The National Catholic Bioethics Center

6399 Drexel Road, Philadelphia, PA 19151 Tel. 215-877-2660 Fax. 215-877-2688 www.ncbcenter.org

March 23, 2021

David Mulligan, 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

Dear Dr. Mulligan:

Thank you for the opportunity to provide public comment on behalf of The National Catholic Bioethics Center (NCBC) on the 2021 - 2024 OPTN Strategic Plan. We wish to focus on:

Goal 1: An increase in the number of transplants from machine perfused organs;
Goal 3: Promote living donor and transplant recipient safety; and
Goal 4: Improve waitlisted patient, living donor, and transplant recipient outcomes.

Specifically, we wish to respond to your stated inquiries:

3) Are there goals or initiatives that should not be included in this plan? If so, should they be maintained in the OPTN's future operations or discontinued altogether?
4) Are the stated performance metrics sufficient, measurable and specific?

The 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-governmental, non-profit health care in the United States. The NCBC serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for donation after circulatory death (DCD), as well as 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 and provides consultations 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.

As we have 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. 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. Furthermore, any protocol that creates a disability represents an attack on the human person.

Goal 1: An increase in the number of transplants from machine perfused organs.

This initiative should not be included in this plan, until assurances can be given that the Dead Donor Rule is not being violated through the causation of brain death using Extracorporeal Membrane Oxygenation (ECMO) or Extracorporeal Interval Support for Organ Retrieval (EISOR). Until such assurances can be documented, this initiative should be maintained in the OPTN's future operations. Furthermore, we wish to urge, as we have in the past, compliance with requirements that canulization and administration of medications such as heparin are not at doses that will hasten death.

A mandated five-minute post-cardiac arrest waiting timeframe after circulatory death is recommended by the Institute of Medicine [1997, 2000] to obviate the possibility of autoresuscitation. This is not required by OPTN despite scientific support for its use. For an adequate determination of death, recognizing that the exact moment of death cannot be measured by absolute certitude, the use of physiological signs provides moral certitude. In other words, since medical science cannot determine with absolute certainty the moment when the animating source separates from the body, and thus the moment of death, there needs to be the absence of reasonable doubt through physiological signs that natural death has occurred. Again, for DCD the Institute of Medicine has documented that no life has auto resuscitated after five minutes. Also, for neurological death strict criteria have been developed by the American Academy of Neurology, using physiological signs. However, the use of machine perfusion through ECMO or EISOR has the potential to reanimate the heart once it has been resuscitated. Thus, to use EISOR to create brain death in a person with a beating heart after resuscitated measures raises questions about the reasons for its use. In other words, if as supported in the literature, there is a question as to whether sensation continues to exist, reasonable doubt may remain as to the absence of life. More clarification of this matter is needed.

The use of EISOR confirms the conclusion that ECMO itself creates a real possibility that cessation of respiratory and circulatory function and progression to full brain destruction are not irreversible and, thus, that the donor is not dead. Consequently, since the use of ECMO revives the presumption that the donor is alive, EISOR, by depriving oxygenated blood to the brain (and sometimes to the heart), would of itself constitute an actual cause of death, separate and independent from any underlying terminal pathology or, at the least, an accelerant of its predicted time of death. Further, there is no gainsaying that the ultimate intent in using EISOR is to ensure that the donor is dead. To say EISOR's real aim is to preserve organs below the diaphragm for transplant fails to explain its use since full-body ECMO would accomplish the same result without depriving oxygenated blood to the heart and brain. EISOR thus could constitute an attempt to cause donors' death to harvest their

organs. These problems are not resolved by requiring informed consent since neither the patient, surrogate, nor physician can agree to organ recovery before adequate evidence that the donor is dead.

Goal 3: Promote living donor and transplant recipient safety; and
Goal 4: Improve waitlisted patient, living donor, and transplant recipient outcomes.

We wish to address the use of living donation for vascular composite allografts (VCA), which can include several tissues including face, limbs, omentum, and reproductive tissue. 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.

For VCAs it is hard to conceptualize how donor safety, except perhaps with omentum donation, can be assured. No donation that creates a mutilation or disability to the donor is consistent with the Hippocratic tradition, thus, other than omentum such initiatives should be omitted in this plan. However, it is critical that long-term follow up of both donor and recipient does occur to document outcomes and assess for safety.

While psychosocial and medical evaluation for all donors is needed, this is essential for living donors, especially for mutilating procedures. As microscopic surgery advances, a parent of a child, for whom it has been established after an accident that both hands cannot be salvaged, could decide to donate one hand to a child. Reproductive organs could be donated for an adult sibling unable to have children, and later the donor could decide that losing childbearing potential was a great mistake. The examples of potential physical and psychological harm are expansive. Mandatory criteria and timeframes for long term follow-up of donor and recipient, and in the case of reproductive tissue, offspring, need to be specified. Of significant concern is the paucity of "Living Donor Exclusion Criteria." Despite the evaluation indices for living donors, few identified indices will lead to a denial of the donation.

Of specific concern for all living donors is the assessment for any evidence of coercion (not just high evidence). Any evidence of coercion requires a thorough investigation, and confirmation of its presence or lack thereof, and then a denial of a donation if there is such evidence. Furthermore, 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 an organ or tissue. Of great importance is that exclusion criteria for all living donations need to be expanded for medical exclusions, as well as for exclusion for psychiatric disorders that fall in the diagnostic categories beyond adjustment disorders, such as psychosis (regardless of whether they are "controlled"), as well as exclusion for any evidence of coercion. It could be envisioned that surrogate decision-makers of living donors may be permitted, as they are for the deceased. This would represent a significant abuse of those with disabilities and needs to be prohibited.

The donation of reproductive tissue clearly is mutilating to the donor and the exclusion criteria need to protect the donor. Are donors informed of the likelihood of lost pregnancies and death of

offspring due to the procedure? What age groups, young and old, and history of childbearing are considered? Are such donors followed-up for years, to determine whether harm has been done to them? Furthermore, even though death is less likely after VCA living donation, since the potential for compromise to vital organ function is lower, there is no denying that loss of a uterus or genitalia would constitute a serious and irreparable impairment to the donor. In contrast, the procedure for the recipient is only life-enhancing, not lifesaving; and, since unlike organ donation there is currently no known shortage of deceased donor VCA tissue, the benefit of living donation to the recipient is merely a shorter waiting time. This is clearly insufficient to justify such massive harm to the donor. Further, as technique-enhancement over time may potentially improve outcomes, even the strongest case — identical twin pairs, where the need for immunosuppression is avoided— is insufficient to justify living uterine or other genitourinary donation since the benefit to the recipient fails even to offset, let alone clearly outweigh, the harm to the donor. Simply put, the procedure attempts to remedy the loss in one person by creating the identical loss in another. Moreover, even if the donors have chosen not to bear or beget any or other children, they are irreparably harmed by the living donation.

Thus, there is a great need for Goal 3, as stated: Promote living donor and transplant recipient safety. However, for VCAs, the potential for permanent mutilation for the living donor does not justify the transplantation of most tissues allowed under Goal 4: Improve waitlisted patient, living donor, and transplant recipient outcomes. For both, there is a significant need to address metrics more specifically.

Thank you for this opportunity to provide public comment on this important issue. We recognize the great value of organ transplantation and the tremendous good accomplished by OPTN/UNOS but wish to protect both donor and recipient from outcomes that may be unanticipated, despite every good intention.

If you have any questions, feel free to contact me at 215 871-2016.

Sincerely yours,

Dr. Marie T. Hilliard, MS, MA, JCL, PhD, RN.
Senior Fellow, The National Catholic Bioethics Center
mhilliard@ncbcenter.org