OPTN

Notice of OPTN Data Collection Changes

Update to VCA Transplant Outcomes Data Collection

Sponsoring Committee:	**Vascularized Composite Allograft Transplantation**
Data Collection Affected:	***TIEDI Transplant Recipient Registration (TRR) and Transplant Recipient Follow Up (TRF)*** ***VCA Recipients***
Public Comment:	**January 22, 2020 – March 24, 2020**
Board Approved:	**June 8, 2020**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Data Collection Changes

These updates to VCA transplant outcomes data collection will capture more relevant data as the field of VCA transplantation continues to evolve, particularly with an increase in uterus transplants. The current VCA TRR and TRF data collection instruments do not contain fields specific for uterus transplantation and do not adequately capture transplant outcome data for upper limb, head and neck, and uterus transplant recipients.

Proposal History

The updates to VCA data collection were developed by a subcommittee of the VCA Committee. The Committee consulted numerous experts in the field in developing this proposal. Experts from the American Society for Reconstructive Transplantation (ASRT), the American Society for Transplant Surgeons (ASTS), the American Society for Transplantation (AST), and VCA transplant programs were included in these efforts to amend transplant outcome data collection by VCA type. The proposal was supported in public comment in spring 2020. Some suggestions for changes were made by stakeholders. Based on public comment and OPTN Board Policy Group feedback, the Committee made some changes to the original public comment proposal. The changes to VCA data collection were approved by the Board without amendment at the June 8, 2020 meeting.

Summary of Changes

Data fields on the TRR and TRF for VCA will change. Some data fields will be removed for all types of VCAs and some data fields will be removed only for specific VCA types. There will be some changes such as substituting the SF-12 for the current SF-36. Lastly, data fields will be added to the TRR and TRF for all VCA types with significant additions to the uterus VCA forms. See the “Affected Data Collection” section below for details.

Implementation

VCA transplant programs will need to become familiar with these changes to data required by the OPTN. Transplant hospital staff will need to become familiar with the new data requirements and where to

obtain these data from medical records. This proposal may add additional administrative burden, particularly for data collection related to uterus transplantation, in the interest of protecting recipient safety and improving outcome assessment.

This proposal is not anticipated to affect the operations of Organ Procurement Organizations or histocompatibility laboratories.

This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. As these data are proposed to be collected under §121.11(b)(2) of the OPTN Final Rule, after OPTN Board approval they must be submitted for OMB approval under the Paperwork Reduction Act of 1995. Once OMB-approved, the data will be maintained according to the OPTN System of Records Notice.[1] This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

VCA candidate registration/removal, organ matching, and data submission are not currently programmed in UNet^{SM} but the OPTN plans to program these functions in UNet^{SM} with a target implementation date of December 2021. Once the revisions are approved by OMB, the updated TRR and TRF instruments will also be programmed into UNet^{SM}. Help documentation and instructions will be updated to assist members with data submission.

Affected Data Collection

Table 1: TIEDI Transplant Recipient Registration (TRR) for VCA Recipients

Current Data Collection Instrument Field	Removal	Modification	Addition
Cognitive development	All VCA types		
Patient on life support	All VCA types		
Risk factors at the time of transplant (coagulopathies, other)	All VCA types		
Carroll test	Upper limb		
Topical immunosuppression	Uterus		
Previous skin grafts	Uterus		
Skin changes noted with acute rejection	Uterus		
SF-36		Change to SF-12 All VCA types	
Subsequent surgeries required			Upper limb
Smile restoration			Head and neck
Ability to open and close eyelids			Head and neck
Prior reconstructive gynecological procedures			Uterus
Prior pregnancies			Uterus
Diagnosed Psychiatric condition(s) pre-transplant			Uterus
Subsequent surgeries required during admission			Uterus
Visual changes noted during cervical examination			Uterus

[1] "System of Record Notice 09-15-0055," Health Resources & Services Administration, accessed July 1, 2020, https://www.hrsa.gov/about/privacy-act/09-15-0055.html.

Table 2: TIEDI Transplant Recipient Follow Up (TRF) for VCA Recipients

Current Data Collection Instrument Field	Removal	Modification	Addition
Cognitive development	All VCA types		
Carroll test	Upper limb		
Semmes-Weinstein monofilament test	Upper limb		
Topical immunosuppression	Uterus		
Skin changes noted with acute rejection	Uterus		
SF-36		Change to SF-12 All VCA types	
Subsequent surgeries required			Upper limb, uterus
Grip strength and pinch test			Upper limb
Basic Command Questions • Is the patient able to make a fist? • Can the patient comb their hair? • Can the patient open a door? • Can the patient write on a piece of paper? • Can the patient hold a cup?			Upper limb
Two-point discrimination test			Upper limb
Hot and cold sensation			Upper limb
Smile restoration			Head and neck
Ability to open and close eyelids			Head and neck
Prior pregnancies			Uterus
Blood transfusions required following delivery			Uterus
Embryo transfer(s)			Uterus
Date of positive pregnancy test result			Uterus
Date embryonic heart beat detected by ultrasound			Uterus
Estimated delivery date			Uterus
Miscarriage (y/n) and date (if applicable)			Uterus
New onset maternal diagnosed psychiatric condition(s)			Uterus
Pregnancy complications			Uterus
Maternal complications at delivery			Uterus
Delivery type (vaginal/cesarean)			Uterus
Hysterectomy (y/n) and date, performed following successful delivery or due to complication			Uterus
Reason for readmission(s)			Uterus
Date of admission to Transplant Center for delivery			Uterus
Date of discharge from Transplant Center post-delivery			Uterus
Post-delivery complications			Uterus

Current Data Collection Instrument Field	Removal	Modification	Addition
Surgical, medical, or psychiatric complications after hysterectomy			Uterus
Visual changes noted on cervical examination			Uterus

Please refer to the public comment proposal briefing paper available at https://optn.transplant.hrsa.gov/governance/public-comment/update-to-vca-transplant-outcomes-data-collection/ for rationale, data definitions, and other data collection details. Data definitions will be available in help documentation in the reporting system.