

AWARD NUMBER: W81XWH-18-1-0779

TITLE: Understanding and Supporting Public Information Needs About VCA Donation

PRINCIPAL INVESTIGATOR: Daniel Warren, PhD

CONTRACTING ORGANIZATION: Johns Hopkins University, Baltimore, MD

REPORT DATE: January 2023

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE January 2023	2. REPORT TYPE Final	3. DATES COVERED 30Sep2018-29Sep2022
---------------------------------------	--------------------------------	--

4. TITLE AND SUBTITLE Understanding and Supporting Public Information Needs About VCA Donation	5a. CONTRACT NUMBER
	5b. GRANT NUMBER W81XWH-18-1-0779
	5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S) Daniel Warren, PhD; Macey Levan, JD PhD; Elisa Gordon, PhD MPH; Gerald Brandacher, MD E-Mail: dwarren1@jhmi.edu , Macey.Levan@nyulangone.org , e-gordon@northwestern.edu , gbranda2@jhmi.edu	5d. PROJECT NUMBER
	5e. TASK NUMBER
	5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Johns Hopkins University Department of Surgery 2000 E Monument St Baltimore, MD 21201	Northwestern University 633 N. St Clair Chicago Illinois 60611	8. PERFORMING ORGANIZATION REPORT NUMBER
---	--	---

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
As the field of Vascular Composite Allotransplantation (VCA) grows, demand for VCA donations will increase. VCA donation requires separate authorization, commonly provided by deceased donors' next of kin. Therefore, the public should be educated to make informed decisions about VCA. This study assessed the availability and quality of existing VCA public education materials and developed educational materials that increase public knowledge, understanding, perceptions of comfort, and willingness to donate. We first conducted a qualitative content analysis of 1,314 public education materials about VCA (Van Pilsum Rasmussen 2020; Appendix B). VCA public education materials were lacked key information such as functional benefits, psychosocial outcomes, potential recipients, and the donation authorization process of VCA, and thus we set out to create more comprehensive educational materials to address lacunae of public information. We conducted a 1st round of focus groups (n=6 groups; 42 participants) with the general public at Johns Hopkins University (Baltimore) and Northwestern University (Chicago) to understand perceptions of: information needs of, and barriers to VCA donation (Ferzola 2022; Appendix C). These insights helped us understand topics to address in educational materials about VCA donation to potentially increase willingness to donate in the future. VCA experts (n=18 VCA clinicians) reviewed draft educational materials and created consensus through a two-round Delphi panel about relevant topics and language on which to educate the public (Sidoti 2021; Appendix D). We conducted a 2nd round of focus groups with members of the general public to receive feedback on educational materials and revised materials amongst our research team to create the final educational materials (Appendix A). The final educational materials will be displayed on a website hosted by the Living Legacy Foundation of Maryland and will be promoted by a social media campaign. Non-research videos with VCA recipients and a surgeon discuss the benefits of VCA donation and transplantation to supplement educational materials.

15. SUBJECT TERMS
Vascular Composite Allotransplantation, Vascular Composite Allograft, VCA, Reconstructive Transplantation, Education, Public Opinion, Focus Groups, Content and thematic analysis, Delphi panel, Qualitative research

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 22	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT Unclassified	b. ABSTRACT Unclassified	c. THIS PAGE Unclassified			19b. TELEPHONE NUMBER (include area code)

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	7
5. Changes/Problems	7
6. Products	8
7. Participants & Other Collaborating Organizations	10
8. Special Reporting Requirements	11
9. Appendices	11

1. INTRODUCTION:

As the field of Vascular Composite Allotransplantation (VCA) grows, demand for VCA donations will increase. VCA donation requires separate authorization, commonly provided by deceased donors' next of kin. Therefore, the public should be educated to make informed decisions about VCA. This study assessed the availability and quality of existing VCA public education materials and developed educational materials that increase public knowledge, understanding, perceptions of comfort, and willingness to donate.

2. KEYWORDS: *Provide a brief list of keywords (limit to 20 words).*

Vascular Composite Allotransplantation
Vascular Composite Allograft
VCA
Reconstructive Transplantation
Education
Public Opinion
Focus Groups
Content and thematic analysis
Delphi panel
Qualitative research

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Prepare Regulatory Documents

- Milestone: IRB and HRPO approval at Johns Hopkins
- Milestone: IRB and HRPO approval at NU
Timeline: 6 months, 100% complete

Major Task 2: Coordinate and Train Study Staff in Qualitative Research

- Milestone: Research staff hired and trained in qualitative research
Timeline: 6 months, 100% complete

Specific Aim 1: To assess the availability and quality of information about VCA donation delivered through state and federally sponsored online registries, DoD/VA entities, and public awareness materials.

Major Task 3: Content Analysis of Available VCA Donation Education

- Milestone: content analysis of existing educational materials
Timeline: 12 months, 100% complete
- Milestone: report findings from content analysis
Timeline: 12 months, 100% complete

Major Task 4: Focus Groups with Members of the Public

- Milestone: schedule 1st focus group, consent participants
Timeline: 9 months, 100% complete
- Milestone: conduct 3 focus groups at each site
Timeline: 12 months, 100% complete at JHU (n = 3/3 focus groups, 15 participants total); 100% complete at NU (n = 3/3 focus groups, 27 participants total)

Major Task 5: Analyze Qualitative Data

- Milestone: Report findings from focus groups
Timeline: 14 months, 100% complete

Specific Aim 2: To develop educational materials that increase public knowledge, understanding, perceptions of comfort, and willingness to donate.

Major Task 6: Develop Educational Materials for VCA

- Milestone: create educational materials, social media strategy, and media toolkit
Timeline: 16 months 100% complete

Major Task 7: Conduct Delphi Panel

- Milestone: report results from data analysis
Timeline: 24 months 100% complete at JHU (n = 18 participants total)
- Milestone: Write manuscript detailing the results of the consensus reached through the Delphi method
Timeline: 24 months 100% complete

Major Task 8: Conduct Focus Groups about Developed VCA Education

- Milestone: schedule 1st focus group, consent participants
Timeline: 26 months 100% complete
- Milestone: conduct 3-5 focus groups at each site
Timeline: 26 months 100% complete at JHU (n = 6/6 focus groups completed, 29 participants total)

Major Task 9: Conduct Further Usability Testing via Donate Life America

- Milestone: launch social media strategy from the Donate Life America social media channels (Facebook, Twitter, Instagram)
Timeline: 32 months **95% complete – Website design, pictures, and videos being finalized before launch.**
- Milestone: manuscript preparation/submission for publication report **0% complete. We do not plan**

Major Task 9: The website containing educational materials about VCA donation and videos of VCA recipients is in the final stages of development before being disseminated through Donate Life America's social media channels. Videos filmed of 2 uterus transplant recipients, 1 bilateral arm and face recipient, and 1 VCA surgeon are undergoing video editing. We are finalizing payment for VCA recipient videos and for images of VCA recipients from Getty Images to be displayed on the website. As the study period is over and the website is still being finalized, we will report data about website reach and engagement at a later time point. Finalizing VCA recipient videos for the website and campaign was delayed because in-person video filming was restricted due to COVID-19 Omicron surge concerns.

What was accomplished under these goals?

Major Task 3: Content Analysis of Available VCA Donation Education – 100% complete

Milestone Achieved: content analysis of existing educational materials

- Manuscript published: Van Pilsum Rasmussen SE, Uriarte J, Anderson N, Doby B, Ferzola A, Sung H, Cooney C, Brandacher G, Gordon E, Segev DL, Henderson ML. Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations. **Clin Transplant. 2020 Nov**;34(11):e14066. doi: 10.1111/ctr.14066.(Appendix B)

Major Task 5: Analyze Qualitative Data

Milestone Achieved: Report findings from focus groups – 100% complete

- Manuscript published: Ferzola A, Uriarte J, Sung HC, Anderson N, Sidoti C, Van Pilsum Rasmussen SE, Downey M, Vanterpool KB, Langlee W, Klitenic S, Young L, Cooney CM, Johnson I, Coleman A, Shores JT, Segev DL, Brandacher G, Gordon EJ, Levan ML. Public Perceptions and Information Needs of VCA Transplantation and Donation: A Mixed Methods Study. **Transpl Int. 2022 Nov** 14;35:10752. doi: 10.3389/ti.2022.10752. (Appendix C)

Major Task 6: Develop Educational Materials for VCA

- Subtask 2: Develop social media strategy – **100%**
 - We have finalized educational content for the website and the website is being built and finalized through the LLF. (Appendix A)

- The LLF has completed video interviews with 2 uterine transplant recipients, 1 bilateral arm and face transplant recipient, and 1 arm transplant surgeon. We are reviewing video content and editing to share videos on our social media campaign.
- The LLF is planning a 5th video with a face transplant recipient and determining travel and video filming logistics for this additional video.

Major Task 7: Conduct Delphi Panel

- Milestone Achieved: Write manuscript detailing the results of the consensus reached through the Delphi method – **100% complete**
 - The Delphi Panel **manuscript was submitted** to the *Vascularized Composite Allotransplantation* journal on 10/18/2022 and is currently awaiting an editorial assignment.
 - Delphi panel abstract presented at ATC 2021. Experts rated 21 VCA topics and statements important enough to be retained in the final educational materials. (Appendix D)

Major Task 9: Conduct Further Usability Testing via Donate Life America – **95% complete**

- Subtask 1: Work with Donate Life America on launching the social media strategy
 - Biweekly meetings are being held by the study team and the LLF to finalize payment for 4 filmed VCA recipient/provider videos. 1 more video is scheduled to be filmed with a face transplant recipient. Images of transplant recipients are being acquired to be used on the social media campaign.

What opportunities for training and professional development has the project provided?

Johns Hopkins University:

Carolyn Sidoti, Alexander Ferzola, and Max Downey received training in conducting focus groups, analyzing data through thematic analysis, and manuscript writing. Carolyn Sidoti and Alexander Ferzola presented research findings at international transplant conferences.

Northwestern University:

Jefferson Uriarte, Naomi Anderson, and Ali McLaughan received training in conducting focus groups, qualitative data analysis, and manuscript writing. Jefferson Uriarte also received training in processing financial reimbursements for compensating study participants. Also, learning data management, recruitment processes.

How were the results disseminated to communities of interest?

Educational materials including written text, tables, and graphics based on literature, photos of VCA recipients, and original video content of VCA recipients and a VCA surgeon will be disseminated to the general public through social media hosted by the LLF to expose potential organ donors to VCA donation with which many are previously unaware.

What do you plan to do during the next reporting period to accomplish the goals?

4. **IMPACT:**

Nothing to report; reporting period has ended.

What was the impact on the development of the principal discipline(s) of the project?

Our content analysis publication provided an overview of the scope and lacunae of online VCA educational materials. We identified information gaps in 1,314 online educational materials available in 2019 and then created comprehensive educational materials about topics which only a low percentage of previous materials covered: functional outcomes of VCA (15.5%), potential VCA recipients (14.5%), psychosocial outcomes of VCA (11.9%), and authorization process for VCA donation (6.6%) (Appendix B).

Our focus groups with members of the general public (n = 6 focus groups, 42 participants) identified specific information needs and barriers to donating VCA organs. Three key information needs of the public were to understand the medical purpose for receiving VCA organs, the authorization process for VCA donation, and how VCA donation impacts funeral arrangements (Appendix C). Our Delphi panels created a consensus on relevant VCA topics on which to educate the general public and language to use to communicate these topics to a general public audience. The top 5 most important topics were Potential VCA Recipients, Consent Process for VCA Donation, Definition of VCA, Purpose of VCA, and Most Common VCA Organs Transplanted (Appendix D). This information will help the field of transplantation to address these topics in educational campaigns to potentially increase willingness to donate and increase the supply of VCAs for treatment of those in need of VCAs.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

The results of our study will improve public knowledge on the opportunity to become a VCA organ donor and the authorization process for becoming a VCA donor, which requires additional steps than solid organ donation.

Our study has impacts on society because educating the public about VCA donation will potentially increase willingness to donate VCA organs.

5. **CHANGES/PROBLEMS:**

Nothing to report.

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

COVID surge: The COVID outbreak of the omicron variant has been a logistical barrier to shooting in-person videos of transplant recipients. Transplant recipients are immunocompromised and are at higher risk for COVID infection, so we have decided at the request of the recipients to postpone video shooting until a later time when the surge has subsided and conditions are safer for in-person meetings.

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

Publications, conference papers, and presentations

Report only the major publication(s) resulting from the work under this award.

Journal publications

- **Manuscript Published:**

Van Pilsum Rasmussen SE, Uriarte J, Anderson N, Doby B, Ferzola A, Sung H, Cooney C, Brandacher G, Gordon E, Segev DL, Henderson ML. Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations. *Clin Transplant*. 2020 Nov;34(11):e14066. doi: 10.1111/ctr.14066. Epub 2020 Oct 5. PMID: 32810365. (Appendix B)

- **Manuscript Published:**

Ferzola A, Uriarte J, Sung HC, Anderson N, Sidoti C, Van Pilsum Rasmussen SE, Downey M, Vanterpool KB, Langlee W, Klitenic S, Young L, Cooney CM, Johnson I, Coleman A, Shores JT, Segev DL, Brandacher G, Gordon EJ, Levan ML. Public Perceptions and Information Needs of VCA Transplantation and Donation: A Mixed Methods Study. *Transpl Int*. 2022 Nov 14;35:10752. doi: 10.3389/ti.2022.10752. PMID: 36451683; PMCID: PMC9701711. (Appendix C)

- **Manuscript Submitted:**

Downey M, Sidoti C, Ferzola A, Uriarte J, Anderson N, Sung H, Van Pilsum Rasmussen SE, Langlee W, Vanterpool K, Nalatwad A, Eagleson M, Young L, Cooney C, Kimberly L, Brandacher G, Gordon E, Levan M. Public Education about Vascularized Composite Allograft Donation: A Delphi Panel Study. *Vascularized Composite Allotransplantation*. Submitted 2022 Oct 18.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

- **Poster presented at ATC 2021:** Sidoti C, Ferzola A, Sung H, Rasmussen S, Gordon E, Anderson N, Uriarte J, Cooney C, Brandacher G, Levan M. A Delphi Panel to Develop Public Educational Materials About Vascular Composite Allotransplantation (VCA) [abstract]. *Am J Transplant*. 2021; 21 (suppl 3). [https://atcmeetingabstracts.com/abstract/a-delphi-panel-to-develop-public-educational-materials-about-vascular-composite-allotransplantation-vca/..](https://atcmeetingabstracts.com/abstract/a-delphi-panel-to-develop-public-educational-materials-about-vascular-composite-allotransplantation-vca/)

(*Manuscript under review at *Vascularized Composite Allotransplantation* journal) (Appendix D)

- Sung H, Ferzola A, Uriarte J, Anderson N, Cooney C, Brandacher G, Gordon E, Henderson M. Public Information Needs about VCA Donation and Transplantation in the United States [abstract]. *Am J Transplant*. 2020; 20 (suppl 3). <https://atcmeetingabstracts.com/abstract/public-information-needs-about-vca-donation-and-transplantation-in-the-united-states/>. Accessed October 9, 2020.
- Rasmussen S, Henderson M, Anderson N, Uriarte J, Doby B, Cooney C, Segev D, Brandacher G, Gordon E. Public Education about Vascular Composite Allotransplantation and Donation: A Content Analysis of Social Media and Educational Documents [abstract]. *Am J Transplant*. 2020; 20 (suppl 3). <https://atcmeetingabstracts.com/abstract/public-education-about-vascular-composite-allotransplantation-and-donation-a-content-analysis-of-social-media-and-educational-documents/>. Accessed October 9, 2020.
- Alexander Ferzola, Carolyn Sidoti, Hannah Sung, Naomi Anderson, Jefferson Uriarte, Carisa Cooney, Gerald Brandacher, Elisa Gordon and Macey Henderson. Public information needs about VCA donation and transplantation in the United States. 2020 American Society for Reconstructive Transplantation Conference
- Gordon EJ, Anderson N, Uriarte JJ, Sung HC, Ferzola A, Brandacher G, Henderson ML. Misconceptions and lack of information about VCA can thwart the public’s access to VCA. Poster presented at: Cutting Edge of Transplantation Summit; March 5-7; Phoenix, AZ.
- Henderson M, Van Pilsum Rasmussen S, Uriarte J Anderson N, Doby B, Cooney C, Brandacher G, Segev D, Gordon E. “The Scope and Limitations of Current Public Education Materials on Vascular Composite Allotransplantation and Donation in the United States.” American Transplant Congress. Boston MA, 2019.

Website(s) or other Internet site(s)

The final educational materials will appear on website hosted by LLF (Appendix A)

Other Products

Audio or video products: Two uterine transplant recipient, one bilateral arm and face recipient, and one arm transplant surgeon videos have been filmed and are undergoing video editing to be disseminated on a social media campaign. An additional video with a face transplant recipient is being scheduled.

Educational aids: Final educational materials to appear on website hosted by LLF (Appendix A)

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Calendar Months for Johns Hopkins Collaborators are provided as Average CM

Name:	Daniel Warren
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-1370-466
Nearest person month worked:	0.12 Calendar Months (Average from 02/2022-09/2022)
Contribution to Project:	Oversight of all research activities
Name:	Macey Levan
Project Role:	Former Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-1370-466
Nearest person month worked:	0.98 Calendar Months (Average from 10/2018-01/2022)
Contribution to Project:	Oversight of all research activities
Name:	Dorry Segev
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	0.36 Calendar Months (Average from 10/2018-01/2022)
Contribution to Project:	Oversight of all research activities
Name:	Gerald Brandacher
Project Role:	Partnering Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0001-7790-441X
Nearest person month worked:	0.77 Calendar Months (Average from 09/30/2018-09/29/2022)
Contribution to Project:	Oversight of all research activities
Name:	Carisa Cooney
Project Role:	Co-investigator, Research Manager
Researcher Identifier (e.g. ORCID ID):	0000-0002-5475-206X
Nearest person month worked:	0.75 Calendar Months (Average from 09/30/2018-09/29/2022)
Contribution to Project:	Oversight of regulatory approvals
Name:	Jaimie Shores
Project Role:	Co-investigator
Nearest person month worked:	0.24 Calendar Months (Average from 09/30/2018-09/29/2022)
Contribution to Project:	Oversight of regulatory approvals
Name:	Hannah Sung
Project Role:	Research Data Analyst
Nearest person month worked:	6.7 Calendar Months (Average from 07/2019-10/2020)
Contribution to Project:	Moderation of focus groups, assisted in qualitative analysis and writing the focus group manuscript.

Note: the calendar months for Northwestern collaborators are provided as cumulative months for the entire study period

Name	Elisa Gordon
Project Role:	Partnering Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-0969-1998
Nearest person month worked:	5.97 Calendar months (cumulative)
Contribution to Project:	Study oversight and regulatory oversight at Northwestern. Edited manuscripts.

Name: Jefferson Uriarte
Project Role: Research Project Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0002-8507-963X
Nearest person month worked: 20.64 Calendar months (cumulative)
Contribution to Project: Participant recruitment, co-moderated focus groups, data analysis, edited Focus group manuscript.

Name: Naomi Anderson
Project Role: Research Project Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0002-8507-963X
Nearest person month worked: 15.44 Calendar months (cumulative)
Contribution to Project: Participant recruitment, co-moderated focus groups, data analysis, edited Focus group manuscript.

Name: Ali McLaughan
Project Role: Research Project Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0003-0212-9601
Nearest person month worked: 3.05 Calendar months (cumulative)
Contribution to Project: Getting trained on the project

Name: Madeline Quasebarth
Project Role: Research Project Coordinator
Researcher Identifier (e.g. ORCID ID): 0000-0003-0212-9601
Nearest person month worked: 1.61 Calendar months (cumulative)
Contribution to Project: Getting trained on the project

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report.

What other organizations were involved as partners?

The Living Legacy Foundation (LLF) of Maryland
1730 Twin Springs Rd Ste 200, Halethorpe, MD 21227

Contact: Ieesha Johnson, ijohnson@thellf.org

Contribution: The LLF will host the public-facing educational website and lead the social media campaign. LLF has worked with videographers to film videos of VCA recipients and VCA surgeon, and with a web designer to format educational materials (Appendix A) onto a website format.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

Appendix A: Finalized Educational Materials for LLF-hosted Website

VCA Transplantation

The Living Legacy Foundation of Maryland, in partnership with Johns Hopkins University, is launching a national campaign to raise awareness about Vascularized Composite Allotransplantation (VCA) and VCA donation. The campaign includes educational materials designed to provide the public with information about VCA donation, including statistics, outcomes, risks, and benefits.

What is Vascular Composite Allotransplantation (VCA)?

Vascular Composite Allotransplantation is a medical term used to describe hand, upper limb, face, uterus, penis, and other transplants. It is a surgery in which a body part from a deceased person who had agreed to donate (the donor) is transplanted to a person who needs that body part (the recipient). Only the uterus can be donated from a living person who has agreed to donate.

The hands, upper limbs, face, and uterus are now defined as organs, just like the kidneys, liver, or heart.

Who is VCA for?

People who have experienced severe injury to their face, hands, arms, uterus, or other VCA organs due to disease, infection, or trauma may be eligible for VCA transplant. Some examples of people who might be eligible include:

- A man whose face was damaged from a severe burn.
- A woman who had her uterus removed due to cancer.
- A Wounded Warrior whose hands and arms were injured from an explosive device while serving in the military.

All people seeking a VCA transplant must go through a medical and psychosocial evaluation process before being placed on the waiting list to receive a transplant.

How does VCA donation benefit recipients?

VCA improves the quality of life for many recipients. For many VCA transplant recipients, specifically face and upper limb recipients, this means being able to engage socially and be in public without being stared at or asked about their condition.

Other examples include:

- Hand and upper limb transplants can help recipients eat with utensils, drive a car, and hold hands.
- Face transplants can help recipients speak, chew, and swallow food, and make facial expressions.
- Uterus transplants can help recipients become pregnant and deliver a baby.
- Abdominal wall transplants can help recipients recover from intestinal surgeries and regain strength needed for walking and sitting down.
- Penis transplants can help recipients urinate and regain sexual function.

Some recipients have said that VCA has helped restore their self-esteem, confidence, and feeling of wholeness. Outcomes and results differ for each VCA recipient and are based on the recipient's

physical condition, psychological well-being, and social support system, as well as the body's response to the new organ. Success is measured differently for each VCA organ type and for each recipient.

What are the risks of VCA for recipients?

VCA transplantation is an emerging field in medicine, and research is still being done to understand how VCA affects recipients psychologically and in the long-term. Just like kidney, liver, heart, and other common transplants, VCA transplants carry risks during and after the transplant procedure.

The body may reject the transplanted organ if the body views the organ as a foreign object. That is why it is important for recipients to always take anti-rejection medicines to prevent rejection from happening. For all organs, except for the uterus, recipients must take anti-rejection medicines for their whole life. For uterus transplants, recipients take anti-rejection medication until they have had a maximum of two children. After having children, the uterus is removed and the recipient can stop taking anti-rejection medicines.

Other risks:

- There is no guarantee that the transplanted organ will work the same way as the recipient's original organ.
- There are additional psychological risks associated with VCA, such as problems adjusting to one's new body image after transplant.
 - (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4801807/>)
- There have been a few cases of recipients asking for their transplanted organ to be removed.
 - (<https://time.com/4419959/double-hand-transplant-surgery/>)
- There have been reports of recipients or their partners having difficulty adjusting to the transplant.
- A uterus transplant can be stressful to the recipient because they receive an embryo and become pregnant starting 6 to 12 months after their transplant.

What are the costs associated with VCA?

VCA transplants are innovative procedures, and have been paid for in the past by research grants, donations, and/or the hospitals performing VCAs. The main costs associated with VCA are for the surgery itself, physical therapy after the operation, and anti-rejection medicines. VCA surgeries can last many hours and require a large number of surgeons and other specialists, making them expensive procedures. There are also indirect costs, such as time taken off of work for the procedure and for routine physical therapy.

Some VCA transplant programs received reimbursement for the anti-rejection medicines through insurance. However, insurance coverage is not standard for all programs and insurance types.

Caregivers are needed to help recipients to recover and rehabilitate, including daily care and transportation to appointments.

How do I become a VCA donor?

You must first be a registered organ donor to be contacted for VCA donation. When a person who agreed to be an organ donor dies, a local Organ Procurement Organization (OPO) personnel may ask

the family whether they would like to donate their deceased loved one's organs for VCA. This is called family authorization.

When a deceased donor's family agrees to VCA donation, they can choose which VCA organs they would like to donate.

If you would like to be a living uterus donor, you can talk to a transplant center and undergo an evaluation to see if you are eligible to donate.

- <https://www.donoralliance.org/professional-partners/transplant-centers/>
- There are other requirements and tests to match VCA organs with people who need them.

Does being an organ donor mean you are automatically a VCA donor?

No. Signing up to be an organ donor through your driver's license or state registry **DOES NOT** automatically mean that you are a VCA organ donor. Medical professionals will approach the family of a person who died about the option of VCA donation on a case-by-case basis, if they think you will be a good match for the recipient.

What are the benefits of providing a VCA donation?

Watch/Read about how VCA is already changing lives!

- Face transplant:
 - <https://www.nationalgeographic.com/magazine/issue/september-2018>
 - <https://www.cbsnews.com/pictures/amazing-face-transplants-graphic-images/6/>
 - <https://time.com/5709294/first-african-american-face-transplant/>
 - <https://www.youtube.com/watch?v=B7Och1YkWRl>
 - <https://www.today.com/health/face-transplants-carmen-tarleton-becomes-1st-receive-2nd-face-transplant-t209579>
 - <https://www.youtube.com/watch?v=3Xf-TtkxxA>
- Hand transplant:
 - <https://www.usatoday.com/story/news/nation-now/2017/07/19/zion-harvey/491548001/>
 - <https://www.youtube.com/watch?v=T5DUqeGFGWo>
 - <https://www.usatoday.com/story/news/nation/2013/01/28/double-arm-transplant-soldier/1870357/>
 - <https://www.retirees.af.mil/News/Article-Display/Article/440487/retiree-receives-first-hand-transplant-in-dod/>
 - <https://www.npr.org/sections/thetwo-way/2016/10/05/496781581/former-marine-receives-double-arm-transplant>
 - <https://www.youtube.com/watch?v=qYZqunbNGt8>
 - <https://www.wtvr.com/news/local-news/chesterfield-man-who-lost-hands-in-farming-accident-recovers-from-double-hand-transplant-i-took-the-negative-and-made-it-positive>
- Face and hand transplant:
 - <https://www.cnn.com/2021/02/03/us/face-and-double-hand-transplant/index.html>
 - <https://www.bbc.com/news/world-us-canada-55933848>
- Abdominal wall transplant:
 - <https://spectrumlocalnews.com/nc/triangle-sandhills/news/2018/11/15/duke-doctors-give-fayetteville-vet-a-new-belly-button--you-read-correctly->
 - <https://www.youtube.com/watch?v=jv-vbCgkLyM>
- Uterus transplant:
 - <https://www.inquirer.com/health/uterus-transplant-baby-penn-20210804.html>
 - <https://www.theguardian.com/lifeandstyle/2021/oct/15/experience-i-had-a-baby-using-a-donated-uterus>

- <https://www.nbcdfw.com/news/health/north-texas-mother-becomes-first-in-country-to-deliver-2-babies-after-uterus-transplant/2512851/>
- <https://fertilitycenterofdallas.com/blog/2021/02/01/12-live-births-from-uterus-transplants/>
- Penis transplant:
 - <https://www.nytimes.com/2015/12/07/health/penis-transplants-being-planned-to-heal-troops-hidden-wounds.html>
 - <https://www.capitalgazette.com/bs-hs-hopkins-penis-transplant-20151207-story.html>

Some families have reported feeling happy that their deceased loved ones can donate their organs and help someone even after death. The wife of one donor said, “I am filled with great joy knowing that he was able to give a little of himself to ensure a better quality of life for someone else.”

(<https://www.statnews.com/2017/02/17/face-transplant>)

What can I do now?

- Learn more about VCA:
 - Resources:
 - Health Resources Services Administration <https://www.organdonor.gov/professionals/outreach-materials/vca-organ-transplant-fact-sheet-print-english>
 - Organ Procurement and Transplantation Network: <https://optn.transplant.hrsa.gov/resources/by-organ/vascular-composite-allograft/vcas-from-living-donors/>
 - United Network for Organ Sharing: <https://transplantliving.org/organ-facts/vascular-composite-allografts/>
 - The Alliance: <https://www.organdonationalliance.org/insight/vascularized-composite-allograft-transplants/>
 - American Society of Transplantation: <https://www.myast.org/public-policy/vascularized-composite-allotransplantation-vca-research>
- Share information about VCA with your loved ones, friends, and colleagues.
- Talk to your family or loved ones if you want to be a VCA donor and tell them how you feel. Due to the sensitive nature of VCAs, donation may be distressing to the family who may have to adjust funeral arrangements to accommodate for the differences in the donor’s appearance.
- It is important for family members or loved ones to understand your wishes so they can authorize VCA donation on your behalf.

VCA Transplants Performed in the US as of [July 19, 2022]

Organ Type	Total Number of Transplants Performed
Uterus	36
Abdominal Wall	20
Upper Limb (bilateral)	19
Upper Limb (unilateral)	18
Craniofacial	18
Penis	2
Scalp	1

VCA Transplant Waitlists in the US as of [July 19, 2022]

Transplanted Organ Type	Number of People Waitlisted
Uterus	6
Abdominal Wall	6
Upper Limb (unilateral)	3
Craniofacial	1
Upper Limb (bilateral)	1
Scalp	1

Source: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>

Data is from the Organ Procurement and Transplantation Network (OPTN) national data as of July 19, 2022.

VCA Transplant Centers in the US

Hospital Name	Location	VCA Organ(s)
Baylor University Medical Center	Dallas, TX	Genitourinary, uterine
Boston Children's Hospital	Boston, MA	Abdominal wall, head and neck, upper limb
Brigham & Women's Hospital	Boston, MA	Abdominal wall, genitourinary, head and neck, lower limb, uterine, upper limb
Children's Hospital of Philadelphia	Philadelphia, PA	Upper limb
Cleveland Clinic Foundation	Cleveland, OH	Abdominal wall, genitourinary, head and neck, uterine, upper limb
Duke University Hospital	Durham, NC	Upper limb
Jackson Memorial Hospital	Miami, FL	Abdominal wall
Jewish Hospital/Kleinert Institute	Louisville, KY	Upper limb
Johns Hopkins Hospital	Baltimore, MD	Abdominal wall, genitourinary, head and neck, penile, upper limb
Keck Hospital of USC	Los Angeles, CA	Genitourinary

Massachusetts General Hospital	Boston, MA	Abdominal wall, genitourinary, head and neck, upper limb
Mayo Clinic Hospital, AZ	Phoenix, AZ	Head and neck
Medstar Georgetown Transplant Institute	Washington, DC	Lower limb
Mount Sinai Medical Center	New York, NY	Abdominal wall, head, and neck
New York University Medical Center	New York, NY	Abdominal wall, genitourinary, head and neck, upper limb
St. Mary's Hospital - Rochester Methodist Hospital (Mayo Clinic)	Rochester, MN	Head and neck, upper limb
Stanford Health Care	Stanford, CA	Abdominal wall
The Hospital of the University of Pennsylvania	Philadelphia, PA	Genitourinary, upper limb, uterine
UCLA Medical Center	Los Angeles, CA	Abdominal wall, head and neck, upper limb
University of Maryland Medical System	Baltimore, MD	Abdominal wall, head and neck, penile
University of Alabama Hospital	Birmingham, AL	Genitourinary
University of Chicago Medical Center	Chicago, IL	Abdominal wall, genitourinary, head and neck, lower limb, nerve, vessel and vasculature, upper limb
University of Illinois Medical Center	Chicago, IL	Upper limb
University of Michigan Medical Center	Ann Arbor, MI	Abdominal wall, head, and neck
University of Pittsburgh Medical Center	Pittsburgh, PA	Head and neck, upper limb
University of Washington Medical Center	Seattle, WA	Abdominal wall, head and neck, upper limb
Wake Forest Baptist Medical Center	Winston-Salem, NC	Penile

<https://optn.transplant.hrsa.gov/members/member-directory/>

Timeline of VCA

- 1998 The world's first successful human hand/arm transplantation is performed in France.
- 1999 The first successful human hand/arm transplantation is performed in the United States.
- 2000 The world's first successful uterus transplantation is performed in Saudi Arabia.
- 2003 The world's first abdominal wall transplantations are performed on a total of eight people.
- 2005 The world's first successful face transplantation is performed in France.

- The U.S. Department of Health and Human Services announces that Vascular
- 2014 Composite Allografts are recognized as organs.
- 2015 The first successful scalp transplant is performed in Texas, United States.
- 2015 The world's first successful penile transplant is performed in Cape Town, South Africa.
- 2016 The first uterus transplant is performed Ohio, United States.
- 2016 The first successful penile transplant in the United States is performed in Massachusetts.
- 2019 A woman gives birth after receiving a uterus transplant from a deceased donor for the first time in North America.

Appendix B: Content Analysis Manuscript Publication Abstract

Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations

Sarah E Van Pilsum Rasmussen¹, Jefferson Uriarte², Naomi Anderson², Brianna Doby¹, Alexander Ferzola¹, Hannah Sung¹, Carisa Cooney³, Gerald Brandacher³, Elisa Gordon^{2,4}, Dorry L Segev^{1,5,6}, Macey L Henderson^{1,6}

¹Department of Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.

²Center for Health Services and Outcomes Research, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA.

³Department of Plastic and Reconstructive Surgery, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA.

⁴Department of Surgery, Northwestern University Feinberg School of Medicine, Chicago, Illinois, USA.

⁵Department of Epidemiology, Johns Hopkins University Bloomberg School of Public Health, Baltimore, Maryland, USA.

⁶Department of Acute and Chronic Care, Johns Hopkins University School of Nursing, Baltimore, Maryland, USA.

- DOI: [10.1111/ctr.14066](https://doi.org/10.1111/ctr.14066)

Abstract

As the field of Vascular Composite Allotransplantation (VCA) grows, demand for VCA donations will increase. The public should be made aware of this treatment option to support patients' informed decision-making and authorization for deceased donation. We assessed the availability and quality of existing VCA public education materials from organ procurement organizations (OPOs), transplant centers, the Organ Procurement and Transplant Network, Veterans Affairs, and the Department of Defense. A content analysis was performed to identify topics covered and important gaps. In total, 1314 public education materials were analyzed, including OPO Facebook posts (61.6%), OPO Twitter posts (29.9%), websites (6.4%), and written documents (eg, fact sheets, research reports) (2.1%). Upper extremity (34.7%) and face (34.5%) transplants were more commonly covered than reproductive (6.4%) or other VCA types (2.8%). Most materials (76.6%) referenced a specific VCA story. However, few materials described which patient population could benefit from VCA (eg, Veterans, amputees, burn victims, 16.4%), the authorization requirements for VCA donation (6.6%), or the appearance of transplanted VCA organs (1.2%). Current VCA public education materials do not adequately educate the public. More comprehensive education materials are needed to prepare the public to authorize VCA donation, become potential donors, or learn about transplant options.

Keywords: Vascular Composite Allotransplantation; content analysis; education; reconstructive transplantation; vascular composite allograft.

Citation: Van Pilsum Rasmussen SE, Uriarte J, Anderson N, Doby B, Ferzola A, Sung H, Cooney C, Brandacher G, Gordon E, Segev DL, Henderson ML. Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations. *Clin Transplant*. 2020 Nov;34(11):e14066. doi: 10.1111/ctr.14066. Epub 2020 Oct 5. PMID: 32810365.

Appendix C: Focus Group VCA Information Needs Manuscript Publication Abstract

Public Perceptions and Information Needs of VCA Transplantation and Donation: A Mixed Methods Study

Alexander Ferzola¹, Jefferson Uriarte², Hannah C Sung¹, Naomi Anderson², Carolyn Sidoti³, Sarah E Van Pilsum Rasmussen¹, Max Downey³, Karen B Vanterpool³, Whitney Langlee¹, Samantha Klitenic³, Lisa Young¹, Carisa M Cooney⁴, Ieesha Johnson⁵, Allison Coleman⁵, Jaimie T Shores⁴, Dorry L Segev^{1,3}, Gerald Brandacher⁴, Elisa J Gordon^{2,6}, Macey L Levan^{1,3}

¹Department of Surgery, School of Medicine, Johns Hopkins Medicine, Baltimore, MD, United States.

²Center for Health Services and Outcomes Research, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States.

³Department of Surgery, Grossman School of Medicine, New York University, New York, NY, United States.

⁴Department of Plastic and Reconstructive Surgery, School of Medicine, Johns Hopkins Medicine, Baltimore, MD, United States.

⁵The Living Legacy Foundation, Organ Procurement Organization, Halethorpe, MD, United States.

⁶Department of Surgery, Feinberg School of Medicine, Northwestern University, Chicago, IL, United States.

- DOI: [10.3389/ti.2022.10752](https://doi.org/10.3389/ti.2022.10752)

Abstract

Vascularized Composite Allotransplantation (VCA) involves transplantation of multiple tissues from a donor to a recipient (e.g., skin, muscle, bone). Little is known about the US public's perceptions of and attitudes toward VCA organ donation. This multi-site, cross-sectional, mixed methods study involved focus groups and surveys to assess members of the general public's attitudes about VCA, and willingness and barriers to donate VCA organs. Qualitative data were analyzed by thematic analysis; quantitative data were analyzed by descriptive statistics. In focus groups ($n = 6$, 42 participants), most participants were female (57%) and Black (62%) with mean age of 42.6 years. Three main themes emerged: 1) awareness and perceptions of VCA, 2) purpose of VCA donation, 3) and barriers to VCA donation. Participants had heard little about VCA and sought information about VCA donation. Participants perceived VCA as challenging their concepts of "normality" and voiced concerns that VCA would create "Frankenstein[s]." Barriers to VCA donation included disruptions to end-of-life arrangements and information gaps regarding the donation process. Participants reported moderate to high willingness to donate their hands (69%) and face (50%) Public education efforts should address the specific needs and concerns of the public to facilitate VCA donation and family authorization.

Keywords: donation; focus group; information needs; perceptions; public education; qualitative; vascularized composite allotransplantation.

Citation: Ferzola A, Uriarte J, Sung HC, Anderson N, Sidoti C, Van Pilsum Rasmussen SE, Downey M, Vanterpool KB, Langlee W, Klitenic S, Young L, Cooney CM, Johnson I, Coleman A, Shores JT, Segev DL, Brandacher G, Gordon EJ, Levan ML. Public Perceptions and Information Needs of VCA Transplantation and Donation: A Mixed Methods Study. *Transpl Int.* 2022 Nov 14;35:10752. doi: 10.3389/ti.2022.10752.

Appendix D: Delphi Panel Poster Abstract presented at ATC 2021

A Delphi Panel to Develop Public Educational Materials About Vascular Composite Allotransplantation (VCA)

C. Sidoti¹, A. Ferzola², H. Sung², S. Rasmussen², E. Gordon³, N. Anderson³, J. Uriarte³, C. Cooney⁴, G. Brandacher⁴, M. Levan²

¹Department of Surgery, Johns Hopkins School of Medicine, East Islip, NY, ²Department of Surgery, Johns Hopkins School of Medicine, Baltimore, MD, ³Department of Surgery, Northwestern University Feinberg School of Medicine, Chicago, IL, ⁴Department of Plastic and Reconstructive Surgery, Johns Hopkins School of Medicine, Baltimore, MD

Meeting: [2021 American Transplant Congress](#)

Abstract number: 390

Keywords: [Donation](#)

***Purpose:** As the field of Vascular Composite Allotransplantation (VCA) grows, so does the demand for VCA donations. The education materials about VCA and VCA donation currently accessible to the public are lacking, and there is no consensus on how to best educate the public about VCA.

***Methods:** We conducted an online Delphi panel with clinical and policy experts in the field of VCA to identify which topics should be presented in educational materials for the public about VCA donation in a comprehensive, relatable, and understandable manner. The modified Delphi method involved two rounds of surveys designed to facilitate consensus within a group. We developed an initial list of topics for inclusion in educational materials based on a previously reported focus group study that assessed information needs when considering VCA donation. Round one assessed the importance of different educational topics using Likert Scale questions. After presenting 29 topics to participants in the first round, we removed topics that had a mean Likert Scale response less than “neutral” and added new topics suggested by experts in the first-round survey. In round two, we presented 27 topics and corresponding educational statements and asked respondents to provide additional feedback on the importance of topics on a Likert Scale. The Likert Scale ranged from “Do Not Include” to “Definitely Include”. Responses were analyzed using descriptive statistics.

***Results:** We received 18 and 15 responses to the first-round and second-round surveys, respectively. Participants were affiliated with institutions across the nation. At the conclusion of the second-round survey, 21 topics had a mean Likert Scale response greater than “Neutral”, represented as 3.0 (Table 1). The five most important topics were: potential VCA recipients, the consent process for VCA donation, the definition of VCA, purpose of VCA, and most common VCA organs.

***Conclusions:** Our findings identified expert-driven topic areas for use in educational materials for the public about VCA. Future research will assess whether these materials contribute to the public’s understanding of VCA and VCA donation. Public education about the opportunity to be a VCA donor is crucial to increasing access to VCA.

Table 1: Topics to Include in Educational Materials

Topic	Mean (SD) Likert Scale Inclusion Response (1 = Do not include, 5 = Definitely Include)
Potential VCA Recipients	4.73 (.57)
Consent Process for VCA Donation	4.73 (.44)
Definition of VCA	4.47 (1.02)
Purpose of VCA	4.47 (.88)
Most Common VCA Organs Transplanted	4.47 (.62)
Authorization Process for VCA Donation	4.33 (.70)
VCA Outcomes	4.27 (1.06)
Presence of VCA in US	4.27 (.85)
VCA Success Stories	4.13 (1.31)
Functionality Return after VCA	4.00 (1.32)
VCA Recovery	4.00 (1.21)
Organ Allocation System	3.93 (1.00)
Screening Process for VCA	3.87 (.76)
Pre and Post-Transplant Images of VCA Recipient	3.73 (1.34)
VCA Organ Recovery Process	3.67 (1.40)
Risks of VCA	3.67 (.76)
Presence of VCA Globally	3.53 (1.20)
Specific Consent for Individual VCA Organs	3.40 (1.25)
VCAs are Organs	3.40 (1.12)
Life-long Commitment when Receiving a VCA Organ	3.27 (1.24)
Matching Process for VCA	3.20 (1.28)