

Public Comment Proposal

Modify Graft Failure Definition for VCA

OPTN Vascularized Composite Allograft Transplantation Committee

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Modify Graft Failure Definition for VCA

<i>Affected Policies:</i>	<i>1.2: Definitions</i> <i>12.1 Waiting Time</i>
<i>Data Instruments Affected:</i>	<i>VCA Transplant Recipient Registration (TRR) Form</i> <i>VCA Transplant Recipient Follow-up (TRF) Form</i>
<i>Sponsoring Committee:</i>	<i>Vascularized Composite Allograft Transplantation</i>
<i>Public Comment Period:</i>	<i>January 27, 2022 – March 23, 2022</i>

Executive Summary

The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee is proposing changes to the current OPTN definition of graft failure as it does not appropriately characterize graft failure for VCAs. The current definition states that a graft has failed if "... an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system." While the first two criteria can be broadly applied to VCA, chronic allograft support systems are not applicable to VCA transplants. Additionally, the nuance of VCA transplantation includes instances where a candidate may be re-registered for a covered VCA which would denote graft failure as there is no chronic allograft support for VCA. Also, for certain types of VCAs, most notably uterus, the transplanted graft may be removed intentionally when the transplant is still functioning, but has fulfilled its intended goal (i.e. following a successful birth). These graft removals are reported as graft failure under the current policy definition and the associated required data collection, even though the transplant resulted in a successful outcome for the recipient and the transplant program. This proposal will revise policy and update relevant data collection to more accurately reflect VCA transplant outcomes for all approved covered VCA types.

Background

Effective in 2014, VCAs were designated by the U.S. Department of Health and Human Services as organs under the purview of the OPTN, this inclusion also calls on OPTN to create a list of “covered VCAs”.^{1,2} Since then, the OPTN Vascularized Composite Allograft (VCA) Transplantation Committee (Committee) has been working steadily to recommend updates to OPTN policies and data collection as appropriate to reflect unique aspects of VCA transplantation relative to other solid organ transplants.³

Information on patient graft failure is used in a number of ways. OPTN data regarding graft failures are reported to the SRTR so that they can calculate risk-adjusted graft survival rates and make this information available to the public.⁴ For some organs (kidney, pancreas, and intestine), waiting time is reinstated for transplant candidates following graft failure.⁵ For lung, candidates registered for lung retransplant or graft failure are assigned to a specific diagnosis group that impacts the candidates’ allocation score.⁶ Additionally, hospitals recovering organs from living donors must provide data on transplanted organ survival as part of the informed consent process.⁷

While SRTR does not currently generate program-specific reports (PSRs) for VCA transplant programs due to the low volume of these transplants, the field of uterus transplantation has developed rapidly since the first successful uterus transplant was performed in the U.S. in 2016. As of December 12, 2021, 33 uterus transplants have been performed and at least 21 children have been born to 19 uterus recipients.⁸ Three transplant hospitals in the U.S. have performed these transplants and one additional hospital has begun evaluating patients. At least two of these hospitals have moved beyond clinical research trials and are now offering uterus transplantation outside of those clinical trials. The Committee is aware of at least four other hospitals interested in starting uterus transplant programs and this number is expected to grow.

The term “covered VCA” is used in reference to the list of covered body parts defined in OPTN Bylaws and Policies. This list was first approved by the OPTN Board of Directors in June 2016.⁹ The list of covered VCAs, which are those identified and subject to OPTN Policies and Bylaws, was further amended in June 2021¹⁰. In December 2021, the Board of Directors approved a proposal to split genitourinary organs into three types: uterus, external male genitalia, and other genitourinary organs. This proposal

¹ U.S. Department of Health and Human Services, Final Rule, “Organ Procurement and Transplantation Network.” 78 Fed. Reg. 40,003 (July 3, 2013). <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf> (accessed on November 29, 2021).

² “Implement the OPTN’s Oversight of Vascularized Composite Allografts (VCAs),” Public Comment Proposal, OPTN, accessed April 1, 2021, https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf.

³ “VCA Committee,” Web Page, OPTN, accessed August 6, 2021, <https://optn.transplant.hrsa.gov/members/committees/vca-committee/>.

⁴ “Data That Drives Development,” Web Page, Scientific Registry of Transplant Recipients, accessed December 2, 2021, <https://www.srtr.org/about-the-data/the-srtr-database/>.

⁵ OPTN Policy 3.6.B, *Waiting Time Reinstatement for Non-Function of a Transplanted Organ* (December 2, 2021).

⁶ OPTN Policy 10.1.F.i, *Lung Disease Diagnosis Groups* (December 2, 2021).

⁷ OPTN Policy 18.5 *Living Donor Data Submission Requirements* (December 2, 2021).

⁸ OPTN data as of December 12, 2021.

⁹ *Vascularized Composite Allograft Membership Changes*, Combined Policy Notice, OPTN, accessed December 7, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf.

¹⁰ *Clarification of Policies and Bylaws Specific to VCAs*, OPTN Policy Notice, accessed December 13, 2021, https://optn.transplant.hrsa.gov/media/4673/policy-notice_vca-clarification_june-2021.pdf.

establishes more specific membership requirements for uterus transplant programs to address needs for the most common type of covered VCA performed.¹¹

The current OPTN definition of graft failure does not appropriately characterize graft failure for all VCA, particularly for uterus. The definition outlines that graft failure occurs when "... an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system."¹² The first two criteria are relevant to VCA broadly, but the last criterion is not applicable. Additionally, there may be instances in which a candidate is re-registered for a covered VCA which is a marker for graft failure. Furthermore, for uterus transplantation, the graft may be removed intentionally following a successful transplant outcome (birth of a child) when the graft is still functioning properly.¹³ This practice is done so that the recipient does not require continuous immunosuppression.¹⁴ These graft removals are reported as graft failures under the current definition and associated required data collection, even though the transplant resulted in a successful outcome. As more uterus transplants are performed in the U.S. and the overall volume of uterus transplantation continues to grow, it is important to accurately document uterus graft removal when it indicates a successful transplant outcome separately from all current reports of graft failure.

Purpose

The purpose of this proposal is to appropriately tailor the definition of graft failure and associated data collection for covered VCAs to more accurately represent VCA transplantation outcomes related by:

- Excluding planned removal of a VCA graft - when the graft is no longer needed to achieve the transplant's goal - from the definition of graft failure
- Modifying the policy definition of graft failure to indicate that graft failure has occurred if a candidate requires a re-transplant for a covered VCA
- Adding a policy definition for planned removal of a VCA graft
- Modifying data collection on graft failure for covered VCAs to improve data quality
- Modifying data collection on hysterectomies performed for uterus transplants to improve data quality
- Modifying data collection on causes of VCA graft failure to reduce redundancy
- Modifying policy to reflect the ability to accrue waiting time for the recently approved three covered genitourinary VCA organ types which includes uterus

Overview of Proposal

This proposal would update the policy definition of graft failure, add a policy definition for planned removal of a VCA graft, and revise the associated data collection on VCA Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) data collection instruments. It will also revise policy related to waiting time accrual to reflect the most recently approved covered VCA types.

¹¹ Policy and Bylaws Notice (under draft).

¹² OPTN Policy 1.2 *Definitions* (December 2, 2021).

¹³ Jones, BP, Saso, S, Yazbek, J, Thum, M-Y, Quiroga, I, Ghaem-Maghani, S, Smith, JR, on behalf of the Royal College of Obstetricians and Gynaecologists. Uterine Transplantation. Scientific Impact Paper No. 65. *BJOG*. 2021; 128: e51– e66.

¹⁴ *Ibid*.

Defining VCA Graft Failure

The Committee proposes modifying the current OPTN definition of graft failure as it applies to covered VCAs due to the need for improved data on graft failure for VCA.¹⁵ This proposal would revise the current OPTN definition of graft failure to include a definition that is more applicable to VCA transplantation. The Committee proposes adding a separate definition of graft failure for covered VCAs that would define graft failure as when a recipient re-registers for the same covered VCA, the recipient dies, or an unplanned removal of a covered VCA occurs.

Re-registering for a covered VCA indicates that the graft is no longer functioning adequately and the transplant program and recipient have agreed that retransplant is the suitable option.¹⁶ Additionally, the current definition of graft failure includes “a recipient is placed on a chronic allograft support system” which is not applicable to VCA since this technology does not exist for covered VCA transplantation, but instead these recipients may re-register for the same covered VCA under the proposed definition.¹⁷

The most notable difference in VCA transplantation versus solid organ is the occurrence of planned removal of a graft due to a successful outcome. While this is primarily applicable to uterus, there is opportunity for planned removal to include other VCAs such as abdominal wall grafts and musculoskeletal composite graft segments when transplanted for purposes of temporary coverage or to allow for the regrowth of the original tissue.¹⁸ With the addition of planned removal to the graft failure definition, planned removal will also be defined in policy as occurring when the graft is removed with the intent of removal recorded either pre-transplant or at time of transplant to exclude graft removals due to graft failure.

Revision of VCA TRR and TRF Data Elements

The Committee proposes revising some of the data elements on the VCA TRR and TRF to add clarity and improve data collection for VCA transplants.

In addition to graft status options of “functioning” or “failed,” this proposal would include a new graft status option for “planned removal” to capture removal of VCA grafts that were transplanted with the intention to be removed after the graft is no longer needed for its intended goal. Proposed data collection changes include modifying data collection after the removal of a uterus graft to specify whether the removal was due to successful delivery of a neonate or due to a failed graft (i.e. complications, reproductive failure). The Committee agreed it would be important to capture “non-traditional” causes for graft failure as it pertains to uterus since there are reproductive reasons for removing these grafts such as failure to conceive.¹⁹

The Committee also proposes revising data collection on causes of graft failure to eliminate redundancy to streamline forms and use more positive phrasing to remove onus from being strictly on the

¹⁵ Ibid.

¹⁶ S.G. Chiverton, J.A. Murie, R.D. Allen, P. J. Morris, “Renal Transplant Nephrectomy,” *Surgery, Gynecology & Obstetrics*, 164.4 (1987): 324-328, <https://pubmed.ncbi.nlm.nih.gov/3551155/>.

¹⁷ OPTN Policy 1.2 *Definitions* (December 2, 2021).

¹⁸ VCA Committee Meeting Summary, September 8, 2021, OPTN, accessed November 3, 2021, https://optn.transplant.hrsa.gov/media/g0hlxcgy/20210908_vca-committee-meeting-summary.pdf.

¹⁹ VCA Committee Meeting Summary, October 7, 2021, OPTN, accessed November 5, 2021, https://optn.transplant.hrsa.gov/media/g50hpn0s/optn_vca_summary_20211007_final.pdf.

patient.^{20,21} Current options for causes of VCA graft failure on OPTN forms include “thrombosis” and “ischemia” as distinct options. The Committee proposes combining these options into one field for “vascular complications” as many different types of vascular issues may arise, and these are not limited to thrombosis and ischemia.^{22,23} Currently, there are three causes of graft failure pertaining to non-compliance which include non-compliance: “immunosuppression,” “non-compliance: rehabilitation,” and “non-compliance: level of activity.” The Committee proposes combining these into one more general cause of “non-adherence” to remove some redundancy while also moving away from the negative connotation of “non-compliance”.^{24,25}

The Committee also proposes removing a number of options for cause of death on the VCA TRR/TRF due to redundancy with other existing options. This proposal would also include the addition of an obstetric related cause of death in order to capture those events as they may specifically relate to uterus transplantation. Causes of pregnancy-related deaths in the United States during 2014-2017 included other cardiovascular conditions, infection or sepsis, cardiomyopathy, and hemorrhage.²⁶ The proposed changes are outlined in **Table 1** below.

Table 1: Proposed Data Elements to Add and Remove from the VCA TRF²⁷

Section of TRF	Remove	Add
Patient Status: Primary Cause of Death	MISC – acid/base disorder MISC – fluid/electrolyte disorder MISC – multiple system organ failure (MSOF) Trauma: motor vehicle	Maternal and obstetric mortality: other specify

The Committee also discussed whether planned removals of VCA grafts should be reported on the Interim Report of Graft Failure, Death, or Lost Record. *Policy 18.1* requires programs to report recipient graft failures within 14 days of the program’s knowledge of the event.²⁸ The Committee determined that planned removal of a VCA graft does not need to be reported on the Interim Report, as planned removals do not indicate an immediate patient safety event which would constitute immediate reporting.²⁹

More details on all proposed addition of data elements are located in **Appendix 1: 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 2: Proposed Data Definitions**.

²⁰ VCA Committee Meeting Summary, May 12, 2021, OPTN, accessed November 3, 2021, https://optn.transplant.hrsa.gov/media/4661/20210512_vca-committee-meeting-summary_final.pdf.

²¹ “Adherence To Long-Term Therapies, Evidence for action”, World Health Organization 2003, accessed December 7, 2021, <http://apps.who.int/iris/bitstream/handle/10665/42682/9241545992.pdf;jsessionid=5A7A9CB615699B093818CCFABFBD3D1C?sequence=1>

²² VCA Committee Meeting Summary, September 8, 2021, OPTN, accessed November 3, 2021, https://optn.transplant.hrsa.gov/media/g0hlxcgy/20210908_vca-committee-meeting-summary.pdf.

²³ Gavin Low, Ann M. Crockett, Katherine Leung, Anil H. Walji, Vimal H. Patel, A.M. James Shapiro, David J. Lomas, Richard A. Coulden, “Imaging of Vascular Complications and Their Consequences Following Transplantation in the Abdomen,” *RadioGraphics*, 33.3 (2013), <https://pubs.rsna.org/doi/full/10.1148/rg.333125728>.

²⁴ Ibid.

²⁵ Ibid.

²⁶ “Pregnancy Mortality Surveillance System”, CDC, accessed November 4, 2021, <https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm>.

²⁷ Ibid.

²⁸ OPTN Policy 18.1 *Data Submission Requirements* (December 2, 2021)

²⁹ Ibid.

Administrative Changes

In December 2021, the OPTN Board of Directors approved *Establish Membership Requirements for Uterus Transplant Programs*,³⁰ which splits the current genitourinary organ VCA type into uterus, external male genitalia, and other genitourinary organs. The Committee proposes updating *Policy 12.1: Waiting Time* to align with the changes approved *Establish Membership Requirements for Uterus Transplant Programs*.³¹ This will enable waiting time accrual by genitourinary organ type upon implementation of the approved changes.

NOTA and Final Rule Analysis

The VCA Committee submits this proposal under the authority of NOTA, which requires the OPTN to “collect, analyze, and publish data concerning organ donation and transplants,”³² and the OPTN Final Rule, which requires the OPTN to “maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors...”,³³ “maintain records of all transplant candidates, all organ donors and all transplant recipients”,³⁴ and operate, maintain, receive, publish, and transmit such records and information electronically³⁵ and requires transplant hospitals “as specified from time to time by the Secretary, to submit to the OPTN...information regarding transplantation candidates, transplant recipients, [and] donors of organs...”³⁶ This proposal would collect data on transplant recipients, specifically data regarding their graft status, and if applicable, data on their primary cause of death and functional status of their uterus graft.

Furthermore, per the OPTN Final Rule, “the OPTN shall provide to the Secretary data to assist the Secretary in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of [organ procurement organizations] and the OPTN contractor... Such data shall include... risk-adjusted patient and graft survival rates following transplantation...”³⁷ The OPTN and the Scientific Registry (SRTR) must also “make available to the public timely and accurate program-specific information on the performance of transplant programs,” including “risk-adjusted graft and patient survival following the transplant.”³⁸

This proposal affects information and records pertaining to transplant recipients as it would modify the data required to be submitted to the OPTN by transplant hospitals on graft failure for covered VCA transplant recipients, particularly uterus recipients.

³⁰ Policy and Bylaw Notice (under draft)

³¹ *Programming VCA Allocation in UNet*, Policy Notice, OPTN, accessed December 7, 2021, https://optn.transplant.hrsa.gov/media/3922/20200731_vca_membershipchanges_policynotice.pdf

³² 42 U.S.C. §274(b)(2)(I)

³³ 42 CFR §121.11(a)(1)(i).

³⁴ 42 CFR §121.11(a)(1)(ii).

³⁵ 42 CFR §121.11(a)(1)(iii).

³⁶ 42 CFR §121.11(b)(2)

³⁷ 42 CFR §121.8(c)(3).

³⁸ 42 CFR §121.11(b)(1)(iv).

Implementation Considerations

Member and OPTN Operations

The OPTN and transplant hospitals that perform covered VCA transplants would need to modify data collection and reporting practices to implement this proposal, but this proposal is not anticipated to affect the operations of organ procurement organizations or histocompatibility laboratories.

Operations affecting the OPTN

This proposal would require the submission of official OPTN data that are not presently collected by the OPTN and would modify data that are currently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the proposed data collection changes will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Operations affecting Transplant Hospitals

Transplant hospitals performing covered VCA transplants will need to become familiar with the changes to policy and data collection regarding VCA graft failure and how to properly report graft failure for their patients.

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN, but no impact on organ procurement organizations and histocompatibility laboratories. There will be an impact for transplant hospitals regarding data entry.

Projected Impact on the OPTN

This project would require programming changes to the VCA TRR and TRF forms. The OPTN will incorporate changes approved as part of this proposal into planned programming for VCA into UNetSM including WaitlistSM, DonorNet[®], and associated data collection instruments, along with programming ten types of covered VCA as outlined in the proposal *Establish Membership Requirements for Uterus Transplant Programs*.³⁹

Projected Impact on Transplant Hospitals

This proposal will only impact transplant hospitals that perform VCA transplants. This proposal will not have a significant fiscal impact, and no significant resources are required to implement. There will be initial training required, with costs associated with training data users on the new definitions. That one-time, upfront training will help to streamline consistent data entry for future data analysis. It should take programs less than one month to implement this proposal.

³⁹ Policy and Bylaw Notice (under draft)

Post-implementation Monitoring

Member Compliance

This proposal will not change current routine monitoring of OPTN members. The OPTN may review any data entered in UNetSM, and members must provide documentation as requested.

Policy Evaluation

This policy will be formally evaluated approximately 1 year and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available, and as sample size permits, to compare before and after the implementation of this policy:

- Number of VCA transplants, overall and by organ
- Number and percent of VCA graft failures by organ: overall and by reason(s) for graft failure
- Number of VCA planned removals by organ
- Number of hysterectomies reported for uterus recipients on the TRF, overall and by reason for hysterectomy
- Number of VCA recipient deaths by organ and cause of death

Conclusion

This proposal would define graft failure for VCA transplantation separately from the current OPTN definition of graft failure. The proposed definition would define graft failure for VCA as:

- the recipient re-registers for the same covered VCA
- a recipient dies
- or an unplanned removal of a covered VCA

These proposed changes would capture the planned removal of certain types of VCA transplants, most notably uterus, as a success of the graft rather than inaccurately recording the removal as a graft failure. In addition to the proposed definition of VCA graft failure, planned removal of a VCA graft would also be defined. This proposal will also revise and update relevant data collection to more accurately collect data as it pertains to VCA recipient outcomes as well as further inform the Committee on future projects.

The Committee seeks feedback on the following questions:

- Does the proposed definition appropriately distinguish between graft failure and planned removal of a VCA graft following a successful transplant?
- Is the definition of “planned removal of a VCA graft” clear?
- Are the proposed modifications to data collection regarding uterus transplant outcomes sufficient to capture data on various circumstances (e.g. rejection of uterus graft following live birth, uterus graft removal due to contraindications to pregnancy, etc.)?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary. The [...] signifies language in the current Policy that is not presented here for the purposes of brevity and will not be affected by the proposal.

1 1.2 Definitions

2 The definitions that follow are used to define terms specific to the OPTN Policies.

3 [...]

4 **G**

5 **Graft failure**

6 For all organs except pancreas and covered VCAs, graft failure occurs when *any* of the following occurs:

7

- 8 • A recipient's transplanted organ is removed
- 9 • A recipient dies
- 10 • A recipient is placed on a chronic allograft support system

11 Pancreas graft failure occurs when any of the following occurs:

12

- 13 • A recipient's transplanted pancreas is removed
- 14 • A recipient re-registers for a pancreas
- 15 • A recipient registers for an islet transplant after receiving a pancreas transplant
- 16 • A recipient's total insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- 17 • A recipient dies

18 Covered VCA graft failure occurs when any of the following occurs:

19

- 20 • A recipient re-registers for the same covered VCA
- 21 • A recipient dies
- 22 • An unplanned removal of a covered VCA

23

24 [...]

25 **P**

26 [...]

27 **Planned Removal of a VCA graft**

28 A planned removal of a VCA graft occurs when the graft is removed with the intent of removal recorded
29 either pre-transplant or at time of transplant.

30

31 12.1 Waiting Time

32

33 Waiting time for candidates registered for a covered VCA begins when the candidate is registered on the
34 waiting list. Candidates are registered by covered VCA type: upper limb, head and neck, abdominal wall,

35 ~~genitourinary organ~~ uterus, external male genitalia, other genitourinary organ, vascularized gland, lower
36 limb, musculoskeletal composite graft segment, or spleen.

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Appendix 1: Proposed Modifications to VCA TRR and TRF Data Collection

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Data Element	Form	Current Data Collection	Proposed Removal(s) and Proposed Addition(s)
Graft Status	VCA TRR	Functioning Failed Causes of graft failure Acute rejection (Yes/No) If Yes, Banff score (0, I, II, III, IV) If Yes, Visual skin changes (Yes/No) Chronic rejection (Yes/No) If Yes, Visual skin changes (Yes/No) Sepsis/infection (Yes/No) Trauma (Yes/No) Patient requested removal (Yes/No) Other, Specify	Functioning Failed <u>Planned removal</u> <u>Date of removal</u> Causes of graft failure Thrombosis (Yes/No) Acute rejection (Yes/No) If Yes, Banff score (0, I, II, III, IV) If Yes, Visual skin changes (Yes/No) Chronic rejection (Yes/No) If Yes, Visual skin changes (Yes/No) Ischemia (Yes/No) <u>Vascular complications (Yes/No)</u> Sepsis/infection (Yes/No) Trauma (Yes/No) Patient requested removal (Yes/No) Non-compliance: immunosuppression (Yes/No) Non-compliance: rehabilitation (Yes/No) Non-compliance: level of activity (Yes/No) <u>Non-adherence (Yes/No)</u> Other, Specify
Graft status	VCA TRF	Functioning Failed Causes of graft failure Acute rejection (Yes/No) If Yes, Banff score (0, I, II, III, IV) If Yes, Visual skin changes (Yes/No) Chronic rejection (Yes/No) If Yes, Visual skin changes (Yes/No) Sepsis/infection (Yes/No) Trauma (Yes/No) Patient requested removal (Yes/No) Other, Specify	Functioning Failed <u>Planned removal</u> <u>Date of removal</u> Causes of graft failure Thrombosis (Yes/No) Acute rejection (Yes/No) If Yes, Banff score (0, I, II, III, IV) If Yes, Visual skin changes (Yes/No) Chronic rejection (Yes/No) If Yes, Visual skin changes (Yes/No) Ischemia (Yes/No) <u>Vascular complications (Yes/No)</u> Sepsis/infection (Yes/No) Trauma (Yes/No) Patient requested removal (Yes/No) Non-compliance: immunosuppression (Yes/No) Non-compliance: rehabilitation (Yes/No) Non-compliance: level of activity (Yes/No)

Data Element	Form	Current Data Collection	Proposed Removal(s) and Proposed Addition(s)
			<u>Non-adherence (Yes/No)</u> Other, Specify
Patient Status: Primary Cause of Death	VCA TRF	MISC – acid/base disorder MISC – fluid/electrolyte disorder MISC – multiple system organ failure (MSOF) Trauma: motor vehicle	MISC – acid/base disorder MISC – fluid/electrolyte disorder MISC – multiple system organ failure (MSOF) Trauma: motor vehicle <u>Maternal and obstetric mortality: other specify</u>
Hysterectomy	Uterus TRF	Functional Status – Uterus Hysterectomy performed following successful delivery or due to complications: 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	Functional Status – Uterus Hysterectomy performed following successful delivery or due to complications: 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 <u>If yes then specify reason:</u> <u>Successful delivery of neonate</u> <u>Complication of graft</u> <u>Reproductive Failure</u> <u>Other: _____</u>

Appendix 2: Proposed Data Definitions

VCA TRR

Planned removal: has the recipient had a planned removal of a VCA graft with the intent of removal recorded either pre-transplant or at time of transplant.

Date of removal: If the recipient’s graft status is Planned removal, enter the date of failure or removal using the standard 8-digit format of MM/DD/YYYY.

Vascular complications (Yes/No): has the graft failed due to vascular complication (not limited to thrombosis or ischemia).⁴⁰

Non-adherence (Yes/No): has the graft failed due to recipient non-adherence to post-transplant treatment (i.e. immunosuppression, rehabilitation, level of activity).⁴¹

⁴⁰ VCA Committee Meeting Summary, September 8, 2021, OPTN, accessed November 3, 2021, https://optn.transplant.hrsa.gov/media/g0hlxcgy/20210908_vca-committee-meeting-summary.pdf.

⁴¹ VCA Committee Meeting Summary, May 12, 2021, OPTN, accessed November 3, 2021, https://optn.transplant.hrsa.gov/media/4661/20210512_vca-committee-meeting-summary_final.pdf.

VCA TRF

Planned removal: has the recipient had a planned removal of a VCA graft with the intent of removal recorded either pre-transplant or at time of transplant.

Date of removal: If the recipient's graft status is Planned removal, enter the date of failure or removal using the standard 8-digit format of MM/DD/YYYY.

Vascular complications (Yes/No): has the graft failed due to vascular complication (not limited to thrombosis or ischemia).⁴²

Non-adherence (Yes/No): has the graft failed due to recipient non-adherence to post-transplant treatment (i.e. immunosuppression, rehabilitation, level of activity).⁴³

VCA TRF (Patient Status): Primary Cause of Death

Maternal and obstetric mortality: other specify: was the recipient's death related to pregnancy or obstetric causes. Specify the cause of death in the Specify field.

Uterus TRF

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

If yes then specify reason:

Successful delivery of neonate

Due to complication(s)

Reproductive Failure⁴⁴

Other: _____

⁴² Ibid.

⁴³ Ibid

⁴⁴ VCA Committee Meeting Summary, October 7, 2021, OPTN, accessed December 2, 2021, https://optn.transplant.hrsa.gov/media/g50hpn0s/optn_vca_summary_20211007_final.pdf

