



September 29, 2021

Matthew Cooper, MD
President, Board of Directors
Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing
(UNOS) 700 North 4th Street
Richmond, VA 23218

RE: 2021-2024 OPTN Strategic Plan as it pertains to Public Comment: Proposal Establish Membership Requirements for Uterus Transplant Programs¹

Dear Dr. Cooper:

Thank you for the opportunity to provide public comment on behalf of The National Catholic Bioethics Center, the National Catholic Partnership on Disability, the Catholic Medical Association, and the National Association of Catholic Nurses, USA. We wish to address the *Establish Membership Requirements of Uterus Transplant Programs* proposed by the OPTN Vascularized Composite Allograft (VCA) Transplantation Committee. We wish to focus on the following OPTN Bylaws changes:

- D: Additional Primary Surgeon Requirements for Uterus Transplant Programs
- J.4: Primary Obstetrician-Gynecologist Requirement for Uterus Transplant Programs
- J.5: Uterus Transplant Programs That Perform Living Donor Recovery
 - A. Living Donor Medical Evaluation
 - B. Living Donor Psychological Evaluation
 - C. Independent Living Donor Advocate (ILDA)
 - D. Living Donor Uterus Surgeon Requirements

The National Catholic Bioethics Center (NCBC) is a non-profit research and educational institute committed to applying the moral teachings of the Catholic Church to ethical issues arising in health care and the life sciences. The Catholic Church is the largest provider of non-

¹ OPTN Vascularized Composite Allograft Transplantation Committee, "Public Comment Proposal: Establish Membership Requirements for Uterus Transplant Programs," due September 30, 2021, https://optn.transplant.hrsa.gov/media/4784/establish_membership_requirements_for_uterus_transplant_programs_aug2021.pdf

governmental, non-profit health care in the United States. The NCBC serves numerous health care agencies in their development and analyses of policies and protocols, including protocols implementing OPTN/UNOS policies on organ donation and transplantation that comply with the *Ethical and Religious Directives for Catholic Health Care services*. [U.S. Conference of Catholic Bishops, 2018]. The NCBC has 1300 members throughout the United States. These include numerous health care agencies representing thousands of persons involved in the delivery of health care, including transplantation services. NCBC provides consultations and education to hundreds of institutions and individuals seeking its opinion on these and other matters as they pertain to the appropriate application of Catholic moral teaching in the delivery of health care.

The National Catholic Partnership on Disability (NCPD) is a non-profit agency that affirms the dignity of every person, working collaboratively to ensure meaningful participation of people with disabilities in all aspects of the life of the Church and society. As an organization that advocates for policies respectful of all persons, especially those with disabilities, the NCPD wishes to express its concern for any government sanctioned program that fosters the creation of a disability, even for the laudable cause of providing organs for transplant, thus, violating society's obligation to the human person.

NCBC and NCPD also are joined by the Catholic Medical Association (CMA) and the National Association of Catholic Nurses, USA (NACN-USA). CMA is a non-profit national organization comprised of over 2,000 members representing physicians and other health care providers in over 75 medical specialties. CMA helps to educate the medical profession and society at large about issues in medical ethics, including ethics involved in human transplantation impacting the best interest of those entrusted to their care. CMA accomplishes this through its annual conferences, local Guilds, its quarterly award-winning bioethics journal, *The Linacre Quarterly*, and its other programs, publications, and web communications. It educates thousands of health care professionals through these media, a number of whom are involved in transplantation services.

NACN-USA is the national professional organization for Catholic nurses in the United States representing a membership of hundreds of nurses. Nursing plays an integral role in the process of organ donation and transplantation. In that role, nurses advocate for patients, protect the vulnerable, and promote human dignity and, thus, have a great interest in this policy.

As NCBC, NCPD, CMA, and NACN-USA shared with you in the past, the Catholic Church encourages organ donation as providing a gift of life to those in need. Of course, this is with the understanding that the Dead Donor Rule is rigorously respected and implemented. However, no victim of physician assisted suicide should be considered a potential donor, even with consent. Such a proposal incentivizes the patient abandonment which characterizes physician assisted suicide. In terms of living donors, the same generosity of donors is recognized, if there is respect for true informed consent as well as the protection of the bodily integrity of the donor. That is why rigorous standards for psychosocial and medical evaluation must be in place and regularly monitored for compliance by OPTN. It is important to note that OPTN is defining uterus to include uterus, vagina, and cervix, and in the future may include other reproductive organs, such as ovaries and testes. In fact, already ovarian transplants have been documented

in the United States.² Regardless of the potential provision for enhanced standards, any protocol that creates a disability represents an attack on the human person. There is no denying that loss of a uterus or genitalia would constitute a serious and irreparable impairment to the donor.³ In contrast, the procedure for the recipient is only life-enhancing, not life-saving; and, since “there is currently no known shortage of deceased donor VCA organs,”⁴ in virtually all cases, the benefit of living donation to the recipient relates to a shorter waiting time and scheduling (avoiding cold ischemic preservation). While we recognize that living donors often are family members, decreasing the potential for host rejection, these rationales clearly are insufficient to justify such massive harm to the donor. The importance of full disclosure to achieve informed consent will be addressed later in this document.

Below is the response of NCBC, NCPD, CMA, and NACN-USA to the following areas of request for public comment:

Will the proposed membership requirements ensure that approved uterus transplant programs have the expertise needed to safely perform uterus transplants, and, as applicable, living donor uterus recovery?

**D: Additional Primary Surgeon Requirements for Uterus Transplant Programs; and
J.4: Primary Obstetrician-Gynecologist Requirement for Uterus Transplant Programs**

The Vascularized Composite Allograft (VCA) Transplantation Committee is proposing to define the uterus as a type of VCA separate from other genitourinary organs. By way of comparison, since 2016 there has been two successful penis transplants through deceased donations, while there have been 32 uterus transplants (resulting in at least 21 live births); and 63% of these were made possible through living uterus donation. The uterus is the most sought-after VCA transplant; this tissue transplantation is both expected to grow and to continue to rely heavily on living donors. To increase transplant success and patient safety —as eight of the 32 uterus grafts failed—the Committee is seeking to establish more rigorous expertise requirements concerning the primary surgeon and primary obstetrician-gynecologist involved in the uterus transplant.⁵

While the Committee’s overall goal to increase success and safety by establishing additional standards is certainly with merit, the NCBC, NCPD, CMA and NACN-USA urge that policies, and policy implementors, never lose sight of the human persons, including the donor,

² Sherman J. Silber, Gedis Grudzinskas, and Roger G. Gosden, “Successful Pregnancy after Microsurgical Transplantation of an Intact Ovary,” *New England Journal of Medicine* 359 (2008): 2617-2618, <https://www.nejm.org/doi/full/10.1056/NEJMc0804321>.

³ The Americans with Disabilities Act defines “disability” to include a significant impairment to reproductive functions: (1) The term “disability” means, with respect to an individual—(A) a physical or mental impairment that substantially limits one or more major life activities of such individual; ... (2)(B) For purposes of paragraph (1), a major life activity also includes the operation of a major bodily function, including but not limited to ... *reproductive functions*. 42 U.S.C. § 12102 (1)(A) & (2)(B).

⁴ U.S. Department of Health and Human Services, Organ Procurement and Transplantation Network, “VCA’s from Living Donors,” <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/>.

⁵ OPTN Vascularized Composite Allograft Transplantation Committee, “Background.”

the recipient, and the children that will be engendered. We oppose such live uterus transplants and genitourinary transplants from living donors which create a disability in the donor, whose tissue loss represents a disability. We are not, in principle, opposed to such transplants from deceased donors, if risks to the engendered child can be averted and reproductive technologies do not substitute for the natural engendering of children. However, in practice that is not occurring, and with current advancements are not feasible. Furthermore, currently all involved parties, from donor, to recipient, and especially the children to be engendered, are placed at physiological and psychological risk.

It is not unrealistic that as part of transgender interventions, there will be requests for uterus transplants, further putting the physical wellbeing of engendered unborn children at risk by the number of pharmacological and surgical interventions required. The wellbeing of the child becomes secondary to a person's desire to physically bear a child, when many other less harmful options for becoming a parent are available. Additionally, regardless of the recipient of the uterus transplant, there is no provision assuring that the children engendered will have the benefit of both a mother and a father. The focus is on engendering children for a person who wishes to carry a child who becomes a commodity, putting the children engendered at significant risk, without primary consideration for the best interest of the child.

This OPTN proposal, by the enhanced standards identified, implicitly acknowledges risks involved in uterus transplants by establishing additional requirements for the primary surgeon and the addition of a primary obstetrician and gynecologist. We agree that the highest academic and clinical credentials must be required of the health care providers involved in all aspects of care for donor, recipient, and the unborn child, including post-donation care of the donor. However, the proposal has provisions that weaken credentialing requirements for the primary surgeon, primary physician, and the proposed obstetrician-gynecologists (with certification requirements paralleling those of the primary surgeon). Beyond credentialing, with its optional substitutions, very little is required of the obstetrician-gynecologist to be designated the primary obstetrician-gynecologist, especially pertaining to experience and training. Furthermore, numerous substitutions for achieving credentialing are identified:

The Committee proposes adding more flexibility to this requirement for the primary surgeon of a uterus transplant program so that a surgeon can meet this requirement if they have either observed or completed two multi-organ procurements within the last five years, or completed at least one deceased donor uterus procurement as primary surgeon within the last five years.⁶

Also, clinical experience and certification requirements provide for alternatives that can impact safety of all parties, e.g.:

⁶ OPTN Vascularized Composite Allograft Transplantation Committee, "Primary Surgeon Requirements. General Requirements."

Surgeons who have not completed the fellowships described ... may still qualify to serve as the primary surgeon of a uterus transplant program if they can demonstrate clinical experience with uterus transplantation or radical hysterectomies.⁷

The surgeon [lacking certification] must be ineligible for American board certification. The surgeon must provide a plan for continuing education that is comparable to American board maintenance of certification, as outlined in the OPTN Bylaws.⁸

It is imperative that the primary surgeon has direct experience with more than one uterus transplant, beyond experience with hysterectomies. There is much more to retrieving and affixing the uterus/cervix/vagina than is involved with a radical hysterectomy. Ample vessels and ligaments are required to vascularize and affix the uterus in the recipient.

Certification requirements can be temporality waived by the Membership and Professional Standard's Committee (MPSC) which may grant conditional approval for 24 months, with the potential for an additional 16-month extension. Continuing education requirements are required which allow for repeated attempts to achieve an acceptable score, with a six-month window to address deficiencies.⁹ Similar alternatives are provided for the primary obstetrician-gynecologist but without the 16-month extension.¹⁰

At a minimum, this proposal requiring a primary obstetrician-gynecologist must specify identified board certification, without substitutions, and specified, by number, experience in prenatal care and cesarian section delivery of immune-suppressed mothers.

Furthermore, as has been identified, the embryo/fetus is put at significant risk and there is no requirement listed for the neonatologist whose collaboration is to be sought, nor the degree of collaboration, nor access to a level III (3) neonatal care unit. In fact, how compliance is secured is left to the membership institution. The proposal cites:

The transplant program must ensure that the recipient's uterus graft is receiving adequate blood supply not just for graft survival, but also to support a developing fetus throughout pregnancy. Maternal conditions that can impact blood flow to the fetus in non-transplant patients, like chronic hypertension and preeclampsia, are associated with intrauterine growth restriction (IUGR). IUGR can result in stillbirth, preterm delivery and associated risks, and adverse health effects throughout childhood and adulthood.¹¹

The ultimate goal of uterus transplantation is a healthy newborn. And while we support establishing a new role for a primary obstetrician-gynecologist within uterus transplant programs, the need for neonatologist expertise to achieve this goal is significantly under addressed: "Accordingly, the Committee proposes requiring the primary surgeon to show

⁷ Ibid., "Primary Surgeon Requirements. Clinical Experience."

⁸ Ibid., "Board Certification or Alternative."

⁹ Ibid., "OPTN Bylaws: D. Additional Primary Surgeon Requirements for Uterus Transplant Programs."

¹⁰ Ibid., "J.4. Primary Obstetrician-Gynecologist Requirement for Uterus Transplant Programs."

¹¹ OPTN Vascularized Composite Allograft Transplantation Committee, "Background."

proof of collaboration with experts in these fields.”¹² This is even though the proposal acknowledges that infants born to uterus recipients are generally delivered prematurely (at less than 37 weeks gestation) via planned cesarian section, and experts in neonatology must be available to assist in care of the newborn infants. No certification or training and clinical experience is specified, e.g., American Osteopathic Board of Pediatrics, or American Board of Pediatrics. Furthermore, there is no requirement that the member institution must have access to a Level III (3) Neonatal Intensive Care Unit, and all the appropriately credentialed personnel required for such designation. Such quality assurance standards must be addressed. Furthermore, specific regulatory oversight of compliance with such requirements needs to be specified.

J.5: Uterus Transplant Programs That Perform Living Donor Recovery

A. Living Donor Medical Evaluation

B. Living Donor Psychological Evaluation

C. Independent Living Donor Advocate (ILDA)

Medical and psychosocial evaluation is essential for living donors, especially for mutilating procedures such as uterus donation. We wish to provide comment on the need for enhanced requirements for living donor psychological evaluation. We have continually expressed objections to government endorsed policies that allow for the creation of disabilities in living VCA donors, whose consent can be questionable at best, especially if the recipient is a family member. No donation that creates a mutilation or disability to the donor is consistent with the Hippocratic tradition. However, it is critical that long-term follow-up of both donor, recipient, and the engendered child occurs to document outcomes and assess for safety.

Granted uterus transplants are not essential to life, but clearly threaten the psychosocial and physical wellbeing of a woman, who may later regret this substantial loss. Data support that 28% of American women aged 25 to 45 years of age regret their tubal ligation.¹³ A number of women seek reversals. Removal of reproductive organs is not reversible. Thus, the elective removal of such a healthy organ is mutilating to the human person and should not be allowed; and if it is to occur requires the most rigorous informed consent processes. Documentation of cognitive ability to provide such consent needs to be required and surrogate decision making for another must be prohibited. This proposal does not provide for this basic right of the donor to full informed consent.

Under the “Living Donor Medical Evaluation” and “Living Donor Psychological Evaluation,” the uterus recovery hospital must have the “clinical resources” to assess the “specific risks to the living donor” and to “perform a psychosocial evaluation of the living donor” respectively.¹⁴ However, criteria for denial of donation should be clearly stated, including any evidence of coercion which must be thoroughly investigated. Psychiatric disorders that fall in the diagnostic categories beyond adjustment disorders, such as psychosis should be

¹² Ibid., “Primary Surgeon Requirements. Medical Expert Support.”

¹³ Karina M. Shreffler, Ph.D., Arthur L. Greil, Ph.D., Julia McQuillan, Ph.D., and Kami L. Gallus, Ph.D., “Reasons for tubal sterilisation, regret and depressive symptoms,” *Jo. Reproductive Infant Psychology* 34(3), 2016: 304–313.

¹⁴ OPTN Vascularized Composite Allograft Transplantation Committee, “OPTN Bylaws. J.5 Uterus Transplant Programs That Perform Living Donor Recovery.”

excluded from donation. Even a “controlled” diagnosable psychiatric condition or suicidal ideation should trigger a denial. Psychiatric conditions can be labile, and a decision of someone whose condition is controlled today by medication, may not represent the psychiatric status of the person in the future when they are suffering from the loss of a uterus.

Another area of great concern is the enormous risk that a living donor takes who later decides that losing childbearing potential by donating the uterus was a great mistake. By proposing an Independent Living Donor Advocate (ILDA), the Committee places on such advocate the tempering of interests that might harm the donor. At a minimum, the ILDA must be required to inform donors of the likelihood of lost pregnancies and death of offspring due to the procedure, and the potential for graft and pregnancy failure as well. Existing follow-up data of well-being of donors must be collected to determine whether harm has been done to them, and must be shared with potential donors. Loss of a uterus constitutes a serious and irreparable impairment to the donor. Even if the donors have chosen not to bear or beget any or other children, they are irreparably harmed by the living donation.

Specifically, up to date statistical information must be disclosed to the donor and recipient to assure true informed consent. This current information must include how many embryos were engendered in each of the 32 uterus transplants, how many were implanted, how many of the implanted embryos resulted in live births, and how many were lost either in the process or in the failed grafts and pregnancies. Furthermore, a donor may wish to know if the donor is cooperating in the engendering of a fatherless or single parent family. Without this information informed consent is violated. Thus, ongoing, and long-term data collection on physical and psychological well being of donor, recipient, and engendered child is required for the OPTN goals of the membership (hospital participation) requirements to be properly and ethically assessed. These are the areas of deficiency in the post-implantation monitoring that are significantly underdressed. This proposal only specifies a statistical review of transplant outcomes, prepared by the member agency’s own quality assurance staff (Member Quality Staff) one year post implementation and reviewed by OPTN’s MPSC.¹⁵

The requirements should also specify that the recipient must be a person with a high probability of success. This is to eliminate any possibility of a uterus transplant on a recipient who does not even have the physiology to receive a uterus. Simply because a recipient has the financial means to make such a demand, does not make it ethical or reasonable. Living donors and recipients face significant risks in having the uterus removed or transplanted; these risks should not be trivialized.

Most importantly, the unborn child is placed at great risk and can be considered merely a commodity, replaceable by another invitro-engendered sibling. For these same reasons we are opposed to all in vitro fertilization which places each embryo at great risk of being harmed, but equally harmed by a commodification of his or her very life, which should be a gift, not a commodity. Long-term follow-up concerning the health and wellbeing of each child must be provided, with data analyses and outcome evaluation. Without such data, uterus transplants remain an experimental option placing all parties at risk, especially the children who cannot consent to what they have been exposed. In principle uterus transplants, as defined, from a deceased donor are not unethical endeavors, if the child could be engendered through the

¹⁵ Ibid., “Post-Implementation Monitoring.”

marital conjugal act and the risks placed on the engendered child are proportionate to children conceived in a non-transplanted uterus. However, in the current state of technological advances these standards are not achievable. Thus, we oppose such uterus transplants. Furthermore, the proposal provides no assurances that the vagina transplanted will be sufficient for penetration to accomplish the conjugal act. Also, transplantation of testes and ovaries, living or deceased, should be prohibited. Such procedures further commodify the child; and living donation further mutilates the donor. The recipient becomes a surrogate for the real parent creating tremendous confusion in terms of genetic issues of the child engendered.

That being said, this proposal attempts to provide additional requirements to protect the donor, recipient, and the child engendered. We recognize this intent, while opposing uterine transplants, especially from living donors, and request that the deficiencies we have identified be addressed.

Thank you for this opportunity to provide public comment on this important issue. While we recognize the goal of enhancing safety of VCA transplants, the very risks caused by uterus transplants are not averted by this proposal. We recognize the great value of organ transplantation and the tremendous good accomplished by OPTN/UNOS but wish to protect both donor, recipient, and the unborn children engendered from outcomes that may be unintended, despite these enhanced criteria.

If you have any questions, feel free to contact Dr. Marie T. Hilliard, JCL, MS, MA, PhD, RN, Senior Fellow of NCBC at 215 871-2016.

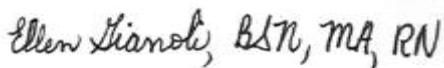
Sincerely yours,



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