OPTN

Briefing to the OPTN Board of Directors on

Update to VCA Transplant Outcomes Data Collection

OPTN Vascularized Composite Allograft Transplantation Committee

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Contents

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Update to VCA Transplant Outcomes Data Collection

Affected Policies:	*None*
Sponsoring Committee:	*Vascularized Composite Allograft Transplantation*
Public Comment Period:	*January 22, 2020 – March 24, 2020*
Board of Directors Date:	*June 8, 2020*

Executive Summary

The VCA Committee is proposing changes to outcomes data collection for VCA types to keep pace with the rapidly-evolving field of VCA transplantation. This proposal aims to modify the 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. This proposal would both add and remove data fields. Most of the added data elements are specific to uterus transplants, as this is the first major revision of the TRR and TRF to include data collection for uterus. The Committee requested feedback on selection of a psychosocial assessment for all VCA types. The Committee also requested feedback regarding potential data elements for other VCA types, including abdominal wall, larynx, musculoskeletal composite graft segment, and penis, to inform a future data collection proposal.

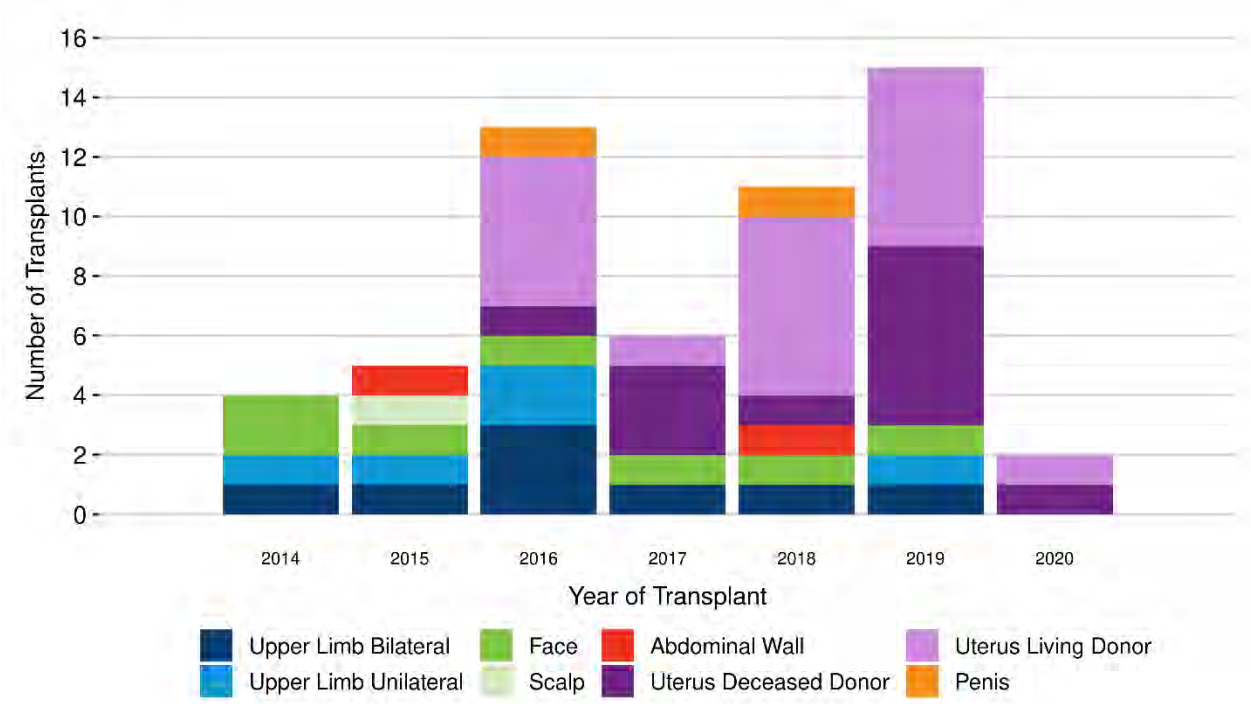
Based on public comment feedback, the Committee chose to retain some data elements that had been identified for removal; clarify the definitions for certain data elements; and change the psychosocial assessment for all VCA types. These updates to VCA data collection will support the OPTN strategic goals of promoting transplant recipient safety and improving transplant recipient outcomes by enabling more accurate and comprehensive assessments of VCA transplant outcomes.

This proposal includes a request to approve an extended implementation timeline with a target date of December 2021.

Background

The OPTN collects data on transplants in accordance with the OPTN Final Rule.[1] Specifically, the OPTN collects post-transplant data to monitor member performance, ensure patient safety, and to inform policy development, among other objectives. The U.S. Department of Health and Human Services added VCA to the definition of organs covered by federal regulation in 2014, making VCA transplants subject to the requirements of the OPTN Final Rule.[2] VCA recipient data collection was implemented the following year. At that time, the most frequently performed VCA transplants were head and neck and upper limb. Since then, the diversity of the VCA waiting list has expanded significantly to include new VCA types such as uterus and penis. The types of VCAs performed have continued to expand, with uterus now being the most common VCA transplant (**Figure 1**).

Figure 1: VCA Transplants in the U.S.: July 4, 2014 – April 17, 2020[3]



Outcome data on certain VCA types are limited because current data collection instruments were designed before these transplants were performed at adequate volume to determine type-specific data elements. Furthermore, the unique nature of VCA transplant outcomes differs from those of other organs because the primary objective of a VCA transplant is life enhancement. 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 not all VCA

[1] "Organ Procurement and Transplantation Network," *Code of Federal Regulations*, title 42 (2019): 804-815, https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol1/pdf/CFR-2019-title42-vol1.pdf

[2] 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.

[3] Based on OPTN data as of April 17, 2020.

transplant programs are collecting the same outcome data for their VCA recipients. Some transplant programs are performing additional outcome assessments specific to VCA types that are not collected by the OPTN. This limits the OPTN's ability to fully understand and assess outcomes of VCA transplants.

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) on the TRR shortly after the time of transplant. 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). The data collection instruments for bilateral upper limbs have several additional fields to provide ability to report variations between right and left grafts.[5]

Follow-up information for all organ transplants, including VCA, 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 several post-transplant data fields such as whether re-hospitalization occurred as well as results on functional outcome tests unique to specific VCA types. Both the TRR and TRF currently have 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 data fields for the Disabilities of the 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 as an evaluation of functional outcome status.[9] For head and neck recipients, the TRF contains other data fields appropriate for those transplants like sensory tests and a speech intelligibility test. **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 include in the discussions to help ensure adequate specialty knowledge and input for all of the various VCA types. They helped the Committee to identify the range of outcome assessments collected currently by VCA programs and how they differ from current OPTN data collection requirements. The Committee, with stakeholder consultation,

[4] OPTN Policy 18.1 *Data Submission Requirements*, accessed April 22, 2020. 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.

[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.

worked to gain consensus on other outcome assessments that should be collected, including those measuring psychosocial and functional outcomes.

The Committee also sought input and guidance from the OPTN Data Advisory Committee (DAC), which is responsible for monitoring and maintaining all OPTN data to ensure its accuracy, completeness, timeliness, and relevance. In that oversight role, the DAC reviewed this data collection proposal to ensure that the data elements proposed for modification and revisions on the TRR and TRF were aligned with the OPTN Principles for Data Collection.[10] The DAC endorsed this project in September 2019.

Purpose

In order to address gaps and limitations in current VCA data collection, this proposal aims to modify current VCA TRR and TRF instruments to capture additional transplant outcome data elements for upper limb, head and neck, and uterus transplant recipients. This proposal also removes data elements that are not relevant to VCA in general or to the specific VCA type.

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[11] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients"[12] and shall "…receive…such records and information electronically…"[13] This data collection proposal is consistent with the OPTN Principles for Data Collection by providing the OPTN with data to support development of transplant, donation, and allocation policies for VCA and to ensure patient safety when no alternative sources of data exist.

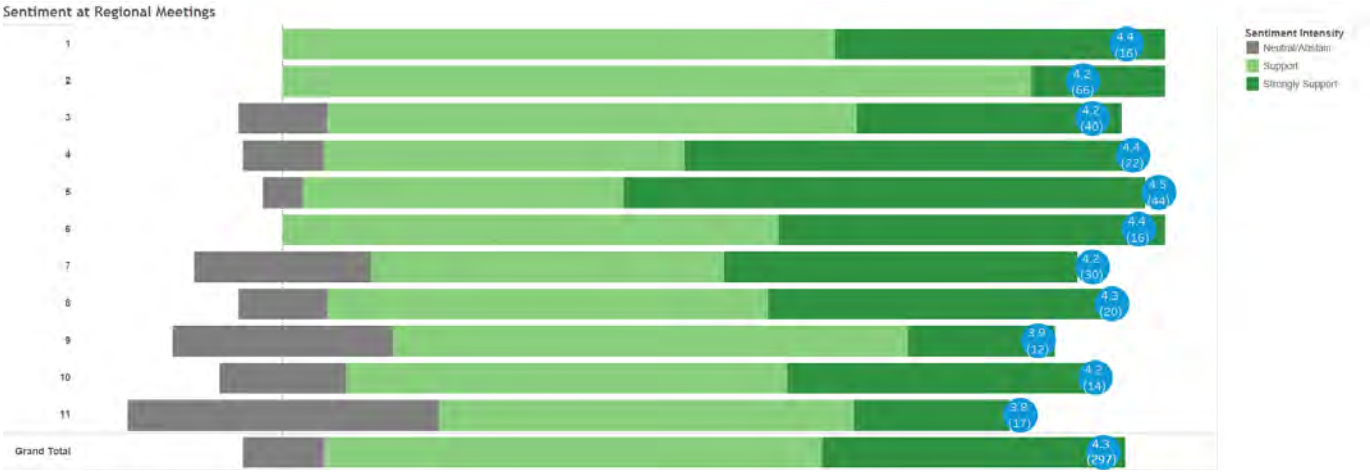
Public Comment Sentiment and Themes

This proposal was issued for public comment from January 22, 2020, to March 24, 2020. The feedback is described below. In addition to feedback on the proposal, the Committee requested feedback on the psychosocial assessment to include on the TRR and TRF for all VCA types. The Committee also requested 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 these VCA types. The Committee also requested 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.*

Public comment sentiment indicated general support for this proposal, with zero votes in opposition of the proposal across all 11 regions, as shown in **Figure 2**. The meetings for Regions 9, 10, and 11 were changed to virtual meetings due to the COVID-19 pandemic. These regional meeting sentiment scores reflect sentiment for the non-discussion agenda, which included this proposal, but are not exclusive to this proposal.

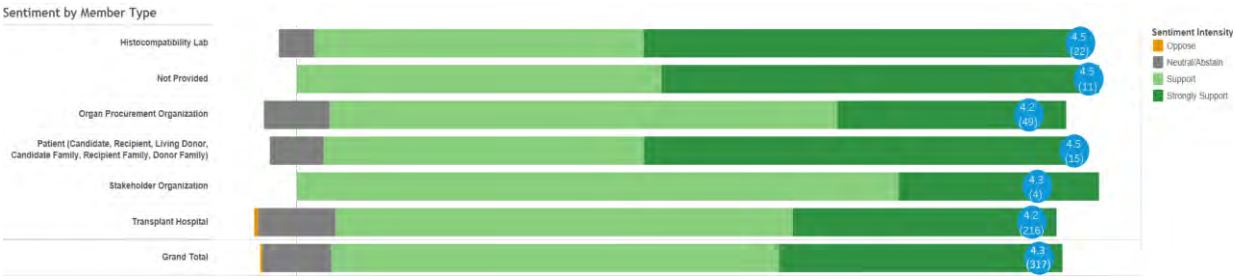
[10] OPTN, *Principles of Data Collection*. Accessed January 2, 2020. https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/
[11] 42 CFR §121.11(b)(2).
[12] 42 CFR §121.11(a)(1)(ii).
[13] 42 CFR §121.11(a)(1)(iii).

Figure 2: Proposal Sentiment by OPTN Region[14]



The proposal was also broadly supported across member types, with one member from a transplant hospital opposing the proposal, as shown in **Figure 3**.

Figure 3: Proposal Sentiment by Member Type[15]



The transplant hospital member who opposed the proposal voted in their capacity as a member of the Living Donor Committee. As shown in **Figure 4**, the Living Donor Committee as a whole supported the proposal.

Figure 4: Proposal Sentiment at Committee Meetings[16]

[14] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

[15] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

[16] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for committees only includes attendees at that committee meeting. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

The proposal was also supported by the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), the Organization for Transplant Professionals (NATCO), and a VCA transplant program. Another VCA transplant program expressed their support for the proposal outside of the public comment period via correspondence to the Committee.

Amidst general support, the Committee did receive some comments with suggestions for modifications to three specific data elements included in the proposal. Those data elements are: 1) skin changes noted with acute rejection; 2) hemoglobin A1C; and 3) the psychosocial assessment.

The initial proposal would have removed the data element on skin changes noted with acute rejection from the TRR and TRF for head and neck because the instruments already contain a data element for collecting biopsy data, which can indicate acute rejection. Additionally, the Committee noted that changes in a patient's skin may not be observed by the transplant program for recipients of a face transplant. However, AST did not support removing this data element from the TRR and TRF for head and neck. AST noted that data elements collected for biopsy data are dissimilar to those observed with skin changes, and the primary method for monitoring for rejection is the skin. Accordingly, AST noted that failure to collect visual changes will impair the ability to comprehensively monitor the graft, leading to poorer outcomes. Similarly, a VCA transplant program agreed that this data element should not be removed from the TRF because obvious changes are an indicator of graft health, even though mucosal skin changes might be more challenging to notice and subtle changes might be missed.

The initial proposal would have removed the hemoglobin A1C data element from the TRF for all VCA types, because this testing may not be completed universally by VCA transplant programs during follow-up. One VCA transplant program did not support removal of this data element from the TRF for head and neck or upper limb because it is a key indicator of complications that may be associated with immunosuppression post-transplant, and the transplant program considers it an important outcome measure. Another respondent agreed that retaining this data element would provide an opportunity to objectively capture new onset diabetes after transplant, which is a concern given evidence that immunosuppressive medications may increase the risk of developing diabetes after transplant.[17] However, the transplant program agreed that monitoring hemoglobin A1C would not be necessary for most uterus recipients as the short duration of immunosuppression is less likely to result in metabolic changes.

The Committee had requested feedback on three psychosocial assessments with the intent of selecting one of these three assessments for all VCA types. The Committee requested feedback on the Medical Outcomes Study Short Form Health Survey (SF)-36, the SF-12, and the Patient Generated Index (PGI).[18, 19, 20] The SF-36 is currently included on the TRR and TRF for all VCA types. Public comment sentiment was generally supportive of collecting quality of life information, though one transplant program did not support the addition of a psychosocial assessment after uterus transplant. The transplant program

[17] Davidson, Jaime; Wilkinson, Alan; and Dantal, Jacques, et al. 2003. "New-Onset Diabetes After Transplantation: 2003 International Consensus Guidelines." *Transplantation 75(10): SS3-SS24.*

[18] 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

[19] 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

[20] 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

stated that "uterus transplant candidates are healthy women desiring a healthy baby and have limited willingness to undergo such an evaluation after transplant," and that the value of gathering this information from uterine transplant recipients will not outweigh the costs. AST supported the use of the SF-12 as it would place a lesser burden on patients and transplant programs than the SF-36 or the PGI. However, AST also expressed support for considering alternative strategies to capture and share more detailed quality of life information. Two respondents expressed support for the PGI given its ability to collect patient-specific goals, based on patients' values and lifestyle, that can be measured objectively over time. No respondents indicated support for selecting the SF-36.

Additionally, one respondent provided suggestions for clarifying definitions for certain new data elements for head and neck, including two-point discrimination, hot and cold sensation, and eyelid function. For two-point discrimination, the respondent requested guidance on how to report differences in findings over the graft, and whether programs should report the best achieved area, the most distal area, the least sensate area, or the range noted on the graft. For hot and cold sensation, the respondent asked how to report on this data element if lips were not included in the graft, as the definition specifies upper and lower lip. Lastly, the respondent asked how to report if a patient has no eyelid function or unilateral function, as the definition in the proposal only accounts for spontaneous blink or voluntary opening and closing of both eyes.

Finally, the Committee had requested feedback regarding data elements to collect for other VCA types, including abdominal wall, larynx, musculoskeletal composite graft segment, and penis, to inform a future proposal requiring data collection for these VCA types. For abdominal wall, a transplant program suggested adding a specific question on the TRF with respect to graft function related to episodes of dehiscence, incision healing or evisceration. The transplant program also suggested adding specific questions regarding the effect of the transplant on activities of daily living and quality of life similar to those outlined in this proposal. For larynx, a transplant program suggested adding specific questions that reflect what a patient can do post-transplant that was not possible prior to transplant. Finally, for penis, a transplant program suggested adding specific questions on whether testicular tissue was transplanted, and requirement for replacement hormones post-transplant for both types of penile grafts. A transplant program also suggested adding specific questions for graft function with respect to urogenital function and reproductive status. While reviewing this feedback after public comment, the Committee suggested two additional data elements for penis: urethral strictures and the Sexual Health Inventory for Men (SHIM).

Proposal for Board Consideration

This proposal would remove data elements from the TRR and TRF that are not relevant to VCA in general or to a specific VCA type; add new data elements specific to VCA type, particularly for uterus; and change the psychosocial assessment included on the TRR and TRF for all VCA types. Changes made in response to feedback received during public comment are highlighted below.

Topic 1 – Removal of Data Elements Not Relevant to VCA

This proposal would remove data elements that are not relevant to VCA in general or a specific VCA type, including head and neck, upper limb, and uterus, to eliminate unnecessary data collection, as outlined in **Table 1.**

Table 1. Data Elements to be Removed from the TRR and TRF

Data Element to be Removed	VCA Type	TRR	TRF
Cognitive development	All VCA	X	X
Patient on life support	All VCA	X	N/A
Risk factors at the time of transplant (coagulopathies, other)	All VCA	X	N/A
Carroll test	Upper limb	X	X
Semmes-Weinstein monofilament test	Upper limb	N/A	X
Topical immunosuppression	Uterus	X	X
Previous skin grafts	Uterus	X	N/A
Skin changes noted with acute rejection	Uterus	X	X

N/A = Not Applicable

The data fields proposed for removal include the Carroll and Semmes-Weinstein tests from data collection instruments for upper limb transplants, as the Committee received reports that these tests are not performed by all programs that perform upper limb transplants and are not preferred for functional measurement. 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. Some removals would only apply to specific VCA types, including removal of skin changes noted with acute rejection from uterus instruments. While the Committee initially proposed removing this data element from the TRR and TRF for head and neck as well, the Committee proposes retaining this data element on both instruments based on public comment feedback. Previous skin grafts and topical immunosuppression are also proposed for removal from uterus VCA data collection as they are not relevant to this transplant type.

Following public comment, the Committee chose to retain one other data element that had been proposed for removal. The Committee had proposed removing data collection on hemoglobin A1C from the TRF, but the Committee now proposes to retain this data collection for all VCA types in response to public comment feedback.[21]

Tables containing more details on all proposed removal of data elements, 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*.**

Topic 2 – Addition of New Data Elements by VCA Type

This proposal would add new data elements specific to certain VCA types, including head and neck, upper limb, and uterus, to improve data collection, as outlined in **Table 2** (TRR) and **Table 3** (TRF).

[21] 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

Table 2. Data Elements to be Added: TRR

Data Element to be Added	VCA Type
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

Table 3. Data Elements to be Added: TRF

Data Element to be Added	VCA Type
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
Surgical, medical, or psychiatric complications after hysterectomy	Uterus
Visual changes noted on cervical examination	Uterus

For upper limb transplants, new proposed data elements for both the TRR and TRF include subsequent surgeries 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

other basic command questions, like whether the patient is able to make a fist. These proposed elements would provide more discrete and measurable outcome data for upper limb transplants with regard to function, relative to the tests currently included on the instruments.

For head and neck transplants, new proposed data elements include smile restoration and ability to open and close eyelids. These data elements are clearer functional indicators of anticipated outcome gains from head and neck transplantation relative to those currently included on the instruments. Additionally, while two-point discrimination and hot and cold sensation are currently on the TRF for head and neck, the Committee proposes updated data definitions for these data elements for clarification.

For uterus transplants, there are a substantial number of proposed data elements aimed at measuring reproductive milestones and outcomes. These include data fields for prior and subsequent post-transplant pregnancies as well as data regarding miscarriage, complications of pregnancy and delivery, and hysterectomy. Other data fields would capture hospitalization dates and related reproductive test results and surgeries. Five 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 not all of these fields would be applicable to all patients as most of these are fields are conditional based on the clinical situation. These added data fields are needed to measure the range of possible outcomes following uterus transplant.

Tables containing more details on all proposed addition of data elements, 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***.

Topic 3 – Selection of Psychosocial Assessment Instrument

The Committee requested feedback from the community regarding the most appropriate psychosocial assessment for all VCA types out of three options: the SF-12, the SF-36, and the PGI.[22, 23, 24] The Committee chose to replace the SF-36 with the SF-12 on the TRR and TRF for all VCA types. The Committee affirmed the importance of collecting quality of life information for all VCA recipients, given that the purpose of VCA transplantation is to enhance lives rather than save lives. The Committee selected the SF-12 as it would require the least administrative burden for transplant programs while the field develops psychosocial assessments that are more tailored for the experiences of VCA recipients. Transplant programs will have the option to report the assessment as not completed.

Based on public comment feedback, the Committee had proposed excluding the psychosocial assessment from the TRR and TRF for uterus, given the unique nature of uterine transplantation. During review of the proposal by the OPTN Board Policy Group on May 15, 2020, a member expressed concern that removing the psychosocial assessment from the uterus instruments would result in lost opportunities to screen uterus recipients for conditions like postpartum depression. While this proposal includes a data element on new onset maternal diagnosed psychiatric condition(s) on the uterus TRF,

[22] 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
[23] 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
[24] 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

the Committee recognized that this data element may not cover undiagnosed conditions. Accordingly, the Committee subsequently decided to add the SF-12 to the TRR and TRF for uterus, in addition to all other VCA types, as it will capture data that could provide information on concerns like postpartum depression. The Committee will continue to monitor the data collected via these instruments, and will continue to assess emerging tools that may be more appropriate for collecting psychosocial information from uterus recipients and other VCA recipients in the future.

OPTN Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[25] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients"[26] and shall "…receive…such records and information electronically…"[27]

Alignment with OPTN Strategic Plan[28]

1. *Improve waitlisted patient, living donor, and transplant recipient outcomes:*
   The data currently collected by the OPTN on VCA transplants has gaps that limit the OPTN's ability to assess VCA transplant outcomes. This proposal updates VCA transplant outcome data collection to enable the OPTN to more accurately monitor and assess outcomes, which will inform policy with the potential to improve transplant recipient outcomes.

2. *Promote living donor and transplant recipient safety:*
   The data currently collected by the OPTN has gaps that limit the OPTN's ability to monitor VCA recipient safety. This proposal updates VCA outcome data collection to enable the OPTN to identify trends or issues related to VCA recipient safety.

Implementation Considerations

Member and OPTN Operations

Communication and OPTN instrument modification will be necessary to effect these changes once approved by the Board. The OPTN will also create help documentation for the new data fields to provide additional instruction for submitting these data, and the Committee will work with the OPTN to continue to refine the data element definitions through implementation of this proposal. The target implementation timeline for this proposal is December 2021. The 18-month implementation timeline is longer than the standard 12-month implementation timeline to allow time for the federal Office of Management and Budget (OMB) to review and approve the data elements, and to synchronize implementation with a project to program VCA allocation into UNet[SM].

[25] 42 CFR §121.11(b)(2).
[26] 42 CFR §121.11(a)(1)(ii).
[27] 42 CFR §121.11(a)(1)(iii).
[28] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

Operations affecting the OPTN

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.[29] 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.

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

Operations affecting Transplant Hospitals

This proposal would gather additional VCA recipient data to better understand transplant outcomes and would apply to all VCA transplant recipients. The largest scope of changes would be for uterus transplant programs. Though there is also a net increase for data required for head and neck and upper limb transplant recipients, certain data elements were removed to eliminate unnecessary data collection. 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.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Projected Fiscal Impact

Projected Impact on the OPTN

Policy and Community Relations (PCR) hosted a cross-departmental workgroup which included meetings, analysis, policy development, writing, outreach, and travel. Additionally, Research worked closely with the PCR team to develop, review, and monitor data reports and consult in internal and committee meetings.

[29] https://www.hrsa.gov/about/privacy-act/09-15-0055.html

A Very Large IT implementation effort, estimated at approximately 4,000 hours, includes removing and adding data collection points on existing TRR and TRF forms. A significant portion will be creating new uterus-specific data elements for both forms. Research estimates 200 hours of work to assist IT during implementation to move these fields into UNet[SM].

Significant ongoing annual monitoring is estimated to create reports and status updates to evaluate outcomes, with Research estimating 40 hours per year. IT estimates 60 hours will be required yearly to assist with monitoring and maintenance.

Projected Impact on Transplant Hospitals

Given the net increase in overall data elements, transplant hospitals may have costs associated with the added administrative burden of new data collection.

The committee sought feedback during public comment on whether to use a new tool to gather VCA recipient quality of life data. The Committee chose to replace the SF-36 on the TRR and TRF for all VCA types with the SF-12. There may be a cost for programs to purchase and implement the tool, train staff, and conduct the evaluation with recipients.

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on organ procurement organizations.

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

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.

Data Collection Monitoring

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 remove irrelevant data elements and to capture additional transplant outcome data elements for head and neck, upper limb, and uterus transplant recipients. The Committee further refined this proposal based on feedback received in public comment through retention of certain data elements for various VCA types; change of the psychosocial assessment for all VCA types; and

clarification of data element definitions. The target implementation date for this proposal is December 2021 to synchronize implementation with a project to program VCA allocation into UNet[SM].

The Committee also requested 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 these VCA types.

The proposed changes to the data collection are supported by the OPTN Final Rule[30], and will support the OPTN strategic goals to promote transplant recipient safety and improve transplant recipient outcomes.

[30] "Organ Procurement and Transplantation Network," *Code of Federal Regulations*, title 42 (2019): 804-815, https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol1/pdf/CFR-2019-title42-vol1.pdf

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 labs (creatinine, hemoglobin 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 1: 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.*
SF-12	**SF-36**	*The SF-12 was selected to replace the SF-36 because the SF-12 i simpler to complete with less administrative burden while still obtaining basic quality of life data.*
	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. This proposal will remove the Carroll test and keep the DASH.*[31]
	Cognitive Development	*There is no standardized definition of "cognitive change" and therefore difficult to measure. It is more applicable to pediatric candidates. It does not inform future policy development or monitor 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.*

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

Table 2: 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		*The Committee proposes 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 upper limb 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.*
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 proposes 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).*
SF-12	**SF-36**	*The SF-12 was selected to replace the SF-36 because the 12 is simpler to complete with less administrative burden while still obtaining basic quality of life data.*
	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. This proposal will 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. This proposal will remove the Semmes-Weinstein test and keep the DASH.*
	Cognitive Development	*There is no standardized definition of "cognitive change" and therefore difficult to measure. It is more applicable to pediatric candidates. It does not inform future policy development or monitor patient safety.*

Table 3: Head and Neck Transplant Recipient Registration (TRR)

Add Following Data Elements	Remove Following Data Elements	Rationale
Smile restoration		*The Committee proposes 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 head and neck VCA transplantation is to restore functionality.*
Ability to open and close eyelids		*It is important to collect outcomes like ability to open and close eyelids, because unlike other solid organ transplants, the intent of this type of VCA transplantation is to restore functionality.*
SF-12	**SF-36**	*The SF-12 was selected to replace the SF-36 because the SF-12 is simpler to complete with less administrative burden while still obtaining basic quality of life data.*
	Cognitive Development	*There is no standardized definition of "cognitive change" and therefore difficult to measure. It is more applicable to pediatric candidates. It does not inform future policy development or monitor 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.*
	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 4: 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.*
Ability to open and close eyelids		*It is important to collect outcomes like ability to open and close eyelids, because unlike other solid organ transplants, the intent of this type of VCA transplantation is to restore functionality.*
SF-12	**SF-36**	*The SF-12 was selected to replace the SF-36 because the SF-12 is simpler to complete with less administrative burden while still obtaining basic quality of life data.*
	Cognitive Development	*There is no standardized definition of "cognitive change" and therefore difficult to measure. It is more applicable to pediatric candidates. It does not inform future policy development or monitor patient safety.*

Table 5: Uterus Transplant Recipient Registration (TRR)

Add Following Data Elements	Remove Following Data Elements	Rationale
Prior reconstructive gynecological procedures (specify)		*This is important to collect as this could increase the candidate's risk of complications, such as sepsis and death.*
Prior pregnancies		*This is important to collect 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.*
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.*
SF-12	**SF-36**	*The SF-12 was selected to replace the SF-36 because the S 12 is simpler to complete with less administrative burden while still obtaining basic quality of life data.*
	Cognitive Development	*There is no standardized definition of "cognitive change" and therefore difficult to measure. It is more applicable to pediatric candidates. It does not inform future policy development or monitor 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.*
	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.*
	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 data element is not 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 6: Uterus Transplant Recipient Follow-up (TRF)

Add Following Data Elements	Remove Following Data Elements	Rationale
Prior pregnancies		*This is important to collect as having a pregnancy is the intended outcome of a uterus transplant.*
Blood transfusions required following delivery		*This is important to collect as it pertains to the surgical 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		*If a woman has had a cesarean delivery, there is an increased risk of uterine rupture for future vaginal deliveries. It is important to collect as it pertains to the surgical and/or medical management of the recipient*
Hysterectomy (y/n) and date, performed following successful delivery or due to complication		*This is important to collect as it pertains to the surgical 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 readmission reason 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 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 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 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 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.*
SF-12	**SF-36**	*The SF-12 was selected to replace the SF-36 because the SF-12 is simpler to complete with less administrative burden while still obtaining basic quality of life data.*
	Cognitive Development	*There is no standardized definition of "cognitive change" and therefore difficult to measure. It is more applicable to pediatric candidates. It does not inform future policy development or monitor patient safety.*
	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.*
	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.*

Appendix 3: *Proposed Data Definitions*

Head and Neck

Ability to open and close eyelids[32]: spontaneous blink and voluntary opening and closing of both eyes during normal awake state.

0 - Eyelids not included in graft
1 - Patient has an observed spontaneous blink/intact blink reflex.
2 - 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- Lips not included in graft
1- Patient unable to sense any temperature on upper and/or lower lip
2- Patient is able to feel either hot or cold stimuli, but not both, on upper and/or lower lip
3- Patient able to feel both hot and cold on upper and lower lip

Smile restoration[33]: 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 [34]
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[35]: 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 [36]

Please record the two-point discrimination from the most sensate area of the face.

[32] 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

[33] 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

[34] 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

[35] 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

[36] 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[37]**:** 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 [38]

Please record the two-point discrimination from the most sensate area of the hand.

Grip strength and pinch test: the examination procedure assesses muscle weakness. This test can help determine weakness of the anterior neuropathy.[39]

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

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

Uterus: TRR

For data fields identified as required, transplant programs must enter information in order for the data instrument to be successfully submitted. For data fields identified as optional, transplant programs do not have to fill in the field in order to submit the data instrument.

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[40]. 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

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

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

Uterus: TRF

For data fields identified as required, transplant programs must enter information in order for the data instrument to be successfully submitted. For data fields identified as optional, transplant programs do not have to fill in the field in order to submit the data instrument.

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)[41] . 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). [42] 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

[41] https://www.miscarriageassociation.org.uk/information/worried-about-pregnancy-loss/ultrasound-scans/
[42] 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