The National Catholic Bioethics Center

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March 24, 2015

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

RE: ***Membership Requirements for Vascularized Composite Allograft Transplant Programs.*** See: http://optn.transplant.hrsa.gov/media/1153/0115_10_vca_membership.pdf.

Dear Dr.Berg:

The National Catholic Bioethics Center and the National Catholic Partnership on Disability wish to respond to the call for comment concerning *the Membership Requirements for Vascularized Composite Allograft Transplant Programs (VCAs)*: hereafter, *Proposal.* As you know the Secretary of the U.S. Department of Health and Human Services has expanded the definition of human organs and added Vascularized Composite Allografts, to the covered list of human organs for transplant under the OPTN modified *Final Rule*. This proposal is in response to a directive from the Health Resources and Services Administration to develop VCA for implementation of the modified *Final Rule* which became effective July 3, 2014. These policy changes were approved by the OPTN/UNOS Board of Directors during its June 23-24, 2014 meeting, with a "sunset" date on September 1, 2015. As you know, we already have submitted comment on the *Proposal to Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs),* to be voted on at the June 1-2, 2015 meeting of the Board of Directors, with the comments on this *Proposal* also to be reviewed at that time. We have reason to trust that our comments will be seriously considered, as we have met with the Chair of the VCA Committee, Dr. Susan McDiarmid, who allowed us to provide verbal comment on the draft "Resource Document for Informed Consent of Living Donors," "Resource Document for Developing Program-Specific Living VCA Donor Medical Evaluation Protocols," and "Guidance for Vascularized Composite Tissue Allografts (VCA) in Living Donation." We understand that these resource documents will be voted upon at the same June 1-2, 2015 meeting of the Board of Directors, with an 18-24-month period of implementation, to fill the gap of lack of oversight for living donors of VCAs until further public comment on the interim

guidance can be garnered. Dr. McDiarmid has offered to us the opportunity to submit written suggestions to her, which we will do at a later date.

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, including biomedical research. The NCBC serves numerous health care agencies in their development and analysis of policies and protocols, including protocols for DCD. The Center has 2500 members throughout the United States, and provides consultations to hundreds of institutions and individuals seeking its opinion on this and other matters as they pertain to the appropriate application of Catholic moral teaching.

The National Catholic Partnership on Disability was established thirty years ago to implement the U.S. bishops' *Pastoral Statement on People with Disabilities*, and serves over fourteen million Catholics who have a disability, and whose rights and protections need to be preserved by our government when any regulatory policy is being developed.

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. In terms of both living and deceased donors, the same generosity of donors is recognized, as long as there is respect for true informed consent, donor and recipient safety, and human physical integrity. Therefore, we hope that our comments contained herein will be helpful in securing the public safety that we all are hoping to protect. Overall, we wish to reiterate that, despite the position being held stipulating that the U.S. Dept. of Health and Human Services has not given the authority to OPTN/UNOS to preclude living donations of VCAs, there is the authority to restrict them as rigorously as possible. We urge such an approach. Our section by section comments are below.

At-a-Glance Preface

Types of VCA Programs

The document states that: "The Committee felt it would be appropriate for a transplant hospital applying for 'other' VCA types (outside of upper limb, head and neck, and abdominal wall) to submit separate applications for each VCA graft the transplant hospital intends to perform." However, it states further: "The Subcommittee decided to include face transplant under the title 'Head and Neck' (Appendix J.3.B). 'Head and Neck' will include those grafts above the shoulders, inclusive of facial, vascularized scalp, and larynx grafts." Clearly, the *Proposal* itself acknowledges that the most commonly performed transplants are those of the upper limb, face, and abdominal wall, and certainly not larynx grafts. Thus, with the regulatory authority of OPTN, it is clear that, at a minimum, as these regulatory frameworks are being developed and tested, even the larynx transplants should be subject to a specific and separate application, including being restricted to deceased donors only. In fact, to remove a larynx most likely will lead to the death of a donor.

Key Personnel

The *Proposal* recognizes "the possibility that well-qualified VCA surgeons may not meet both the new board certification and fellowship training requirements. Therefore, the Committee has included experience pathways." These pathways will sunset on September 1,

2018. Clearly, a minimum qualification for so new a program should be certification in the specialty area of the transplanted VCA. By acknowledging that such transplants are so new and few in number, expertise and certification in the specialty area of the tissue is critical to a good outcome. For example, the *Proposal* specifies that "kidney and pancreas transplant surgeons [were added] to the list of individuals who are qualified to be the primary transplant surgeon for an abdominal wall transplant program." Such surgeons do hold specialty certification in their areas, which is appropriate. However, the *Proposal* continues by stating:

> Additionally, the MPSC [Membership and Professional Standards Committee] inquired if training programs for head and neck include the necessary microvascular experience for the primary surgeon and suggested this experience needed to be more prominently stated. The VCA Committee may identify this experience more specifically in post-public comment changes (e.g.: increasing the number of procedures in trauma and microsurgery from 10 to 20 and inclusion of facial nerve operations/dissections).

Clearly, such a provision should have been incorporated in this *Proposal.*

Supporting Evidence and/or Monitoring

We acknowledge that there has been a low volume of VCA transplants, thus impacting the experience of transplant surgeons, but that does not justify such a lowered experiential standard for such surgeons as a minimum of two multi-organ procurement observations. This is critically below any reasonable competency test for such new procedures. In fact, the term "procurement" is not defined. If this qualifies the transplant surgeon to procure a VCA from a living donor, this is totally unacceptable due to the ensuing mutilation. It would be better, clinically and ethically, to limit approval to a few regional centers for such transplants until there are enough qualified and experienced transplant surgeons to justify more numerous centers.

Expected Impact on Living Donors or Living Donation

The example given herein is one of the most egregious and, whenever it is shared with consumers, they are appalled. That removing a limb from a not-dead-yet conjoined twin even could be justified puts in question the integrity of the entire transplant program. We understand from Dr. McDiarmid, that the draft Resource documents restrict living donors to competent adults, which should be a minimum standard for any VCA donation.

If we are reading the *Proposal* correctly, "any VCA recovery from a living donor must take place at a transplant hospital that is approved for VCA transplantation involving grafts from deceased donors," this is something that clearly should be required, at a minimum. That is, significant experience with deceased donor VCAs should be a pre-requisite for participation with living VCA donors.

Appendix J: Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs

J.2 Primary VCA Transplant Physician Requirements

This section allows an exception to existing OPTN primary transplant surgeon and physician requirements. The type of board certification is not specified for the transplant physician (and can be waived for the transplant surgeon as specified, below), with only continuing education and a medical or surgical fellowship in the area of transplantation being required. Furthermore, there are no identified credentials specific for the recovery [from the living donor] surgeon, and it is the living donor patient who has the most to lose in terms of mutilation and creating a disability. Both this exception itself, and the lack of specified credentials, are unacceptable and must be addressed. At a minimum, certification and experience with dead donor retrieval specific to the tissue part being retrieved, are crucial to both donor and recipient safety.

J.3 Primary VCA Transplant Surgeon Requirements

This and the following sections are of grave concern. Basically, all that is required herein is that the VCA transplant surgeon be merely a licensed physician with privileges in the hospital seeking to do such transplants, and have observed two multi-organ transplants (with the additional specialty requirements stipulated, below). This is totally unsatisfactory, and could be remedied by limiting VCA transplant centers to a few regional centers until the requisite credentialing and expertise of such surgeons can be achieved. Furthermore, there are no specified credentials for the recovery [from the living donor] physician. The donor is the patient who has the most to lose in terms of mutilation and the creation of a disability. This inadequate requirement must be addressed by assuring that recovery physicians have significant experience with deceased donors, as well as adequate credentialing, more specifically addressed, below.

A. Additional Primary Surgeon Requirements for Upper Limb Transplant Programs

Certification in Plastic Surgery, Surgery or Orthopedic Surgery, which can be deferred for up to 36 months, could be the only specialty certification required, and even that could be waived, before September 1, 2018, if the primary surgeon has: observed at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement; done a pre-operative evaluation of at least 3 potential upper limb transplant patients; acted as primary surgeon of a least 1 upper limb transplant; completed a post-operative follow-up of at least 1 upper limb recipient for 1 year post-transplant. This basically means that the primary surgeon needs no certification, and if not certified, needs only to have operated as the primary surgeon on one upper limb procurement and transfer. This also means that the primary surgeon for the living donor could have no experience in upper limb procurement or as a transfer primary surgeon. Upper limb transplantation/recovery is a mutilating and life-altering donation for which such lack of credentialing and minimal experience are entirely unsatisfactory. In addition, there is the requirement of the completion of

an approved hand surgery fellowship program approved by the MPSC; and any Accreditation Council of Graduate Medical Education (ACGME) approved hand surgery fellowship program will be automatically accepted as meeting this requirement. However, in lieu of this, the *Proposal* states that any other hand surgery fellowship program which has physicians and program standards meeting certain specific criteria is acceptable, ***or*** in lieu of even this, the primary surgeon must have 2 years of practice with a minimum of 114 specified (by type) surgical cases completed. It would be more appropriate to make this latter requirement a minimum, and not an alternative pathway for credentialing.

B. Additional Primary Surgeon Requirements for Head and Neck Transplant Programs

Certification in Plastic Surgery, Otolaryngology, Oral and Maxillofacial Surgery ***or*** just Surgery, which can be deferred for up to 36 months, could be the only specialty certification required, and even that could be waived before September 1, 2018 if the primary surgeon has: observed at least 2 multi-organ procurements and acted as the first-assistant or primary surgeon on at least 1 VCA procurement; done a pre-operative evaluation of at least 3 potential head and neck transplant patients; acted as primary surgeon of a least 1 head and neck transplant; and completed a post-operative follow up of at least 1 head and neck recipient for 1 year post transplant. This basically means that the primary surgeon needs no certification, and if not certified, only needs to have operated as the primary surgeon on one head and neck patient procurement and transfer. That also means that, for the living donor, the primary surgeon might only have had experience with one procurement as the primary head and neck surgeon or, if certified, no such primary surgeon experience. This procurement could include the larynx – vital to life. This is a mutilating and life altering donation and such lack of credentialing is entirely unsatisfactory. In addition, there is the requirement of completion of an approved Plastic Surgery, Otolaryngology, Oral and Maxillofacial Surgery, or Craniofacial Surgery fellowship program approved by the MPSC, and any Accreditation Council of Graduate Medical Education (ACGME)-approved fellowship program will be automatically accepted for this requirement. However, in lieu of this, any other Plastic Surgery, Otolaryngology, Oral and Maxillofacial Surgery, or Craniofacial Surgery fellowship program which has physicians and program standards meeting certain specific criteria is acceptable, ***or*** in lieu of even this, the primary surgeon must have 2 years of practice in head and neck procedures, been primary surgeon on one facial transplant, and have completed 20 other specified head and neck procedures. It would be more appropriate to make this latter requirement a minimum, and not an alternative pathway, for credentialing.

C. Additional Primary Surgeon Requirements for Abdominal Wall Transplant Programs

The primary surgeon for an abdominal wall transplant program must meet the primary transplant surgeon requirements of a head and neck, kidney, liver, pancreas, or upper limb transplant program, but these are not specific to VCAs. In addition, the primary surgeon must have current American Board of Medical Specialties certification in a specialty relevant to the type of VCA transplant the surgeon will be performing, have observed at least 2 multi-organ procurements, have completed pre-operative evaluation of at least 3 potential VCA transplant

patients, and have current working knowledge in the surgical specialty, defined as independent practice in the specialty over a consecutive five-year period. The primary surgeon is to have assembled a multidisciplinary surgical team that includes the primary surgeon with board certification in the relevant surgical specialty and other specialists necessary to complete the VCA transplant including, for example, plastic surgery, orthopedics, otolaryngology, obstetrics and gynecology, urology, or general surgery. This team must include a team member that has extensive microvascular experience including replantation, revascularization, free tissue transfer, and major flap surgery. The team must have demonstrated detailed planning and cadaver rehearsals that are specific to the type or types of VCA transplant the program will perform. However, the primary surgeon does not have to have done a VCA procurement or transfer. While the requirement for the surgical team seems adequate, the primary surgeon has no requirement of direct surgical experience with this or other types of VCA procurement or transfer. This is a significant deficiency in experience and needs to be addressed. It becomes more problematic since recovery, especially with this surgery, can be from a living donor.

In Summary

While we recognize attempts at meeting the safety needs through experience and credentialing of the primary physicians and primary surgeons, there are significant gaps to assure public safety, not only of the living donor, but also of the recipient. We recognize that there is a paucity of cases from which primary surgeons can garner experience. This can be remedied by limiting approval of such programs to a few regional centers where experiences can be multiplied for surgeons, who can train in such centers, and become adequately credentialed, rather than merely observe organ procurements in order to qualify as a primary surgeon. This is crucial for the wellbeing of the living donor, who has the most to lose, as well as for follow-up for both the donor and recipient. Furthermore, there are no specified credentials specific for the recovery [from the living donor] surgeon. Patients who are living donors have a great deal to lose in terms of mutilation and creating a disability. This must be addressed.

There is virtually no requirement for assuring adequate medical follow-up and safety to protect these persons over time, be they donor or recipient. These are critical flaws that need to be addressed before any approval is given. Furthermore, the larynx transplant programs should be subject to a specific and separate application, including being restricted to deceased donors only.

We thank you for your very obvious willingness to collaborate with us in addressing the concerns we raise. Any program that involves the medical community in deliberately creating a disability, which living VCA donor-ship clearly creates, needs to be rejected as inconsistent

with any medical standards. However, in the absence of being able to achieve this, the strictest standards for donor and recipient wellbeing need to be promulgated.

Sincerely yours,

Marie T. Hilliard, JCL, PhD., RN
Director of Bioethics and Public Policy