

AWARD NUMBER: W81XWH-18-1-0779

TITLE: Understanding and Supporting Public Information Needs about VCA Donation

PRINCIPAL INVESTIGATOR: Macey Levan (Henderson), JD, Ph.D.

CONTRACTING ORGANIZATION: Johns Hopkins University

REPORT DATE: OCTOBER 2021

TYPE OF REPORT: Annual Technical

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.**

<b>1. REPORT DATE</b> OCTOBER 2021	<b>2. REPORT TYPE</b> Annual Technical Report	<b>3. DATES COVERED</b> 9/30/2020-9/29/2021
<b>4. TITLE AND SUBTITLE</b>  Understanding and Supporting Public Information Needs About VCA Donation		<b>5a. CONTRACT NUMBER</b>
		<b>5b. GRANT NUMBER</b> W81XWH-18-1-0779
		<b>5c. PROGRAM ELEMENT NUMBER</b>
<b>6. AUTHOR(S)</b> Macey Levan (Henderson), JD PhD Elisa Gordon, PhD MPH Gerald Brandacher MD  E-Mail: <a href="mailto:macey@jhmi.edu">macey@jhmi.edu</a> <a href="mailto:e-gordon@northwestern.edu">e-gordon@northwestern.edu</a> <a href="mailto:gbranda2@jhmi.edu">gbranda2@jhmi.edu</a>		<b>5d. PROJECT NUMBER</b>
		<b>5e. TASK NUMBER</b>
		<b>5f. WORK UNIT NUMBER</b>
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b>  Johns Hopkins University Department of Surgery 2000 E Monument St Baltimore, MD 21201  Northwestern University Center for Health Services and Outcomes Research 20th Floor 633 N. St Clair Chicago Illinois 60611		<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b>  U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012		<b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>
		<b>11. SPONSOR/MONITOR'S REPORT NUMBER(S)</b>
<b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b>  Approved for Public Release; Distribution Unlimited		
<b>13. SUPPLEMENTARY NOTES</b>		

**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 aims to assess the availability and quality of existing VCA public education materials and to develop educational materials that increase public knowledge, understanding, perceptions of comfort, and willingness to donate.

To date, 1,314 public education materials have been analyzed. Materials commonly covered upper limb (34.7%) and face (34.5%) transplants, and often referenced a specific VCA story (76.6%). Materials less commonly covered reproductive VCA (6.4%) or other VCA types (2.8%). In addition, six focus groups with members of the public have been conducted (n=42 total) in two metropolitan cities. Focus group participants discussed their impressions of and concerns about VCA, willingness to be a VCA donor, willingness to authorize VCA donation, perceived barriers to VCA donation, and recommendations for public education about VCA. We analyzed focus group transcriptions using thematic analysis.

Participants recommended educating the public about VCA by making information clear, comprehensible, and relatable.

**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:**

a. REPORT

b. ABSTRACT

c. THIS PAGE

Unclassified

Unclassified

Unclassified

**17. LIMITATION OF ABSTRACT**

Unclassified

**18. NUMBER OF PAGES**

15

**19a. NAME OF RESPONSIBLE PERSON**  
USAMRMC**19b. TELEPHONE NUMBER** (include area code)

## TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	5
2. Keywords	5
3. Accomplishments	5
4. Impact	8
5. Changes/Problems	9
6. Products	10
7. Participants & Other Collaborating Organizations	11
8. Special Reporting Requirements	12
9. Appendices	12

## 1. INTRODUCTION:

As the field of Vascular Composite Allograft Transplantation (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 aims to assess the availability and quality of public information about VCA donation, and to develop educational materials to increase public knowledge of and comfort with VCA.

## 2. KEYWORDS:

Vascular Composite Allograft Transplantation  
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

**Major Task 5:** Analyze Qualitative Data

- Milestone: Report findings from focus groups  
Timeline: 14 months 95% 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 95% complete

**Major Task 7: Conduct Delphi Panel**

- Milestone: report results from data analysis  
Timeline: 24 months 100% complete
- Milestone: Write manuscript detailing the results of the consensus reached through the Delphi method  
Timeline: 24 months 95% 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 focus groups at each site  
Timeline: 26 months 100% complete at JHU (6 focus groups); 100% at NU (6 focus groups)

**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 50% complete
- Milestone: manuscript preparation/submission for publication report 0% complete

**What was accomplished under these goals?**

**Major Task 5: Analyze Qualitative Data**

**Milestone Achieved: Report findings from focus groups – 95% complete**

- The manuscript is being revised and prepared by co-authors to be submitted to *VCA Journal*

**Major Task 6: Develop Educational Materials for VCA**

- Subtask 2: Develop social media strategy – **95% complete**
  - The study team has held bi-weekly meetings with the collaborating organization (The Living Legacy Foundation) to carry out the social media campaign for educating the public and reaching potential VCA donors:
  - A combination of participant-submitted videos, pictures, and news stories will be used to draw users to the main website (hosted by the LLF) where all of the education materials will be available
  - The study team is coordinating with a Graphic Designer to assist with VCA Education taglines, slogans, and infographics. Logos were reviewed by focus group participants.
  - Given focus group responses, we will refine and finalize materials in the next quarter.
  - We have begun reaching out to VCA experts, recipients, donor advocates, and others to create videos telling their story. The LLF has met with three people to record a video for the social media campaign.

**Major Task 7: Conduct Delphi Panel**

- Milestone Achieved: Write manuscript detailing the results of the consensus reached through the Delphi method – **95% complete**
  - The Delphi Panel manuscript is being revised and prepared by co-authors to be submitted to *VCA Journal*

**Major Task 8: Conduct Focus Groups about Developed VCA Educational Materials– 100% at JHU, 100% at NU complete**

- JHU completed 6 online focus groups during this reporting period (n=28 consented participants). NU completed 6 online focus groups during this reporting period (n=28 consented participants). Focus group participants were recruited via a Facebook advertisement that lasted 10 days and recruited 217 interested individuals. Contacts were allocated to both study sites for recruitment.
- Focus groups were conducted online via Zoom. The moderator and moderator's assistants were on each call. The moderator walked participants through each part of the education materials (writing section, graphs/diagrams, pictures, logos) seeking feedback from each portion. After the focus group, participants completed an online demographics survey through Qualtrics.

- Preliminary findings from the focus groups suggest that participants found the content informative, persuasive and easy to read; graphs/diagrams needed further clarity for readability; feedback from the images shown varied, and the logos needed further detail. Additionally, at NU further clarification was requested about the registration process to be a VCA donor, and the stories behind individuals who have received a VCA.
- We have begun analysis, compiling themes from the focus groups and making changes to the educational materials to be presented online

#### Major Task 9: Conduct Further Usability Testing via Donate Life America – **50% complete**

- Subtask 1: Work with Donate Life America on launching the social media strategy
  - The PI's and Grant admins have shifted this responsibility from Donate Life America to the local OPO, the Living Legacy Foundation to facilitate more feasible meetings and strategy. Biweekly meetings between the study team and the LLF have begun for video production towards the social media campaign.

#### Discussion of stated goals not met:

- Usability Testing is delayed and has not been accomplished in Y3 as we had stated in our goals. A no-cost extension was submitted for this project. We are currently preparing the website for launch and usability testing.

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

The study team at Northwestern and Johns Hopkins were trained in qualitative research methods, including the design and facilitating of focus groups and the analysis of qualitative data. Johns Hopkins is collaborating with the LLF to learn about and implement a social media campaign to help awareness about VCA.

### **How were the results disseminated to communities of interest?**

The content analysis was published:

Van Pilsum Rasmussen SE, Uriarte J, Anderson N, Doby B, Ferzola A, Sung H, Cooney C, Brandacher G, Gordon EJ, Segev DL, Henderson ML. Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations. Clin Transplant. 2020 Aug 18:e14066. doi: 10.1111/ctr.14066. Epub ahead of print. PMID: 32810365.

### **Posters and Oral Presentations**

Henderson M, 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. 2019 American Transplant Congress, Boston, MA.

Rasmussen S, Henderson ML, Uriarte J, Anderson N, Doby B, Cooney C, Segev DL, Brandacher G, Gordon E. The Scope and Limitations of Public Education Materials about Vascular Composite Allotransplantation and Donation in the United States. 2020 American Society of Transplant Surgeons, Miami, FL.

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 14, 2021.

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 14, 2021.

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. Cutting Edge of Transplantation Summit 2020, Phoenix, AZ.

C. Sidoti, A. Ferzola, H. Sung, S. Rasmussen, E. Gordon, N. Anderson, J. Uriarte, C. Cooney, G. Brandacher, M. Levan. A Delphi Panel to Develop Public Education Materials About Vascular Composite Allotransplantation (VCA). 2021 American Transplant Congress, Virtual.

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

During the next annual reporting period, we will:

- Analyze feedback from the focus groups and modify education materials
- Continue our social media strategy in collaboration with LLF
- Prepare to submit our manuscript that reports on the qualitative results from the first round of focus groups
- Prepare to submit our manuscript that reports Delphi Panel findings
- Develop website to be hosted by the LLF with educational materials.

#### **4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**  
*If there is nothing significant to report during this reporting period, state "Nothing to Report."*

*Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).*

Ensuring that the public is aware of the option of VCA donation in advance of family authorization is important for priming the public for greater understanding, receptivity, and willingness to donate VCA organs.

The overall goal of the study is to increase public awareness and knowledge of VCA. We employed qualitative research methods and analytic strategies consisting of focus groups, thematic analysis, and content analysis of existing VCA educational materials 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.

Then, we used the Delphi method, a well-validated technique for gathering consensus data from a group of experts through a structured, iterative process of group communication to generate an appropriate lexicon for communicating public messages and dissemination strategies about VCA donation. This involved focus groups with members of the public to assess their perceptions of the new materials and delivery platforms (traditional media and digital/social media) for the communication and dissemination of the VCA donation awareness education.

Lastly, we will use social media research methods to conduct a sentiment analysis of the social media response to the disseminated VCA education materials.

**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?**

Nothing to report

**5. CHANGES/PROBLEMS:**

**Changes in approach and reasons for change**

Nothing to report

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

**COVID clinical trials:** At JHU – JHU’s kidney transplant center started conducting a 3<sup>rd</sup> Dose COVID-19 vaccine clinical trial called “COVID-19 Protection After Transplantation (CPAT)” in August that pulled staff away from the DOD-Ethics study. An Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) was released on 8/12/2021 which allowed immuno-compromised people, including kidney transplant patients, to receive a 3<sup>rd</sup> dose of Modern/Pfizer-BioNTech at local pharmacies due to low antibodies from the first 2 doses. Since patients could now receive a 3<sup>rd</sup> dose independently from this clinical trial, help was needed urgently to recruit and consent as many patients as possible to the NIH-funded clinical trial. If a potential participant already received their 3<sup>rd</sup> dose outside of JHU, then they would become ineligible for this study.

JHU’s study team members for DoD-Ethics are involved in kidney transplant research as well, so they were asked to help with the clinical trial and another observational study for the 3<sup>rd</sup> Dose COVID-19 Vaccine. Study members from JHU were onboarded onto this project and observational COVID study in the week of 8/16/2021-8/20/2021 and participation in these studies continued through 9/29/2021.

**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**

**Significant changes in use or care of human subjects**

Nothing to report

## **Significant changes in use or care of vertebrate animals**

Nothing to report

## **Significant changes in use of biohazards and/or select agents**

Nothing to report

## **6. PRODUCTS:**

### **Publications, conference papers, and presentations**

#### **Journal publications.**

Van Pilsum Rasmussen SE, Uriarte J, Anderson N, Doby B, Ferzola A, Sung H, Cooney C, Brandacher G, Gordon EJ, Segev DL, Henderson ML. Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations. Clin Transplant. 2020 Aug 18:e14066. doi: 10.1111/ctr.14066. Epub ahead of print. PMID: 32810365.

#### **Books or other non-periodical, one-time publications.**

Nothing to report

#### **Other publications, conference papers and presentations.**

Henderson M, 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. 2019 American Transplant Congress, Boston, MA.

Rasmussen S, Henderson ML, Uriarte J, Anderson N, Doby B, Cooney C, Segev DL, Brandacher G, Gordon E. The Scope and Limitations of Public Education Materials about Vascular Composite Allotransplantation and Donation in the United States. 2020 American Society of Transplant Surgeons, Miami, FL

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

C. Sidoti, A. Ferzola, H. Sung, S. Rasmussen, E. Gordon, N. Anderson, J. Uriarte, C. Cooney, G. Brandacher, M. Levan. A Delphi Panel to Develop Public Education Materials About Vascular Composite Allotransplantation (VCA). 2021 American Transplant Congress, Virtual

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. Cutting Edge of Transplantation Summit 2020, Virtual.

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 14, 2021.

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 14, 2021.

### **Website(s) or other Internet site(s)**

Nothing to report

### **Technologies or techniques**

### **Inventions, patent applications, and/or licenses**

Nothing to report

### **Other Products**

Nothing to report

## **7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:**

### **What individuals have worked on the project?**

Note: Reported for this quarter only, not entire year (June 29<sup>th</sup> – Sept. 29<sup>th</sup> 2021)

Name:	Macey Levan (Henderson)
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-4239-1252
Nearest person month worked:	0.9 Calendar Months
Contribution to Project:	Oversight of all research activities

Name:	Dorry Segev
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0002-1924-4801
Nearest person month worked:	0.25 Calendar Months
Contribution to Project:	Oversight of all research activities

Name:	Jeffrey Kahn
Project Role:	Co-Investigator
Nearest person month worked:	0.12 Calendar Months
Contribution to Project:	Oversight of research activities

Name	Elisa Gordon
Project Role:	Partnering Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-0969-1998
Nearest person month worked:	1.84 Calendar months
Contribution to Project:	Study Oversight at Northwestern, edited VCA content analysis manuscript and resubmission letter, guided focus group coding and qualitative analysis, guided study design during COVID

Name: Jefferson Uriarte  
Project Role: Research Project Coordinator  
Researcher Identifier (e.g. ORCID ID): 0000-0002-8507-963X  
Nearest person month worked: 4.85 Calendar months  
Contribution to Project: Edited focus group materials. Assisted in conducting focus groups and participant recruitment. Assisted in analysis and writing of the focus group manuscript.

Name: Madeline Quasebarth  
Project Role: Research Project Coordinator  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 1.18 Calendar months  
Contribution to Project: Trained on the project.

Name: Naomi Anderson  
Project Role: Research Project Coordinator  
Researcher Identifier (e.g. ORCID ID): 0000-0002-8991-9739  
Nearest person month worked: 3.44 Calendar months  
Contribution to Project: Edited focus group materials. Assisted in conducting focus groups and participant recruitment. Assisted in analysis and writing of the focus group manuscript.

Name: Gerald Brandacher  
Project Role: Partnering Principal Investigator  
Researcher Identifier (e.g. ORCID ID): 0000-0001-7790-441X  
Nearest person month worked: 0.90 Calendar Months  
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: 0.49 Calendar Months  
Contribution to Project: Oversight of regulatory approvals

Name: Jaimie Shores  
Project Role: Co-investigator  
Nearest person month worked: 0.12 Calendar Months  
Contribution to Project: Oversight of regulatory approvals

Name: Hannah Sung  
Project Role: Research Data Analyst  
Nearest person month worked: 0.00 Calendar months  
Contribution to Project: Moderation of focus groups, assisted in qualitative analysis and writing the focus group manuscript.

Name: Carolyn Sidoti  
Project Role: Research Program Supervisor  
Nearest person month worked: 0.00 Calendar months  
Contribution to Project: Moderation of focus groups, coordinator for all regulatory updates, assisted in qualitative analysis and writing the focus group manuscript.

Name: Samantha Klitenic  
Project Role: Research Assistant  
Nearest person month worked: 0.00 Calendar months  
Contribution to Project: Coordinator for all regulatory updates, communication with LLF, helping to edit educational materials.

Name: Max Downey  
Project Role: Research Assistant  
Nearest person month worked: 0.00 Calendar months  
Contribution to Project: Moderation of focus groups, coordinator for all regulatory updates, and assisted in qualitative analysis.

**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?**

Nothing to Report

**8. SPECIAL REPORTING REQUIREMENTS:**

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:**

**9. APPENDICES:**

**Appendix 1**

Van Pilsum Rasmussen SE, Uriarte J, Anderson N, Doby B, Ferzola A, Sung H, Cooney C, Brandacher G, Gordon EJ, Segev DL, Henderson ML. Public education materials about Vascular Composite Allotransplantation and donation in the United States: Current scope and limitations. Clin Transplant. 2020 Aug 18:e14066. doi: 10.1111/ctr.14066. Epub ahead of print. PMID: 32810365.

**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.

## Appendix 2

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.

### **Title: Public Information Needs about VCA Donation and Transplantation in the United States**

Authors: A. Ferzola (1), C. Sidoti (1), H. Sung (1), N. Anderson (2), J. Uriarte (2), C. Cooney (1), G. Brandacher (1), E. Gordon (2), M. Henderson (1)

1. Johns Hopkins University, Baltimore, MD
2. Northwestern University, Evanston, IL

### **Background**

Vascularized Composite Allotransplantation (VCA) involves transplantation of multiple tissues (e.g., skin, muscle, bone, nerves, blood vessels, etc.) as a structural unit from a donor to a recipient. Little is known about the public's understanding of VCA. Prior research found that the public may be less willing to donate VCA organs compared to other solid organs but has not examined the reasons for such reticence in depth. This qualitative study assessed the public's understanding of and informational needs about VCA.

### **Methods**

We conducted focus groups (n=6 groups, n=41 participants) with members of the general public in two geographically distinct metropolitan cities. Focus groups assessed participants' awareness of and attitudes about VCA, information needs about VCA, willingness to be a VCA donor, and willingness to authorize VCA donation. We analyzed focus group transcriptions using thematic analysis.

### **Results**

Across all focus groups we identified impressions and concerns about VCA. Impressions included statements on: the newness of VCA, the risks and benefits, and its medical necessity. Commonly shared concerns ranged from a personal level, like one's appearance after receiving a VCA, to a societal one—whether VCA will push the boundaries of “normalcy.” Participants also expressed varying perspectives on VCA donation. Some felt comfortable donating any VCA organ and saw no difference between VCA and solid organ donation, while others identified specific VCA organs they were not as comfortable donating, the latter pertaining to reproductive organs. We found that an individual's opinion regarding VCA donation does not necessarily reflect their views on a family member's decision to donate. We also captured perceived barriers to VCA donation and incorporate suggestions from the focus groups on how to properly educate the public about VCA.

### **Conclusions**

The public lacked knowledge and held misperceptions about VCA. Public education is needed to address information needs and concerns so that the public is better prepared to become VCA donors or authorize donation of VCA organs.

### Appendix 3

C. Sidoti, A. Ferzola, H. Sung, S. Rasmussen, E. Gordon, N. Anderson, J. Uriarte, C. Cooney, G. Brandacher, M. Levan. A Delphi Panel to Develop Public Education Materials About Vascular Composite Allograft Transplantation (VCA). 2021 American Transplant Congress, Virtual.

**\*Purpose:** As the field of Vascular Composite Allograft Transplantation (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.