternative to UTx. The results of this study indicate that adoption is indeed valued as a parenthood option by young Australians and features particularly prominently as an endorsed alternative when considered against the potential option of UTx. Alongside that finding, however, the data presented by Lotz also adds to the growing body of evidence indicating widespread social acceptance of UTx, and underscores Cavaliere's view that despite ethical concerns about its provision, a commitment to reproductive liberty and anti-paternalism prevails as the justification for maintaining and extending access to UTx.

While Cavaliere and Lotz's chapters focus on preference development and satisfaction in the context of UTx, in the third chapter of this collection: "A Right to Gestate? Uterus transplants and the language of rights" Gulzaar Barn explores how a focus on reproductive autonomy and procreative liberty in debates surrounding UTx have been used to motivate claims regarding positive and negative rights to UTx. In this chapter Barn explores appeals to rights to gestate as grounding access to UTx and suggests that if a moral or legal right to UTx exists, it is a *pro tanto* negative right, that may be constrained by overriding considerations, such as harm to living donors. While Barn does not attempt to settle the question as to whether there ought to be a right to procreate, she does express doubts regarding the existence and viability of rights to gestate as they have been presented in the UTx literature so far, highlighting both the peculiarity of the objects of such rights, and the embodied nature of the resources that are required for their realisation.

Following on from Barn's discussion of uterus donation, chapter four of the collection focusses on various ethical questions raised by donation in the context of UTx. In "Deceased vs. Living Uterus Donation: A Cross-Sectional Survey Study of American Women's Perspectives" Bethany Bruno McClanahan and Kavita Arora present the results of a recent survey they conducted investigating public attitudes towards uterus donation among 50 women in the USA. Motivated by a lack of empirical data exploring donation willingness with respect to both living and deceased uterus donation, the data presented in their chapter provides useful context to enrich normative and policy discussions of each donor model. Relevant findings include that eighty percent of respondents were willing to donate their uterus after death, whereas only 40% were willing to serve as a living uterus donor. Some noted that uterus donation differs from other organs given its reproductive and quality-of-life implications, but others considered the procedure similar to donation of more traditional organs to save lives, and 82% supported including consent to uterus donation as part of general donor registration with allowance for surrogate consent by family members should a deceased individual's wishes remain unknown. While more research is certainly needed to investigate the perspectives of potential uterus donors, given the small sample size of the survey, this chapter provides valuable insights that can and should be used to inform current discussions surrounding donation and transplantation policy.

In chapter five of the collection: "Subjective Experience, Gestational Preferences and Justice: Valuing Both Uterus Transplantation and Ectogestation," Evie Kendal and Chloe Romanis explore UTx alongside another reproductive technology currently in development: ectogenesis, or artificial womb technology. Previous work published by Kendal and Koplin on ectogenesis and UTx has focused on whether UTx (particularly using living donors) could be justified if ectogenesis becomes a reality given the harms to donors necessitated by UTx and worries about exploitation.[60] In this chapter, however, Kendal and Romanis take a more holistic approach in their considerations of the practical and ethical dimensions of these alternative routes to parenthood. In exploring the differences between these technologies and how these might account for variations in individual preferences regarding the use of artificial womb technologies, UTx and other forms of assisted gestation like surrogacy, Kendal and Romanis provide valuable insights into how these technologies may be used to promote equitable access to ART, particularly among marginalised communities.

[60] Evie Kendal and Julian Koplin, 'The moral superiority of bioengineered wombs and ectogenesis for absolute uterine factor infertility' (2022) 31(1) Cambridge Quarterly of Healthcare Ethics 73

Chapter six of the collection: "Gatekeeping Uterus Transplants: A Proposal for eligibility criteria and the fair allocation of wombs" constitutes an exploration and critical analysis of criteria for determining eligibility for UTx as well as allocation criteria for ranking access to non-directed donor uteri. In this chapter Ryan Tonkens both explores existing selection and allocation criteria and proposes a system for selecting and allocating uteri for transplant. He forwards several provocative arguments, arguing that those who are already parents should be deemed ineligible for UTx, and that when UTx becomes available outside of research trials and awareness of UTx becomes common knowledge common allocation criteria such as recipient age, heightened tissue sensitivity, or length of time on the UTx waiting list should not be used to rank recipients. Finally, he proposes a "womb lottery" as the fairest manner to allocate non-directed UTx to eligible recipients.

Chapter seven: "Child Welfare and the Regulation of Access to Uterus Transplantation" continues Tonkens discussion of eligibility and allocation criteria for UTx with a narrower focus on the welfare of children who may be born as a result of UTx. In this chapter Laura O'Donovan critically examines the role of welfare considerations in the context of UTx as both a threshold requirement of access to IVF and as a potential criterion to inform transplant listing and allocation policy. Noting that as UTx is currently a hybrid treatment that requires both organ transplant and IVF, she explores and rejects proposals in favour of utilising pre-conception welfare principles to determine both patient listing for transplantation and organ allocation on the basis that it would lead to unjust discrimination against patients, be unduly burdensome for patients who will already be subject to child welfare assessments by IVF providers, and contrary to established ethical and policy guidance on organ transplantation.

In chapter eight of the collection: "Moral Claims for the Subsidy of Uterus Transplantation," Timothy Murphy continues discussions of questions regarding justice and access to UTx, with a particular focus on funding in both public and insurance-based healthcare systems. As UTx moves from bench to bedside and more data becomes available regarding the high financial costs of the procedure, questions regarding subsidy (whether whole or in part) of UTx become increasingly pressing, especially given the controversial status of decisions to fund medically assisted reproduction more generally. Thus, Murphy's identification of possible claimants for the subsidy of UTx (including ciswomen, transwomen, transmen, and cismen, taxonomy of the comparative strengths of various claims for subsidy of UTx, and discussion of the strengths and weaknesses of the various justifications for subsidy, constitutes a valuable addition to the literature which should prove useful for policy discussions regarding UTx funding.

Chapter nine of the collection: "The Limits of Expressivist Arguments Against State Support for Uterus Transplantation" continues the focus on questions of subsidy for UTx present in Murphy's discussions in chapter eight, but with a particular focus on discussions within the existing UTx literature on the potential social consequences of state provision of UTx (a topic also explored by Cavaliere in chapter one). Drawing on previous work they have published on the prospect of state funding for UTx, Stephen Wilkinson and Nicola Williams explore 'expressivist arguments' against state support for UTx. Such critiques focus on the 'message' that may (consciously or otherwise) be sent or received through state support for UTx and the broader harms to which this may contribute, in terms of the endorsement or entrenchment of problematic and harmful socio-cultural norms and values. While sensitive to the worries expressed by those who criticise UTx on such grounds Wilkinson and Williams also note the limits of expressivist arguments with respect state-support of UTx, considering the inevitable opacity of human communication and the nature of reasonable interpretation. They also put forward a positive case for state funding, arguing that it is possible for the state to support UTx for women with AUFI while simultaneously reducing the potential for state funding of UTx to cause expressive harm.

In chapter 10 of the collection, "On the Complexity of Needs and Uterus Transplantation" Lars Sandman also explores questions surrounding UTx and priority setting in needs-based healthcare systems. Sandman tackles the question of how to prioritise UTx in relation to other interventions in public healthcare systems and begins his chapter from the assumption that UTx constitutes the right *kind* of healthcare need to warrant funding in needs-based medical systems like Sweden and the UK. Noting,

however, that UTx involves several different individuals/potential individuals (the individual with AUFI, their partner where applicable, and the child who may be created through UTx) with different individual needs, he explores both whose needs should be considered when it comes to priority setting decisions in UTx, and how these various needs should factor into the prioritization of UTx and interventions required as a result of UTx.

Finally, in chapter 11 of the collection "Ethical Data Management and Sharing in Uterus Transplantation: Reflections and Recommendations" we explore questions surrounding research and publication ethics with a focus on the benefits (and challenges) of data sharing in the context of UTx research. Given the pace of UTx research and increasing volume of data that may be used to inform the development and regulation of UTx, Hammond-Browning and Williams provide arguments suggesting an obligation for those involved in UTx research to share data absent competing considerations and explore several concerns that may be expressed regarding such a commitment to open data sharing (e.g., worries regarding privacy, confidentiality, and fairness to researchers). In their chapter the authors also explain *how* data is currently shared by clinicians conducting research into UTx and discuss several concerns that may be raised regarding these practices and discuss *how* data sharing practices may be improved in this context.

3.2. Part II – Legal Perspectives on UTx

Part II of this book explores the international legal landscape surrounding UTx and thus provides valuable context for the preceding chapters exploring the ethical and policy questions raised by UTx. First, we present three countries that have performed UTx and where live births have subsequently taken place, Sweden, the United States, and Lebanon. Second, we present the United Kingdom as an example of a country that has performed UTx but where recipients have not yet given birth (at the time of writing). Finally, we present Japan as an example of a country that is currently interested in performing UTx but in which no transplants have yet taken place. From a legal perspective, UTx is unique within the medical arena as it encompasses both organ donation and assisted reproduction regulation (if in force) as well as the ethical issues that both areas of medicine raise. These are two areas that until now, have rarely had to interact. Indeed, while assisted reproduction does encompass gamete and embryo donation, the regulations (if any) that govern this are generally distinct from the regulations that govern organ donation.

In chapter 12, "Uterine Transplantations in Sweden", Titti Mattsson, Lena Wahlberg and My Bergius explore and discuss the fundamental legal requirements for UTx to make the transition from clinical trial to clinical treatment within the Swedish public health care system. Within the chapter, the authors present the requirements for organ donation from both living and deceased donors in Sweden, and then focus on three legal requirements that new treatments, including UTx, must fulfil prior to being offered within the public health system: that the treatment accords with science and proven experience, that an ethical assessment is undertaken, and that treatments are offered in accordance with the platform for prioritisation in healthcare which involves a consideration of the principles of human dignity, need and solidarity, and cost-effectiveness.

Next, in chapter 13, "Regulating Uterus Transplantation: The United States", Valarie Blake and Seema Mohapatra summarise and analyse the legal landscape regulating UTx in the United States which is currently the only country to offer UTx as both a clinical trial and as a clinical treatment. Within this chapter, Blake and Mohapatra explain how organ donation laws are poorly suited to handle complex matters of gestation, whilst there is a divisive battle currently in progress over reproductive freedoms since the Dobbs verdict in 2022. They note the impacts of this on the regulation of assisted reproduction, embryo research, and abortion and how these may potentially impact the ability of UTx to fully come to fruition as a clinical treatment within the United States. The authors recognise the differing federal and

states law applicable to each area of medicine, and how the overlap of UTx into these different areas means that clinicians are navigating a variety of regulations, laws, and policies.

In Chapter 14, "Uterine Transplantation in Lebanon: Social, Ethical, and Legal Considerations", Hazar Haidar, Tala Khansa, and Thalia Arawi explore the different religious positions, socio-cultural perspectives, and legal considerations in Lebanon towards the alternatives to motherhood available to women with AUFI, adoption and surrogacy. Through this examination of the religious positions the authors explore how UTx may be seen to be an appealing alternative for those who are unable for religious or legal reasons to access other means of family formation such as surrogacy and adoption. The authors then examine the ethical and social issues that may arise when UTx becomes clinically available. Finally, the authors highlight the need for research aimed at developing a health policy to guide the implementation and utilization of UTx technology in Lebanon.

In contrast to the Lebanese situation where there is a lack of formal secular legislation governing UTx, IVF, and organ donation, in chapter 15, "Regulating Uterus Transplantation: The United Kingdom", Natasha Hammond-Browning examines the application of the United Kingdom's comprehensive legal frameworks that govern organ donation, and assisted reproduction. As with other jurisdictions, the regulatory framework that applies was not designed specifically with UTx in mind, so that the application of the law raises distinct legal issues. This includes the legal parentage of children born after UTx, and the legality of transferring embryos to someone other than a cisgender woman. Finally, the author argues that the legally problematic questions raised by the application of established regulation to new medical advances are discussed before UTx becomes an established clinical treatment for AUFI.

Finally, Japan is presented as a country exploring the possibility of conducting UTx clinical trials. In chapter 16, "Ethical, Legal and Social Issues on Uterus Transplantation: Japanese Perspectives", Nobuhiko Suganuma and Ayako Hayashi explore Japanese ethical, legal, and social perspectives on UTx, along with relevant guidelines and law that govern organ donation and assisted reproduction. The authors also present the findings of two surveys conducted to assess the awareness and acceptability of UTx within Japanese society. Finally, developments in professional regulation of UTx, including the establishment of the Japanese society for UTx are presented. The authors suggest the establishment of guidelines are crucial for the future clinical application of UTx.

The chapters within this section of the book highlight the differences in the formal (or lack of) regulation of organ donation and assisted reproduction amongst different countries, and how the unique position of UTx, in encompassing two different medical specialities, raises unique legal questions. The chapters also highlight how regulation, where it exists, is being stretched to apply to situations that were not contemplated or considered by lawmakers when such regulation was designed, as such regulation governing organ donation, assisted reproduction, and abortion is or will be applied to a unique situation, outside of contemplation at the time of enactment. These chapters also demonstrate how law and regulation cannot be formulated without also consideration of the ethical, religious, and social perspectives.

This book is the culmination of an idea that we, the editors, first discussed in 2019, and we thank all our contributors for their time in participating in Zoom discussions/workshops during covid pandemic lockdowns in 2020 and 2021, and for their continued support and patience in bringing this collection together. We are pleased and proud to present the first collection on international legal and ethical perspectives on uterus transplantation, we hope that our readers find this informative, interesting, and thought-provoking.