OPTN

Notice of OPTN Policy and Data Collection Changes

Modify Data Collection on VCA Living Donors

Sponsoring Committee:	**Vascularized Composite Allograft Transplantation**
Policies Affected:	***14.5.C: Living Donor Blood Type Determination and Reporting*** ***18.1.B: Timely Submission of Certain Data*** ***18.2: Timely Collection of Data***
Instruments Affected:	***TIEDI Living Donor Registration (LDR) and Living Donor Follow-Up (LDF) VCA Living Donors***
Public Comment:	**August 4, 2020 – October 1, 2020**
Board Approved:	**December 7, 2020**
Board Amended:	**June 14, 2021**
Effective Date:	**Pending OMB approval, implementation, and notice to OPTN members**

Note: The OPTN Board of Directors approved a clarification to VCA-specific policies and bylaws at its meeting in June 2021. Amendments approved as part of the clarification are noted by a corresponding footnote. For more information regarding this clarification, please contact member.questions@unos.org.

Purpose of Policy and Data Collection Changes

These policy changes align data collection for living donors of vascularized composite allografts (VCA) with data collection for other living donors by requiring submission of the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) for VCA living donors. This action also amends policy to enable programming of data collection on VCA living donors in UNet^{SM}. Additional changes to policy were approved in June 2021 via *Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts*. The changes to data collection add VCA-specific data elements to the LDR and LDF, particularly for uterus.

Proposal History

The OPTN collects data on living donors to ensure patient safety when no alternative sources of data exist. When the OPTN first established data collection requirements for living donors, living donation of VCA was not occurring in the U.S. The first living donor VCA transplant was a uterus transplant performed in 2016. Uterus transplants have since increased in frequency and most have been made possible through living donation. Living donation of other VCA types may be performed in the U.S. in the future. This action will improve the OPTN's ability to monitor patient safety through data collection on VCA living donors, including living uterus donors and living donors of other VCA types.

Summary of Changes

Data collection for VCA living donors will be required and will be submitted via UNet.[1] Living donor blood type determination and reporting for VCA living donors will also be managed in UNet rather than documented in a separate record. Data fields specific to VCA will be added to the LDR and LDF. Most of the data fields are specific to uterus but some apply to other or all types of VCA living donors, in the event that living donation of other VCA types occurs.

Implementation

Living donor recovery hospitals supporting uterus transplant programs will need to become familiar with these data collection changes required by the OPTN, and recovery hospital staff will need to become familiar with where to obtain these data from medical records. This proposal may add some administrative burden, particularly for data collection related to living donor uterus transplantation. Transplant hospitals will also conduct living donor blood type verification for VCA recoveries via UNet rather than documenting blood type via donor medical records. Histocompatibility laboratories will need to submit the Donor Histocompatibility data collection instrument for living VCA donors via UNet. This proposal is not anticipated to affect the operations of organ procurement organizations.

The OPTN will modify data collection instruments and communicate the changes to the transplant community. The OPTN will create help documentation for the new data elements to provide additional instruction for submitting these data. This action requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through Office of Management and Budget (OMB) approved data collection forms. Therefore, the forms have been submitted for OMB approval under the Paperwork Reduction Act of 1995.[2] This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline. Implementation of these changes will be coupled with another project to program VCA into UNet.[3]

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

14.5.C Reporting of Living Donor Blood Type and Subtype

The recovery hospital must report and verify the living donor blood type prior to registration with the OPTN using the *Living Donor Feedback Form* as required below:

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[1] Changes to move VCA data collection and allocation to UNet are outlined in a separate OPTN Board of Directors action, and will be implemented concurrently to allow this data to be collected through UNet instruments. Briefing to the OPTN Board of Directors on Programming VCA Allocation in UNet, OPTN Vascularized Composite Allograft Transplantation Committee, December 2020, https://optn.transplant.hrsa.gov/media/4211/bp_202012_programming-vca-allocation-in-unet.pdf (accessed December 11, 2020).

[2] Organ Procurement and Transplantation Network Contract HHSH250201900001C, Performance Work Statement at Task 3.5: Collect official OPTN data to support the operations of the OPTN.

[3] Briefing to the OPTN Board of Directors on Programming VCA Allocation in UNet, OPTN Vascularized Composite Allograft Transplantation Committee, December 2020, https://optn.transplant.hrsa.gov/media/4211/bp_202012_programming-vca-allocation-in-unet.pdf (accessed December 11, 2020).

1. Two different qualified health care professionals, as defined in the recovery hospital's protocol, must each make an independent report to the OPTN for blood type. ~~For covered VCA recoveries, the blood type verification and reporting must be recorded in the living donor's medical record.~~[4]
2. If blood subtype is used for ensuring transplant compatibility or allocation, a qualified health care professional must report blood subtype to the OPTN. This report must be verified by a different qualified health care professional according to the recovery hospital's protocol. ~~For covered VCA recoveries, the blood subtype verification and reporting must be recorded in the living donor's medical record.~~[5]
3. Both qualified health care professionals must use all blood type and subtype determination source documents to verify they:
    a. Contain blood type and subtype (if used for ensuring transplant compatibility or allocation) results for the donor
    b. Indicate the same blood type and subtype (if used for ensuring transplant compatibility or allocation) on the test results. If the results are conflicting or indeterminate, the recovery hospital must refer to their written protocol as outlined in *Policy 14.5.A: Living Donor Blood Type Determination*.
    c. Match the result reported to the OPTN ~~or VCA donor medical record~~

The recovery hospital must document that reporting was completed according to the hospital's protocol and the above requirements.

18.1.B Timely Submission of Certain Data

Members must submit data to the OPTN according to Table 18-1.

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following instruments to the OPTN:*	*Within:*	*For:*
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	60 days after the DHS record is generated	Each living and deceased donor ~~This does not apply to living VCA donors~~
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory

[4] Amended by the OPTN Board of Directors on June 14, 2021.
[5] Ibid.

The following member:	*Must submit the following instruments to the OPTN:*	*Within:*	*For:*
OPO	*Death Notification Registration (DNR)*	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	All imminent neurological deaths and eligible deaths in its DSA
OPOs	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	All deaths reported by a hospital to the OPO
Allocating OPO	*Potential Transplant Recipient* (PTR)	30 days after the match run date by the OPO or the OPTN	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each covered deceased donor VCA organ that is offered to a potential VCA recipient[6]
Host OPO	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered
Host OPO	*Deceased Donor Registration* (DDR)	60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital ~~This does not apply to covered VCA donor organs~~[7]

[6] Amended by the OPTN Board of Directors on June 14, 2021.
[7] Ibid.

The following member:	*Must submit the following instruments to the OPTN:*	*Within:*	*For:*
Recovery Hospitals	*Living Donor Feedback*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living Donor Registration* (LDR)	90 days after the Recovery Hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital ~~This does not apply to covered VCA donor organs~~[8]
Recovery Hospitals	*Living Donor Follow-up* (LDF)	90 days after the six-month, 1-year, and 2-year anniversary of the donation date or	Each living donor organ recovered at the hospital This does not apply to ~~covered VCA,~~[9] domino donor, and non-domino therapeutic donor organs.
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or • 30 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital

[8] Amended by the OPTN Board of Directors on June 14, 2021.
[9] Ibid.

The following member:	*Must submit the following instruments to the OPTN:*	*Within:*	*For:*
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	*Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each covered VCA[10] recipient transplanted by the hospital
Transplant hospitals	*Recipient Malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital
Transplant hospitals	*Transplant Candidate Registration* (TCR)	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. **Error! Reference source not found.** sets standards for when the member must collect the data from the patient.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or 42 days following the transplant date, whichever is first.

[10] Amended by the OPTN Board of Directors on June 14, 2021.

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or 42 days following the transplant date, whichever is first. ~~This does not apply to covered VCA transplants.~~[11]
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date or ~~This does not apply to covered VCA transplants.~~[12]

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[11] Amended by the OPTN Board of Directors on June 14, 2021.
[12] Ibid.

Affected Data Collection

Table 1. TIEDI Living Donor Registration (LDR) for VCA Living Donors

Section of LDR	Data Elements Added
Pre-Donation All VCA Clinical Information	Toxoplasma IgG
Pre-Donation Uterus Clinical Information	Human Papillomavirus (HPV) - cervical specimen only by DNA or mRNA
	Herpes Simplex Virus (HSV) 1/2 (IgG)
	Gonorrhea (NAT)
	Chlamydia (NAT)
	Vaginal Candidiasis (collected at the time of evaluation)
	Vaginal Candidiasis (collected at the time of donation)
	Bacterial Vaginosis *(Gardnerella vaginalis)*
	Trichomoniasis
	Other Testing
	Uterine Imaging
	Gravidity
	Parity
	Spontaneous Abortion
	Induced Termination
	Prior Full Term Live Births
Uterus Surgical Information	Intended Procedure Type
	Conversion from Robotic to Open
	Operative Time (surgical time from skin to skin)
	Ovaries Removed
	Intra-Operative Complications
	Ureter Injury
	Anesthetic Complications
	Other Complications
Other VCA Surgical Information	Intra-Operative Complications
	Anesthetic Complications
Uterus Post-Operative Information	Length of ICU Stay (days)
Uterus Related Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	Post-Operative Complications
Other VCA Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	Post-Operative Complications
All VCA Post-Operative Complications (At discharge or 6 weeks, whichever occurs first)	Reoperation

Table 2. TIEDI Living Donor Follow-up (LDF) for VCA Living Donors

Section of LDF	Data Elements Added
Complications	Complications Since Uterus Donation
	Menopausal Symptoms (uterus donors only)
	New Onset Psychological Symptoms (all VCA)
	Complications Since Other VCA Donation