At a glance

Title: Update to VCA Transplant Outcomes Data Collection
Sponsoring Committee: Vascularized Composite Allograft Transplantation

What is current policy and why change it?

OPTN data submission requirements for Vascular Composite Allograft transplant (VCA) recipients were implemented September 2015. A review of data reported to the OPTN since that time noted opportunities to refine the data collection to further capture recipient outcomes. This proposal will modify data reported to the OPTN on VCA transplants.

What's the proposal?

- **Modify existing Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) instruments** used to collect data on head and neck, and upper limb transplant recipients.
- **Add new data elements** for uterus on TRR and TRF instruments
- **Request feedback** on the data elements to collect for VCA types such as larynx, abdominal wall and penis.

What's the anticipated impact of this change?

- **What it's expected to do**
  - Create consistent data elements across VCA types that are developed by consensus in the field.
  - Develop VCA outcomes data that can be used for future policy decision making.
- **What it won't do**
  - Change data reporting policy requirements, e.g., when instruments are due, for OPTN members.

Themes to consider

- Additional data submitted on uterus transplant recipients
- What data elements should be collected for other VCA types, including abdominal wall, larynx, musculoskeletal graft segments and penis? The feedback received from the transplant community will inform a future data collection proposal requiring data collection on the above VCA types other than upper limb, head and neck and uterus.
- Which is the most appropriate psychosocial assessment to be included on the Transplant Recipient Follow-up (TRF) instrument for all VCA types?

Terms you need to know

- **Transplant Recipient Registration (TRR):** The data collection instrument completed and submitted by the transplant center when a patient is transplanted. The form contains patient status, pre-transplant clinical measures, transplant procedure, post-transplant clinical measures, graft status, treatment and immunosuppression.
- **Transplant Recipient Follow-up (TRF):** The data collection instrument completed and submitted by the transplant center containing recipient information at six months post-transplant (all but thoracic) and annually thereafter. The data collection instrument contains patient status, clinical measures at follow-up, graft status, viral detection, treatment and immunosuppression.
- Click here to search the OPTN glossary

OPTN

Public Comment Proposal

Update to VCA Transplant Outcomes Data Collection

OPTN Vascularized Composite Allograft (VCA) Transplantation Committee

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Update to VCA Transplant Outcomes Data Collection

Sponsoring Committee: *Vascularized Composite Allograft (VCA) Transplantation*
Public Comment Period: *January 22, 2020– March 24, 2020*

Executive Summary

Since 2014 when the OPTN received authority to collect data on VCA transplants, the diversity of the VCA waiting list has expanded significantly to include other VCA types, such as uterus and penis. Current VCA data collection only covers outcomes data specific to the VCA types performed in higher numbers prior to 2014. These were primarily upper limb and head and neck transplants. Outcomes data on newer VCA types are limited. Furthermore, the unique nature of VCA transplant outcomes differs from more established organs because the primary objective of a VCA transplant is life-enhancing. Existing data collection instruments for VCA transplant recipients are modeled after other solid organ transplant instruments in the Transplant Information Electronic Data Interchange (TIEDI®) to capture core data and assess safety. As the field continues to evolve, the VCA Committee (Committee) has observed that transplant programs are performing additional outcome assessments on OPTN data collection instruments, as well as performing different outcomes assessments not reported to the OPTN. This limits the OPTN's ability to understand and fully assess outcomes from VCA transplants.

In order to address these identified gaps and limitations in VCA data collection, this proposal aims to modify current VCA Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) instruments to capture more relevant transplant outcome data elements for upper limb, head and neck, and uterus transplant recipients. Both data field removals and additions are proposed. The majority of additions are proposed for uterus data collection. This is the first major revision for uterus data collection and there are unique complications and outcomes associated with this transplant type that are not required reporting at this time. The Committee is also requesting feedback from the transplant community regarding data elements to collect for other VCA types, including abdominal wall, larynx, musculoskeletal composite graft segment, and penis. Feedback received from the transplant community will inform a future data collection proposal requiring data collection for those VCA types.

Purpose of the Proposal

In order to address gaps and limitations in current VCA data collection, this proposal aims to modify current VCA Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) instruments to capture additional transplant outcome data elements for upper limb, head and neck, and uterus transplant recipients. This proposal removes data elements that are not relevant to VCA in general or the specific VCA type. The Committee is also requesting feedback from the transplant community regarding the data elements to collect for other VCA types, including abdominal wall, larynx, musculoskeletal graft segments and penis. The feedback received from the transplant community will inform a future data collection proposal requiring data collection on the above VCA types other than upper limb, head and neck and uterus.

The Committee is also requesting feedback during this winter 2020 Public Comment period, in a separate document entitled: *Measuring Transplant Outcomes by Collecting Data on Children Born to Uterus Recipients.*

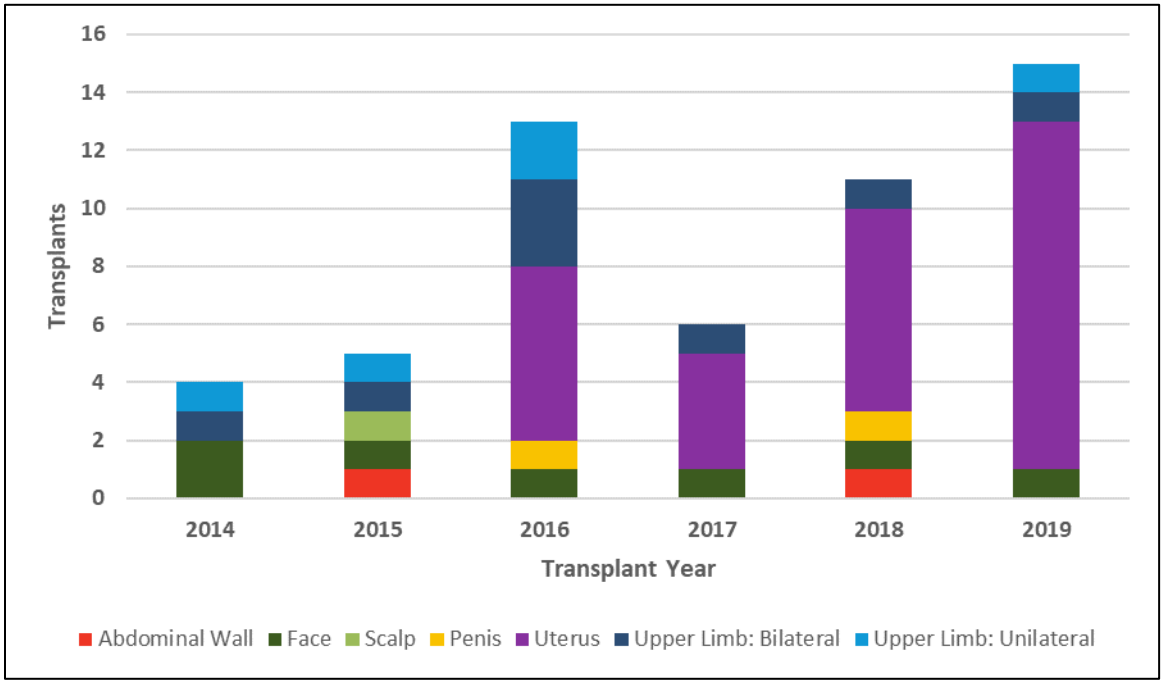
Background

In 2014, OPTN regulatory authority for VCA transplants went into effect.[1] VCA recipient data collection was implemented the following year. Section 121.11 (b)(2) of the Final Rule gives the OPTN authority to collect data from OPTN members on transplant recipients.[2] Throughout this document, there are references to required versus optional data fields. These references are to delineate which data fields must be completed in order to meet the OPTN data collection requirements. The term optional refers to data fields that can be submitted yet if omitted will not cause the data submission to be considered incomplete due to the omission of data in optional fields.

When the OPTN first started data collection, the primary VCA performed were head and neck (craniofacial) and upper limb. The types of VCAs performed have continued to expand with uterus now being the most common VCA transplant (Figure 1, next page).

[1] Organ Procurement and Transplantation Network, "Vascular composite allografts to be added to OPTN final rule and federal definitions of organs" (2013). https://optn.transplant.hrsa.gov/news/vascular-composite-allografts-to-be-added-to-optn-final-rule-and-federal-definitions-of-organs/. Accessed January 2, 2020.
[2] 42 C.F.R. § 121.11(b)(2) https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5#se42.1.121_111. Accessed January 19, 2020.

Figure 1: VCA Transplants in the U.S.: July 3, 2014-2019[3]



OPTN *Policy 18.1: Data Submission Requirements* outlines basic data submission requirements for all transplant programs, including VCA.[4] VCA data collection is currently stratified by abdominal wall, head and neck, upper limb, and other VCA types. All VCA programs report general information (e.g. demographics and recipient status) and recipient clinical information (e.g. primary diagnosis/cause of transplant and pre-transplant lab test results) shortly after the time of transplant on the TRR. VCA TRRs also contain fields for reporting pre-transplant functional status (e.g. cognitive and motor development); transplant procedure clinical information (e.g. procedure type); and post-transplant clinical information (e.g. graft status and medications). Bilateral upper limbs have several additional requirements to provide ability to report variations between right and left grafts.[5]

Follow up information for all organ transplants, including VCAs, are submitted to the OPTN at six months and then annually from the date of transplant on the TRF.[6] The VCA TRF currently contains data fields related to general information, recipient clinical information, and functional status. The TRF contains some unique post-transplant data fields such as whether re-hospitalization has occurred as well as results on functional outcome tests. Both the TRR and TRF currently have required data fields for completing the Short Form Health Survey (SF)-36 which measures physical and mental health. For upper limb recipients, both the TRR and the TRF contain required data fields for the Disabilities of the

[3] Based on OPTN data as of January 9, 2020.
[4] OPTN Policy 18.1 *Data Submission Requirements*, accessed January 2, 2019. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf
[5] See Appendix 1 of this document for a summary table of data elements.
[6] See OPTN Policy 18.1 *Data Submission Requirements,* Table 18-1 for Transplant Hospital requirements.

Arm, Shoulder, and Hand (DASH) score and the Carroll hand function test.[7, 8] Upper limb follow-up data instruments also require submission of information on the Semmes-Weinstein Monofilament Test to help reflect functional outcome status.[9] Appendix 1: *Current VCA TRR and TRF Data Collection Summary* contains more details of the current VCA TRR and TRF data collection instruments.

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. These stakeholders also provided recommendations for additional professionals to be included in the discussions to help ensure adequate specialty knowledge and input for all of the various VCA types. They helped the Committee identify the range of outcome assessments collected currently by VCA programs and how they differ from current OPTN requirements. The Committee, with stakeholder consultation, worked to gain consensus on what other outcome assessments should be collected, including those measuring psychosocial and functional outcomes.

The Committee also sought input and guidance from the OPTN Data Advisory Committee (DAC) to improve data quality and to ensure that the data elements proposed for modification and revisions on the TRR and TRF were in alignment with the OPTN Principles for Data Collection.[10] The proposed data elements have been evaluated against the DAC's newly developed Data Element Standards of Review Checklist. VCA Committee leadership presented this checklist analysis to the DAC in September 2019 and the DAC endorsed the project.

The OPTN final rule authorizes the OPTN to collect data on transplant recipients.

This proposal aligns with the OPTN strategic plan goals related to outcomes and safety.[11] The proposed improvements and clarifications in VCA data collection will help promote transplant recipient safety and improved outcomes by capturing more relevant and VCA type specific data elements.

Proposal

This proposal aims to modify current VCA TRR and TRF instruments to remove unnecessary and add relevant transplant outcome data elements for head and neck, upper limb, and uterus transplant recipients. The majority of additions are in the proposed uterus TRR and TRF instruments.

First the proposal would remove data fields that are not considered pertinent to VCA in general or a specific VCA type. The data fields proposed for removal include the Carrol and Semmes-Weinstein from

[7] Christina Gummesson, Isam Atroshi, and Charlotte Ekdahl. "The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: longitudinal construct validity and measuring self-rated health change after surgery". *BMC Musculoskeletal Disorders 4* no. 11 (2003). doi: 10.1186/1471-2474-4-11

[8] Daniel Carroll. "A quantitative test of upper extremity function," *Journal of Chronic Disease, 18* no. 5 (1965): 478-91, doi.org/10.1016/0021-9681(65)90030-5.

[9] Mukund R. Patel, Lynn Bassini. "A Comparison of Five Tests for Determining Hand Sensibility", *Journal of Reconstructive Microsurgery 15* no. 7 (1999): 523-26, DOI: 10.1055/s-2007-1000132.

[10] OPTN, *Principles of Data Collection*. Accessed January 2, 2020. https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/

[11] OPTN, *Visions and Goals*. Accessed January 2, 2019. https://optn.transplant.hrsa.gov/governance/about-the-optn/vision-goals/

all data collection instruments and VCA types. These tests are no longer performed or preferred for VCA upper limb functional measurement. The Committee recommends keeping the DASH solely for upper limb transplants. Also recommended for removal are fields that are not universally collected, defined to the degree needed for useful data collection, or appropriate for VCA. These proposed removals for all VCA types include: cognitive development, patient on life support, and risk factors at the time of transplant (coagulopathies, other). Hemoglobin A1c is proposed to be changed to collection on the TRR instead of the TRF.[12] Pre-transplant psychological disorders would be removed from VCA TRFs as this field is only a pre-transplant measure. Some removals would only apply to specific VCA types. These include removal of skin changes noted with acute rejection for head and neck and uterus instruments. Previous skin grafts and topical immunosuppression are proposed for removal from uterus VCA data collection as they are not relevant to this transplant type.

For upper limb transplants, new proposed data collection fields include subsequent surgeries both on the TRR and TRF as well as other tests to measure post-transplant functionality. Additional functional outcome data fields would include grip strength and pinch, two-point discrimination, hot and cold sensation, and additional basic command questions. These proposed elements would provide more discrete and measurable outcome data for upper limb transplants.

For face and neck transplants, new proposed data collection fields include smile restoration; two-point discrimination; and hot and cold sensation. In addition, the ability to open and close eyelids would replace the current blink data field. These are proposed as clearer functional indicators of anticipated outcome gains from face and neck transplantation.

For uterus transplants, there are substantial new proposed elements aimed at measuring reproductive milestones and outcomes. These include data fields for prior and subsequent post-transplant pregnancies. Data would be required on miscarriage, complications of pregnancy and delivery, and hysterectomy. Other data fields would capture hospitalization dates as well as other related reproductive test results and surgeries. Seven new fields would be added to the TRR and 19 new fields would be added to the TRF. Nine out of the 19 new fields are date fields and it is important to note that not all fields would be applicable. Most of these are fields are conditional based on the clinical situation. These fields are needed to measure the range of possible outcomes following uterus transplant.

Tables containing more details on all proposed data element changes, both removals and additions, along with supporting rationale for each VCA type and data collection instrument are located in Appendix 2: *Proposed Modifications to VCA TRR and TRF Data Collection*.

Proposed data definitions are also included for all new data elements and are found in Appendix 3: *Proposed Data Definitions*. Data definitions are part of all OPTN data collection instruments to use as a reference tool for members when inputting data on the TRR and TRF instruments. These are being included in the proposal to allow for public comment and potentially improve the definitions as needed prior to approval and implementation. Through robust discussion and feedback, the Committee developed these proposed modifications aiming for the revised data collection to be objective, consistent, and clinically reflective of differences between VCA types.

[12] National Institute of Diabetes and Digestive and Kidney Diseases. *The A1c Test and Diabetes*. Accessed January 2, 2019. https://www.niddk.nih.gov/health-information/diabetes/overview/tests-diagnosis/a1c-test

The Committee is requesting feedback from the community regarding the most appropriate psychosocial assessment to be included on the TRF for all VCA types. Although the SF-36 is on the current instrument, the Committee is considering three potential psychosocial instruments: Medical Outcomes Study, Short Form Health Survey (SF)-36, SF-12 and the Patient Generated Index (PGI).[13, 14, 15] One of these instruments is planned for inclusion with the other proposed data elements as part of a proposal planned for OPTN Board of Directors consideration following this public comment. The psychosocial evaluation chosen to be included on the TRF would not be required per OPTN policy for transplant programs to complete. Table 1 outlines advantages and disadvantages the Committee discussed for each proposed psychosocial evaluation instrument.

Table 1: Psychosocial Assessment Comparison

Psychosocial Evaluation	Overview	Advantages	Disadvantages
SF-36	Is a health survey that asks 36 questions to measure functional health and well-being from the patient's point of view	• Is currently being used by the OPTN • Is generic enough to be used and compared across ages, disease, and treatment group • Meaningful to patients and clinicians across the healthcare spectrum • Practical and reliable measure of physical and mental health • Provides scores for each of the eight health domains	• The SF-36 is longer than SF-12 and requires more time to complete
SF-12	Is a shorter version of the SF-36 that uses 12 questions to measure functional health and well-being from the patient's point of view	• Shorter than the SF-36 and easier to complete • Practical and reliable measure of physical and mental health • Is useful in large population health surveys or for applications that combine a generic and disease-specific health survey	• Possible lack of familiarity among providers

[13] Rand Health Care. "36-item short form survey (SF-36)". Accessed January 2, 2020. https://www.rand.org/health-care/surveys_tools/mos/36-item-short-form.html
[14] Rand Health Care. "12-item short form survey (SF-12)". Accessed January 2, 2020. https://www.rand.org/health-care/surveys_tools/mos/12-item-short-form.html
[15] Danny A. Ruta, et al. "A New Approach to the Measurement of Quality of Life: The Patient-Generated Index". *Medical Care 32* no. 11, (1994): 1109-26. www.jstor.org/stable/3766320

Psychosocial Evaluation	Overview	Advantages	Disadvantages
Patient Generated Index (PGI)	Quantifies the effect of a medical condition on a patients' quality of life in a way that has meaning and relevance in the context of their daily lives. Patients formulate their own responses in an open-ended format.	• Created to reflect the patient's perception of their health • Allows the patient to rate the extent to which those aspects of life are affected by the condition • Is reproducible over time • Suitable for a wide variety of patients in different settings • Has been used with lower extremity amputees	• Lack of familiarity • May involve more explanation to the patient • May involve some additional cost (e.g. training of staff) • Is currently under research • Takes approximately five minutes to complete

Request for Feedback for Future Data Proposal

The Committee discussed the need to capture additional data on miscellaneous VCA types, including those performed on very low volume basis driven by unique patient needs. They have discussed potential modifications to data collected on abdominal wall, larynx, musculoskeletal composite graft segment, and penis transplants. The ideas under consideration would better capture unique functionality and complications specific to these types of transplants. Tables 2 and 3 outline areas for data elements under consideration and needing community comment.

Table 2: Potential VCA Transplant Recipient Data Reported Shortly After Transplant on TRR

	Abdominal Wall	Larynx	Musculoskeletal composite graft segment	Penis
Complications (specify)	X	X	X	X

Table 3: Potential VCA Transplant Recipient Data Reported at Six Months, Then Annually on TRF

	Abdominal Wall	Larynx	Musculoskeletal composite graft segment	Penis
Complications (hernias, fistulas, dehiscence)	X			
Other complications (specify)	X	X	X	X
Tissue coverage	X		X	
Vocalization		X		
De-cannulation		X		

	Abdominal Wall	Larynx	Musculoskeletal composite graft segment	Penis
Ability to achieve an erection				X
Ability to void through penis				X

The Committee believes that additional feedback is necessary for any new data requirements to be compliant with the OPTN Principles of Data Collection. They are seeking feedback from the transplant community regarding whether the proposed data elements in Tables 2 and 3 are appropriate, or if other data elements should be collected for abdominal wall, larynx, musculoskeletal composite graft segment, and penis transplants. The Committee will consider public comment and develop an additional public comment proposal for these potential TRR and TRF changes.

Potential Impact on Select Patient Populations

Completion of a psychosocial assessment using the SF-36, SF-12, or Patient Generated Index (PGI) that is not required by OPTN policy could be time-consuming. Other mandatory data collection elements proposed for the TRR and TRF should enhance assessment of post-transplant outcomes and provide meaningful data for patient consideration when researching VCA types and transplant program outcomes.

Implementation and Operational Considerations

Overview

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN and would eliminate certain data that are presently collected by the OPTN. Collection of official OPTN data is subject to the Paperwork Reduction Act of 1995, which requires approval from the federal Office of Management and Budget (OMB).[16] The OMB approval process may impact the implementation timeline. If finalized, the data collected would be protected consistent with the Privacy Act of 1974[17], as amended.

Education, communication, and OPTN instrument modification will be necessary to effect these changes once approved by the Board.

OPTN Actions

This proposal will require submission of data to the OPTN that are not presently collected and would eliminate some data that are currently collected. If approved by the OPTN Board of Directors, a review

[16] Office of Management and Budget (1995). Paperwork Reduction Act. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/index.
[17] Privacy Act of 1974, as amended, 5 USC § 522a. https://www.govinfo.gov/content/pkg/USCODE-2018-title5/pdf/USCODE-2018-title5-partI-chap5-subchapII-sec552a.pdf.

by the U.S. Office of Management and Budget (OMB) will be required prior to implementation. The OMB review process may impact the implementation timeline.[18]

Once approved, the TRR and TRF instruments will be disseminated to OPTN-approved VCA transplant programs. Help documentation and instructions will be updated to assist members with data submission.

VCA candidate registration/removal, organ matching, and data submission are not currently programmed in UNet^{SM}. The OPTN plans to program these functions into UNet in the upcoming year as part of implementation.

The feedback received regarding data elements to collect for miscellaneous VCA types will be utilized to develop a future data collection proposal.

Member Actions

VCA transplant programs will need to become familiar with 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.

Fiscal Impact

This proposal is aimed at gathering additional VCA recipient data to better understand transplant outcomes and would apply to all VCA transplant recipients. Uterus transplant activity has increased substantially since 2016, thus the OPTN proposes collecting additional data to ensure safety and efficacy. The largest scope of changes would be for uterus transplant programs. Though there is a net increase for data required for head and neck or upper limb transplant recipients, this is inclusive of both additions and deletions to these data sets.

A secondary goal of this proposal is to decrease the data and reporting burden on transplant hospitals by programming the VCA transplant recipient data collection instruments into UNet. Transplant center staff supporting head and neck or upper limb transplant programs will be able to spend less time submitting data not pertinent to VCA transplantation.

The committee seeks feedback during public comment on a new tool to gather VCA recipient quality of life data. Depending on the tool selected by the Committee, there may be a cost for programs to purchase and implement the tool, train staff, and conduct the evaluation with recipients.

There is no expected fiscal impact for OPOs or histocompatibility laboratories.

[18] The collection of official OPTN data is subject to the Paperwork Reduction Act of 1995. Office of Management and Budget (1995). Paperwork Reduction Act. Retrieved from https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/index

Post-implementation Monitoring

Member Compliance

The proposed data collection will not change the current routine monitoring of members. All data submitted to the OPTN may be subject to further review and members are required to provide documentation as requested.

Policy Evaluation

Although there is no proposed policy language and formal evaluation, the Committee will monitor and review completion rates for the new data elements.

Conclusion

In order to address gaps and limitations in VCA data collection, this proposal aims to modify current OPTN TRR and TRF instruments to capture additional transplant outcome data elements for head and neck, upper limb, and uterus transplant recipients.

The Committee is also requesting feedback from the transplant community regarding data elements to collect for other VCA types, including abdominal wall, larynx, musculoskeletal composite graft segment, and penis. The feedback received from the transplant community will inform a future data collection proposal requiring data collection on the above VCA types.

- What data elements should be collected for these other miscellaneous VCA types?
- Which is the most appropriate psychosocial assessment to be included on the TRF instrument for all VCA types?

The proposed changes to the data collection will support the OPTN strategic goals to promote transplant recipient safety and improve transplant recipient outcomes.

Appendix 1: Current VCA TRR and TRF Data Collection Summary

Data Fields on VCA TRR Instrument	Abdominal Wall	Head and Neck	Upper Limb	Other VCA
General information				
Recipient information (demographics)	X	X	X	X
Provider information (physician, surgeon)	X	X	X	X
Donor information (UNOS Donor ID, donor type, OPO)	X	X	X	X
Recipient status (transplant admission and discharge date, living/deceased/re-transplanted, cause of death if applicable)	X	X	X	X
Socio-demographic information (level of education, work status, disability, transplant funding source)	X	X	X	X
Recipient clinical information				
Height/Weight/Body Mass Index (BMI)	X	X	X	X
Primary diagnosis/cause of transplant	X	X	X	X
Amount of tissue loss	X	X		X
Level of amputation (limb specific)			X	
Previous transplants (VCA & non-VCA)	X	X	X	X
Previous skin grafts	X	X	X	X
Inpatient hospitalization prior to transplant	X	X	X	X
Life support (if applicable)	X	X	X	X
Viral detection (HIV, CMV, HBV, HCV, EBV)	X	X	X	X
Tolerance used	X	X	X	X
Pre-transplant transfusions	X	X	X	X
Pre-transplant pregnancies	X	X	X	X
Pre-transplant malignancies	X	X	X	X
Pre-transplant lab test results (creatinine, A1c, calculated panel reactive antibody (CPRA), donor cross-match results)	X	X	X	X
Risk factors (coagulopathies, other)	X	X	X	X
Pre-transplant functional status				
Cognitive development	X	X	X	X
Motor development	X	X	X	X
Short Form Health Survey (SF)-36 (Physical/Mental Health)	X	X	X	X
Disabilities of the Arm, Shoulder, and Hand (DASH)			X	
Carroll Test			X	
Transplant procedure clinical information				
Multiple graft recipient (including non-VCA)	X	X	X	X
Extra allograft vessels/nerves/tissues from outside the donated graft	X	X	X	X
Procedure type	X	X	X	X
Preservation information (warm and cold ischemic times (WIT/CIT))	X	X	X	X
Post-transplant clinical information				
Graft status (functioning/failed, other related information if failed)	X	X	X	X
Bilateral limb graft status			X	
Laboratory data at time of discharge (creatinine, A1c)	X	X	X	X
Major transplant complications (thrombosis, blood transfusions, cardiac arrest, disseminated intravascular coagulation (DIC), graft/reperfusion syndrome, other)	X	X	X	X
Acute rejection (after transplant, but before discharge)	X	X	X	X
Treatment (anti-viral/bacterial/fungal prophylaxis)	X	X	X	X
Topical and non-topical immunosuppressive medications	X	X	X	X
Bilateral upper limb complications			X	

Data Fields on VCA TRF Instrument	Abdominal Wall	Head and Neck	Upper Limb	Other VCA
General information				
Recipient info (demographics)	X	X	X	X
Provider information (physician, surgeon, follow-up location)	X	X	X	X
Donor information (UNOS Donor ID, donor type, OPO)	X	X	X	X
Recipient status (date last seen, living/deceased/re-transplanted, re-hospitalization)	X	X	X	X
Socio-demographic info (work status, disability, transplant funding source)	X	X	X	X
Recipient clinical information				
Height/Weight/Body Mass Index (BMI)	X	X	X	X
Noncompliance issues (immunosuppression, rehab, level of activity, other)	X	X	X	X
Graft Status (Functioning/failed, details if failed)	X	X	X	X
Complications (diabetes, metabolic, infection, other)	X	X	X	X
Malignancy screening	X	X	X	X
Treatment (antiviral, antibacterial, antifungal)	X	X	X	X
Topical immunosuppressive	X	X	X	X
Non-topical immunosuppressive	X	X	X	X
Functional status				
Cognitive development	X	X	X	X
Motor development	X	X	X	X
Psychosocial consult (Y/N)	X	X	X	X
Short Form Health Survey (SF)-36 (Physical/Mental Health)	X	X	X	X
Disabilities of the Arm, Shoulder, and Hand (DASH)			X	
Carroll Test			X	
Semmes-Weinstein			X	
Olfactory restoration		X		
Sensory tests (2 point, hot/cold)		X		
Motor Function (oral competence, corneal protection)		X		
Functional occlusion restoration		X		
De-cannulation		X		
Feeding tube removal		X		
Speech intelligibility test (speaking rate, intelligibility)		X		
Bilateral Limb graft function (multiple points for each limb-functioning/failed, rejection & Banff score, ischemia, sepsis/infection, trauma, noncompliance, recipient requested removal, other)			X	

Appendix 2: Proposed Modifications to VCA TRR and TRF Data Collection

Table 3: Upper Limb Transplant Recipient Registration (TRR)

Add Following Data Elements	Remove Following Data Elements	Rationale
Subsequent surgeries required, date and procedures		*This data element would inform the Committee about any complications resulting post-transplant, such as multiple surgical repairs.*
Hemoglobin A1c		*Hemoglobin A1c is an indicator of average blood sugar for the past 2-3 months. The Committee felt it valuable to collect this information at time of transplant since this can indicate pre-transplant blood sugar levels, thereby creating a baseline for subsequent testing. This is important for VCA transplants because long term use of immunosuppressive medications may increase the risk of developing diabetes, which is diagnosed using Hemoglobin A1c.*
	Carroll Test (upper limb)	*The OPTN received reports that Carroll testing (measures patient's ability to perform tasks requiring a combination of mobility, motor function and sensation) was not universally performed by all upper limb transplant programs. The recommendation is to remove the Carroll test and keep the DASH.*[19]
	Cognitive Development	*There is no standardized definition of "cognitive change". As such, this may be difficult to measure and more applicable to pediatric candidates. This does not inform future policy development or monitor for patient safety.*
	Patient on life support	*VCA transplant candidates are typically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Risk factors at the time of transplant (coagulopathies, other)	*VCA transplant candidates are typically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*

[19] Mukund R. Patel. "A Comparison of Five Tests for Determining Hand Sensibility"

Table 4: Upper Limb Transplant Recipient Follow-up (TRF)

Add following Data Elements	Remove Following Data Elements	Rationale
Grip strength and pinch test		
Two-point discrimination test		*Suggested modifying current collection by capturing more specific data related to the functional outcomes of the VCA transplant. It is important to collect such outcomes, because unlike other solid organ transplants, the intent of VCA transplantation is to restore functionality.*
Hot and Cold sensation		
Subsequent surgeries required, date and procedures		*This data element would inform the Committee about any complications resulting post-transplant, such as multiple surgical repairs.*
Include 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?**		*The Committee suggested modifying the joint function measurement tests to include more basic and specific command questions. These questions will enable a more detailed portrayal of how a patient is able to perform activities of daily living (ADLs).*
	Hemoglobin A1c	*Would not need to have this value on the TRF, because it may not be universally done post-transplant by VCA transplant programs*
	Carroll Test (upper limb)	*The OPTN received reports that Carroll testing (measures patient's ability to perform tasks requiring a combination of mobility, motor function and sensation) was not universally performed by all upper limb transplant programs. The recommendation is to remove the Carroll test and keep the DASH.*
	Semmes-Weinstein Monofilament Test (upper limb)	*The OPTN received reports that Semmes-Weinstein testing was not universally performed by all upper limb transplant programs. The recommendation is to remove the Semmes-Weinstein test and keep the DASH.*
	Cognitive Development	*There is no standardized definition of "cognitive change". As such, this may be difficult to measure and more applicable to pediatric candidates. This does not inform future policy development or monitor for patient safety.*
	Patient on life support	*VCA transplant candidates are typically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*

Add following Data Elements	Remove Following Data Elements	Rationale
	Risk factors at the time of transplant (coagulopathies, other)	*VCA transplant candidates are typically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Psychological disorder(s) pre-transplant (specify)	*This data element only pertains to the TRR.*

Table 5: Head and Neck Transplant Recipient Registration (TRR)

Add Following Data Elements	Remove Following Data Elements	Rationale
Smile restoration		*Suggested modifying current collection by capturing more specific data related to the functional outcomes of the VCA transplant. It is important to collect such outcomes, because unlike other solid organ transplants, the intent of VCA transplantation is to restore functionality.*
Hemoglobin A1c		*Hemoglobin A1c is an indicator of average blood sugar for the past 2-3 months. The Committee felt it valuable to collect this information at time of transplant since this can indicate pre-transplant blood sugar levels, thereby creating a baseline for subsequent testing. This is important for VCA transplants because long term use of immunosuppressive medications may increase the risk of developing diabetes, which is diagnosed using Hemoglobin A1c.*
Ability to open and close eyelids	**Blink R/L**	*The ability to open and close eyelids is more specific and relevant to face transplantation. It is important to collect such outcomes, because unlike other solid organ transplants, the intent of VCA transplantation is to restore functionality.*
	Skin changes noted with acute rejection	*There is already a data element for collecting biopsy data. Also, changes in a patient's skin may not be seen or noticed for recipients of a face transplant.*
	Cognitive Development	*There is no standardized definition of "cognitive change". As such, this may be difficult to measure and more applicable to pediatric candidates. This does not inform future policy development or monitor for patient safety. An alternative question is proposed below.*
	Patient on life support	*VCA transplant candidates are clinical stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Risk factors at the time of transplant (coagulopathies, other)	*VCA transplant candidates are typically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*

Table 6: Head and Neck Transplant Recipient Follow-up (TRF)

Add Following Data Elements	Remove Following Data Elements	Rationale
Smile restoration		*Suggested modifying current collection by capturing more specific data related to the functional outcomes of the VCA transplant. It is important to collect such outcomes, because unlike other solid organ transplants, the intent of VCA transplantation is to restore functionality.*
Two-point discrimination test		
Hot and Cold sensation		
Ability to open and close eyelids	**Blink R/L**	*The ability to open and close eyelids is more specific and relevant to face transplantation. It is important to collect such outcomes, because unlike other solid organ transplants, the intent of VCA transplantation is to restore functionality.*
	Hemoglobin A1c	*Would not need to have this value on the TRF, because it may not be universally done post-transplant by VCA transplant programs*
	Skin changes noted with acute rejection	*There is already a data element for collecting biopsy data. Also, changes in a patient's skin may not be seen or noticed for recipients of a face transplant.*
	Cognitive Development	*There is no standardized definition of "cognitive change". As such, this may be difficult to measure and more applicable to pediatric candidates. This does not inform future policy development or monitor for patient safety. An alternative question is proposed below.*
	Patient on life support	*VCA transplant candidates are clinical stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Risk factors at the time of transplant (coagulopathies, other)	*VCA transplant candidates are typically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Psychological disorder(s) pre-transplant (specify)	*This data element only pertains to the TRR.*

Table 7: Uterus Transplant Recipient Registration (TRR)

Add Following Data Elements	Remove Following Data Elements	Rationale
Prior reconstructive gynecological procedures (specify)		*This would be important to collect as this could increase the candidate's risk of complications, such as sepsis and death.*
Prior pregnancies		*This is important to have as it pertains to the surgical management and/or medical management of the recipient.*
Diagnosed Psychiatric condition(s) pre-transplant (specify)		*Psychological disorders for candidates undergoing organ transplantation are an important issue, as waiting for or receiving a transplant can result in psychological distress (ranging from minor anxiety, to fear of death and organ rejection). This would be important to know, as it may affect how well a candidate is able to cope with receiving a uterus transplant, compliance with medications, and overall outcomes.*
Date of admission to Transplant Center		*This is important to have as it pertains to the surgical management and/or medical management of the recipient. Furthermore, it may be used to calculate length of stay (LOS). It is collected on other TIEDI collection instruments.*
Date of discharge from Transplant Center		*This is important to have as it pertains to the surgical management and/or medical management of the recipient. Furthermore, it may be used to calculate length of stay (LOS). It is collected on other TIEDI collection instruments.*
Subsequent surgeries required during admission (date and procedures)		*This data element would inform the Committee about any complications resulting post-transplant, such as multiple surgical repairs.*
Visual changes noted during cervical examination		*Noting visual changes from cervical examination of a Uterus transplant recipient could indicate organ rejection.*
	Hemoglobin A1c	*Would not need to have this value on the TRF, because it may not be universally done post-transplant by VCA transplant programs*
	Carroll Test (upper limb)	*This data element is not pertinent to uterus transplantation, only upper extremity transplantation.*
	Cognitive Development	*There is no standardized definition of "cognitive change". As such, this may be difficult to measure and more applicable to pediatric candidates. This does not inform future policy development or monitor for patient safety.*
	Patient on life support	*VCA transplant candidates are clinical stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Topical immunosuppression	*This data elements is not pertinent to uterus transplantation, because topical medications would not be used due to a uterus transplant being an internal, not external, allograft transplant.*

Add Following Data Elements	Remove Following Data Elements	Rationale
	Previous skin grafts	*This would not be pertinent to uterus transplantation, because uterus transplant candidates are usually clinical stable, and would not have a history of skin grafts.*
	Skin changes noted with acute rejection	*This data element is not pertinent to uterus transplantation, because skin changes would not be observed due to a uterus transplant being an internal, not external, allograft transplant.*

Table 8: Uterus Transplant Recipient Follow-up (TRF)

Add Following Data Elements	Remove Following Data Elements	Rationale
Prior pregnancies		*This is important to have as having a pregnancy is the intended outcome of a uterus transplant.*
Blood transfusions required following delivery		*This is important to have as it pertains to the surgical management and/or medical management of the recipient.*
Embryo transfer(s) and date(s)		*Pregnancy following uterus transplant may be achieved following one embryo transfer or multiple separate embryo transfers.*
Date of positive pregnancy test result		*Though this may not necessarily be needed for every recipient, it would be useful to know if embryo transfer date is unknown.*
Date embryonic heart beat detected by ultrasound		*Though this may not necessarily be needed for every recipient, it would be useful to know if embryo transfer date is unknown.*
Estimated delivery date		*Would only need to complete this if the embryo transfer date is unknown.*
Miscarriage (y/n) and date (if applicable)		*This is important to have as it pertains to the surgical management and/or medical management of the recipient because if uterus transplant recipients have a higher risk of miscarriage, this would be important to know for the safety of the recipient.*
New onset maternal diagnosed psychiatric condition(s) (specify)		*Psychological disorders for candidates undergoing organ transplantation are an important issue, as waiting for or receiving a transplant can result in psychological distress (ranging from minor anxiety, to fear of death and organ rejection). This would be important to know, as it may affect how well a candidate is able to cope with receiving a uterus transplant, compliance with medications, and overall outcomes.*
Pregnancy complications (specify)		*Pregnancy complications are health problems that occur during pregnancy. Since they often involve the health of the mother, the baby or both, it would be important to track this information for uterus recipients.*
Maternal complications at delivery (specify)		*Maternal complications are health problems that occur during delivery. Since they often involve the health of the mother, the baby or both, it would be important to track this information for uterus recipients.*
Delivery type (vaginal/cesarean) and date		*Once a woman has had a cesarean delivery, there is an increased risk of uterine rupture for future vaginal deliveries. Also, this is important to have as it pertains to the surgical management and/or medical management of the recipient*
Hysterectomy (y/n) and date, performed following successful delivery or due to complication		*This is important to have as it pertains to the surgical management and/or medical management of the recipient.*

Add Following Data Elements	Remove Following Data Elements	Rationale
Reason for readmission(s) (specify)		*Specifying reason for admission is necessary as it could be for hysterectomy, delivery, or another complication. Not knowing what the admission was for would make the length of stay (LOS) difficult to interpret.*
Date of admission to Transplant Center for delivery		*This is important as it pertains to the surgical management and/or medical management of the recipient post-delivery. May be used to calculate LOS.*
Date of discharge from Transplant Center post-delivery		*This is important as it pertains to the surgical management and/or medical management of the recipient post-delivery. May be used to calculate LOS.*
Post-delivery complications (specify)		*This is important as it pertains to the surgical management and/or medical management of the recipient post-delivery.*
Surgical, medical, or psychiatric complications after hysterectomy (specify) and date		*This is important as it pertains to the surgical management and/or medical management of the recipient*
Subsequent surgeries required, date and procedures		*This data element would inform the Committee about any complications resulting post-transplant, such as multiple surgical repairs.*
Visual changes noted on cervical examination		*Noting visual changes on cervical examination of a uterus transplant recipient could indicate organ rejection.*
	Hemoglobin A1c	*Would not need to have this value on the TRF, because it may not be universally done post-transplant by VCA transplant programs*
	Carroll Test	*This data element is not pertinent to uterus transplantation, only upper extremity transplantation.*
	Semmes-Weinstein Monofilament Test	*This data element is not pertinent to uterus transplantation, only upper extremity transplantation.*
	Cognitive Development	*There is no standardized definition of "cognitive change". As such, this may be difficult to measure and more applicable to pediatric candidates. This does not inform future policy development or monitor for patient safety. An alternative question is proposed below.*
	Patient on life support	*VCA transplant candidates are clinically stable pre-transplant. This is more applicable for urgent status heart, liver, and lung transplant candidates.*
	Topical immunosuppression	*This data element is not pertinent to uterus transplantation, because topical medications would not be used due to a uterus transplant being an internal, not external, allograft transplant.*
	Previous skin grafts	*This would not be pertinent to uterus transplantation, because uterus transplant candidates are usually clinical stable, and would not have a history of skin grafts.*
	Skin changes noted with acute rejection	*This data element is not pertinent to uterus transplantation, because skin changes would not be observed due to a uterus transplant being an internal, not external, allograft transplant.*

Add Following Data Elements	Remove Following Data Elements	Rationale
	Psychological disorder(s) pre-transplant (specify)	*This data element only pertains to the TRR.*

Appendix 3: Proposed Data Definitions

Head and Neck

Ability to open and close eyelids[20]: spontaneous blink and voluntary opening and closing of both eyes during normal awake state.

0 - Patient has an observed spontaneous blink/intact blink reflex.
1 - Upon verbal command, patient is able to open and close both eyes.

Hot and Cold sensation: a patient's ability to feel hot, and cold stimulus on the upper and/or lower lip

0- Patient unable to sense any temperature on upper and/or lower lip
1- Patient is able to feel either hot or cold stimuli, but not both, on upper and/or lower lip
2- Patient able to feel both hot and cold on upper and lower lip

Smile restoration[21]: is a test used to determine a patient's facial symmetry and ability to smile post-surgery

0- Upon verbal command to smile, the patient is unable to produce recognizable smile [22]
1- Upon verbal command to smile, the patient is able to smile; smile is asymmetric
2- Upon verbal command to smile, the patient is able to smile; smile is symmetric

Two-point discrimination test[23]: is a diagnostic test used to assess if a patient is able to identify two close points on a small area of skin, and how fine the ability to discriminate between the two points. Typically, the test determines a patient's ability to sense or feel light touch, blunt (punctate), sharp (punctate), vibration, and deep pressure.

S0 - No recovery
S1- Return of some superficial pain/tactile sensation
S2- Return of some superficial pain/tactile sensation with overreaction
S3- Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination 7 mm or greater
S4- Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination static 7 mm or less [24]

[20] Joon Yeop Kim, Yong Wook Kim, and Hyoung Seop Kim. "Simultaneous Loss of Bilateral Voluntary Eyelid Opening and Sustained Winking Response Following Bilateral Posterior Cerebral Artery Infarction". *Annals of Rehabilitative Medicine 39* no. 2 (2015): 303-7. doi: 10.5535/arm.2015.39.2.303

[21] Mariana Morales-Chávez,María A. Ortiz-Rincones, and Fabiola Suárez-Gorrin. "Surgical techniques for smile restoration in patients with Möbius syndrome". *Journal of Clinical and Experimental Dentistry 5* no. 4 (2013). doi: 10.4317/jced.51116

[22] Jean-Michel Dubernard, et al. "outcomes 18 Months after the First Human Partial Face Transplantation". *The New England Journal of Medicine* (2007: 2451-60. DOI: 10.1056/NEJMoa072828

[23] https://www.sciencedirect.com/topics/medicine-and-dentistry/two-point-discrimination-test; Paul Rea. "Two Point Discrimination Test" *Essential Clinical Anatomy of the Nervous System* (Academic Press, 2015). doi.org/10.1016/C2014-0-01830-8

[24] S.E. Mackinnon, A.L. Dellon. *Surgery of the Peripheral Nerve*. (New York: Thieme Medical Publishers; 1988)

Upper Limb

Hot and Cold sensation: a patient's ability to feel hot, and cold stimulus on the upper limb

0- Patient unable to sense any temperature on upper limb
1- Patient is able to feel either hot or cold stimuli, but not both, on upper limb
2- Patient able to feel both hot and cold on upper limb

Two-point discrimination test[25]**:** is a diagnostic test used to assess if a patient is able to identify two close points on a small area of skin, and how fine the ability to discriminate between the two points. Typically, the test determines a patient's ability to sense or feel light touch, blunt (punctate), sharp (punctate), vibration, and deep pressure.

S0 - No recovery
S1- Return of some superficial pain/tactile sensation
S2- Return of some superficial pain/tactile sensation with overreaction
S3- Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination 7 mm or greater
S4- Return of some superficial pain/tactile sensation without overreaction and the presence of static two-point discrimination static 7 mm or less [26]

Grip strength and pinch test: the examination procedure assesses muscle weakness. This test can help determine weakness of the anterior neuropathy.[27]

0 – Observable muscle weakness
1- No observable muscle weakness

Subsequent surgeries required: Any surgeries that were required post-transplantation of the limb. Subsequent surgeries required post-transplantation of limb?

Yes or No
If yes, then specify the date(s) and the surgical procedure(s) performed

Basic Command Questions:

- Is the patient able to make a fist? Yes or No
- Can the patient comb their hair? Yes or No
- Can the patient open a door? Yes or No
- Can the patient write on a piece of paper? Yes or No
- Can the patient hold a cup? Yes or No

[25] Paul Rea. "Two Point Discrimination Test".
[26] S.E. Mackinnon, A.L. Dellon. *Surgery of the Peripheral Nerve*.
[27] https://medisavvy.com/pinch-grip-strength-test/

Uterus: TRR

Prior reconstructive gynecological procedures (specify): has recipient had reconstructive gynecological procedure(s) including procedures to treat urogynecological conditions, and/or restore normal female anatomy and function prior to the date of transplant. Reconstructive gynecological procedures include those performed in an outpatient or inpatient setting[28]. This field is required.

Yes / No / Unknown
If Yes, specify the procedure(s) in the Specify field

Prior pregnancies: has recipient had a pregnancy prior to the date of transplant. This field is required.

Yes/ No

Diagnosed Psychiatric condition(s) pre-transplant (specify): has recipient had or currently have any diagnosed psychiatric conditions. This field is required.

Yes/ No/ Unknown
If Yes, you must specify each disorder in the Specify field

Date of admission to Transplant Program: Enter the date the recipient was admitted to the transplant center, using the standard 8-digit MM/DD/YYYY format. If the patient was admitted to the hospital before it was determined a transplant was needed, enter the date it was determined the patient needed a transplant. This field is required.

Date: MM/DD/YYYY

Date of discharge from Transplant Program: Enter the date the recipient was released to go home, using the standard 8-digit MM/DD/YYYY format. The recipient's hospital stay includes total time spent in different units of the hospital, excluding rehab. This field is required.

Date: MM/DD/YYYY

Subsequent surgeries required during admission (date and procedures): has the recipient had any surgeries between transplant and discharge. This field is required.

Yes/ No/ Unknown
If Yes, specify the procedure(s) in the Specify field
If Yes, specify the date of each surgery (MM/DD/YYY)

Visual changes noted on cervical examination: has recipient had any visual changes noted during cervical examination since transplant. This field is required.

Yes / No
If Yes, specify the visual change(s) in the Specify field

[28] https://www.bcm.edu/healthcare/care-centers/obstetrics-gynecology/procedures/gynecologic-reconstructive-surgery

Uterus: TRF

Pregnancy post-transplant of uterus: recipient had pregnancy since transplant of uterus. This field is required.

Yes/ No

Embryo transfer(s) and date(s): Embryo transfer is a pelvic speculum exam that allows for the embryo to be placed past the cervix and into the uterus with a transfer catheter. Specify the number of embryo transfers conducted post-transplant of uterus and the dates each occurred. This field is required.

Number of embryo transfers: enter value between 1 and 10
Date(s) of each embryo transfer: MM/DD/YYYY
Not applicable/ Unknown

Date of positive pregnancy test result: The date that human chorionic gonadotropin (hCG) was first detected post-transplant of uterus, including positive result via urine or blood test. This field is required.

Date of positive pregnancy test result: MM/DD/YYYY
Not applicable/ Unknown

Date embryonic heartbeat detected by ultrasound (if applicable): The date an ultrasound first detects an embryonic heartbeat post-transplant of uterus (including trans-vaginal scan or trans-abdominal scan)[29] . This field is optional.

Date embryonic heartbeat detected by ultrasound: MM/DD/YYYY
Not applicable / Unknown

Estimated delivery date (if applicable): The estimated delivery date (EDD or EDC) is the date that spontaneous onset of labor is expected to occur. The EDD may be estimated by adding 280 days to the first date of the last menstrual period (LMP). [30] This field is optional.

Estimated Delivery Date: MM/DD/YYYY
Not applicable / Unknown

Miscarriage(s) and date (if applicable): has the recipient experienced the loss of a fetus before the 20th week of pregnancy post-transplantation of uterus. This field is optional.

Yes/ No/ Unknown

[29] https://www.miscarriageassociation.org.uk/information/worried-about-pregnancy-loss/ultrasound-scans/
[30] http://perinatology.com/calculators/Due-Date.htm

Pregnancy complications (specify): has the recipient experienced any pregnancy complications since transplant. This field is required.

Yes/ No / Not applicable
If Yes, specify the pregnancy complication(s) in the Specify field

Maternal complications at delivery (specify): has recipient experienced any medical, physical or psychological complications during the delivery of neonate post-transplant. This field is required.

Yes/ No/ Not applicable
If Yes, specify the maternal complication(s) in the Specify field

Delivery type (vaginal/cesarean) and date: select delivery method of neonate and enter the date of delivery. This field is required.

Delivery Method: vaginal, cesarean
Delivery Date: MM/DD/YYYY
Not applicable

Blood transfusions required following delivery: has recipient required blood transfusions post-delivery of neonate. This field is required.

Yes/ No / Not applicable

Hysterectomy (y/n) and date, performed following successful delivery or due to complication: has the recipient received a hysterectomy since transplant of uterus, either performed following successful delivery of neonate or due to complication(s). This field is required.

Yes/ No/ Other- specify
If Other, specify the reason for the hysterectomy in the Specify field

Reason for readmission(s) (specify): has the recipient been readmitted to the hospital, due to complications related to transplant or pregnancy. This field is required.

Yes/ No
If Yes, you must enter the reason for each readmission in the Specify field
If Yes, you must enter the date of each readmission (MM/DD/YYYY)

Date of admission to Transplant Center for delivery: Enter the date the recipient was admitted to the transplant center for delivery of neonate, using the standard 8-digit MM/DD/YYYY format. This field is required.

Date: MM/DD/YYYY
Not applicable

Date of discharge from Transplant Center post-delivery: Enter the date the recipient was released to go home post-delivery of neonate, using the standard 8-digit MM/DD/YYYY format. The recipient's hospital stay includes total time spent in different units of the hospital, excluding rehab. This field is required.

Date: MM/DD/ YYYY
Not applicable

New onset maternal diagnosed psychiatric condition(s) (specify): has recipient been diagnosed with any new psychiatric conditions since transplant of uterus. This field is required.

Yes/ No/ Unknown
If Yes, you must specify each disorder in the Specify field

Post-delivery complications (specify): has the recipient experienced complications post-delivery of neonate. This field is required.

Yes / No / Not applicable
If Yes is selected, you must enter the type of complications in the Specify field.

Surgical, medical or psychiatric complications after hysterectomy (specify) and date: has the recipient experienced complications post-surgical removal of transplanted uterus. This field is required.

Yes / No / Not applicable
If Yes, you must enter specify each complication in the Specify field
If Yes, you must enter the date of each complication (MM/DD/YYYY)

Subsequent surgeries required, date and procedures: has the recipient had any surgeries since delivery of neonate. This field is required.

Yes/ No/ Not applicable/ Unknown
If Yes, specify the procedure(s) in the Specify field
If Yes, specify the date of each surgery (MM/DD/YYY)

Visual changes noted on cervical examination: has recipient had any visual changes noted during cervical examination since transplant. This field is required.

Yes /No
If Yes, specify the visual change(s) in the Specify field