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### 13. SUPPLEMENTARY NOTES

#### 14. ABSTRACT

Hand and upper limb transplantation (a form of vascularized composite allotransplantation, or VCA) is an innovative treatment option that aims to restore motor and mobility function and sensation of the hand/arm. Upper extremity (UE) transplantation raises multiple ethical issues, particularly, about informed consent. The overall long-term objective of the proposed study is to optimize the informed consent process for people with upper limb amputations. The proposed study aims to: 1) Qualitatively assess the decision making and informed consent processes for hand transplantation; 2) Develop prototype educational materials (video, website, question prompt sheet) that provide patient-centered information to enhance understanding and reduce undue influence to pursue hand transplantation, and are sensitive to different levels of dysfunction, residual limbs, health literacy, and different racial/ethnic groups; and 3) Formatively evaluate the educational materials through usability testing on people with upper limb amputations' and UE VCA candidates' understanding, satisfaction, and usability.

We accomplished all study aims. We completed all data collection activities including in-depth interviews, semi-structured interviews, focus groups, and usability testing. We developed our website "Within Reach" and began disseminating it to healthcare professionals and patient support groups and advocacy organizations.

Thus far, we published **2** papers on: 1) information needs about UE VCA and the Question Prompt Sheet (QPS) based on **n=50** in-depth interviews and **n=56** semi-structured interviews, and 2) the Within Reach website development process based on **9** focus groups and **n=14** usability testing interviews. We have 2 manuscripts under re-review: a qualitative analysis of patients' perceptions of UE VCA success, and a qualitative analysis of patients' perceptions of UE VCA patient selection criteria; and 1 manuscript under initial peer review: a qualitative analysis of decision making and informed consent about UE VCA based on n=50 interviews. Overall, we presented **8** papers and **7** posters at professional conferences.

In sum, we identified myriad ethical and psychosocial considerations influencing the UE VCA informed consent process and decision-making. While some participants were motivated to consider UE VCA due to dissatisfaction with current treatment options and the desire to regain hand functioning, improve appearance, and gain more independence, their enthusiasm to pursue it was diminished by concerns about jeopardizing their current health and numerous psychosocial factors regarding commitment to rehabilitation, logistical burdens, and interrupting family and work life. Addressing patients' psychosocial concerns may help facilitate informed treatment decisions.

#### 15. SUBJECT TERMS

Ethics  
Hand Transplantation  
UE Amputation  
Informed Consent  
Decision Making  
Vascular Composite Allotransplantation (VCA)  
Reconstructive transplantation  
Education  
In-Depth interviews  
Focus groups  
Thematic analysis  
Qualitative research  
Communication

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## **1. INTRODUCTION:**

Little is known about the informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA). Consequently, the amount and type of information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed, under-prepared, and feeling unduly pressured when considering this option. This study aimed to examine the decision-making process, psychosocial concerns, and information needs about UE VCA among people with UE amputations, and to develop educational materials (i.e., website, videos, question prompt sheet) to help people with UE amputations make informed treatment decisions.

## **2. KEYWORDS:**

Ethics  
Hand Transplantation  
UE Amputation  
Informed Consent  
Decision Making  
Vascular Composite Allotransplantation  
Vascular composite Allograft  
VCA  
Reconstructive transplantation  
Education  
In-Depth Interviews  
Focus groups  
Thematic analysis  
Qualitative research  
Communication

## **3. ACCOMPLISHMENTS:**

### **What were the major goals of the project?**

We wish to clarify two important points with regard to our study sites:

1. Walter Reed National Military Medical Center (WR) received one grant award with Dr. Scott Tintle as a partnering Principal Investigator. Henry M. Jackson Foundation (HJF) and Uniformed Services University of the Health Sciences (USUHS) are collaborating with WR as a single study site. In other words, only one patient population and recruitment process occurred across WR, HJF, and USUHS, acting as 1 study site. These are not 3 different study sites. All reporting below refers to WR on behalf of WR, HJF, and USUHS.
2. Johns Hopkins University (JHU) received two grant awards, with Dr. Macey Levan and Dr. Gerald Brandacher as the partnering Principal Investigators, who are collaborating as a single study site. In other words, only one patient population and recruitment process occurred at JHU, across both awards, as 1 study site. These are not 2 different study sites. All reporting below refers to JHU on behalf of Dr. Levan and Dr. Brandacher.

**Specific Aim 1: Qualitatively assess the informed consent process for upper extremity-VCA transplantation.**

**Major Task 1:** Submit IRB documents for local IRB review

Timeline: 9 months, 100% completed (NU, JHU, WR)

- Milestone #1: HRPO approval

Timeline: 6-9 months, 100% completed (NU, JHU, WR)

**Major Task 2:** Recruit and consent human subjects

- Subtask 1: Place advertisements in newsletters and fliers in clinics

Timeline: 9 months, 100% complete (NU, JHU, WR)

- Subtask 2: Submit internal requests, and contact collaborators and community clinics to obtain lists of eligible potential participants for recruitment, at all sites

Timeline: 9 months, 100% complete (NU, JHU, WR)

- Subtask 3: Recruit participants and obtain informed consent

Timeline: 10-15 months, 100% complete (NU, JHU, WR)

**Major Task 3:** Conduct cognitive interviews, in-depth interviews, and online focus groups to assess: UE amputees' information needs, understanding of VCA risks, benefits, alternatives, and procedures, perceptions of voluntariness for UE VCA, candidates' perceptions of the informed consent process, and decision-making about UE VCA

- Subtask 1: Conduct cognitive interviews with (n=12) participants: UE amputees (n=11) and VCA candidates (n=1)

Timeline: 10-11 months, 100% complete (NU only)

- Subtask 2: Revise in-depth interview guide based on cognitive interview feedback

Timeline: 10-11 months, 100% complete (NU, JHU, WR)

- Subtask 3: Submit revised in-depth interview guide for local IRB and HRPO review

Timeline: 11-12 months, 100% complete (NU, JHU, WR)

- Subtask 4: Conduct in-depth interviews with (n=50) participants

Timeline: 12-18 months, 100% complete (NU, JHU, WR)

- Subtask 5: Conduct online focus groups with UE amputees

Timeline: 12-18 months, 100% complete (NU only)

- Subtask 6: Transcribe in-depth interviews and online focus groups

Timeline: 12-18 months, 100% complete (NU, JHU, WR)

- Subtask 7: Conduct qualitative data analysis

Timeline: 10-21 months, 100% complete

- Subtask 8: Co-author manuscript on Aim 1 findings

Timeline: 18-24 months, 100% complete

- Milestone #2: Manuscript on informed consent, information needs for VCA

Timeline: 18-24 months, 100% complete

**Specific Aim 2: Develop educational materials (video, website, question prompt sheet) that provide patient-centered information about upper extremity VCA**

**Major Task 1:** Develop the website

Timeline: 12-26 months, 100% complete

- Subtask 1: Set up server, obtain web domain, establish ADA standards compliance

Timeline: 12 months, 100% complete

- Subtask 2: Establish learning objectives to guide content based on information obtained from Aim 1, clinical expertise in UE, VCA, military health, ethics, and adult learning theories

Timeline: 12-14 months, 100% complete

- Subtask 3: Write initial draft of website content, create and revise prototypes and wireframes of website design and functionality for review in phase 1 telephone focus groups

Timeline: 15-18 months, 100% complete

- Subtask 4: Create graphics, logo, website name, and illustrations, purchase photographs, based on phase 1 focus groups, and for review in phase 2-3 focus groups

Timeline: 15-21 months, 100% complete

- Subtask 5: Submit website content and telephone focus group moderators guide to local IRBs and HRPO for review

Timeline: 19 months, 100% complete (NU, JHU, WR)

- Subtask 6: Recruit and conduct 9 telephone focus groups  
Timeline: 19-24 months, 100% complete (NU, JHU, WR)
- Subtask 7: Transcribe telephone focus groups  
Timeline, 19-24 months, 100% complete (NU, JHU, WR)
- Subtask 8: Iteratively analyze telephone focus group data to inform revisions of website content and website design for further review in subsequent telephone focus groups  
Timeline, 19-26 months, 100% complete
- Subtask 9: Iteratively review and provide feedback on website design, instructional design, and functionality to Advantage Marketing website developers  
Timeline: 19-26 months, 100% complete
- Subtask 10: Revise website design and content  
Timeline, 19-26 months, 100% complete

**Major Task 2: Create Video Testimonials (n=15)**

- Subtask 2: Recruit and audition amputees for videotaping  
Timeline: 21-24 months, 100% complete
- Subtask 3: Videotape UE amputee and clinician testimonials  
Timeline: 21-24 months, 100% complete
- Subtask 4: Edit and link in video testimonials into website  
Timeline: 21-24 months, 100% complete

**Major Task 3: Develop the Question Prompt Sheet (QPS)**

- Subtask 1: Prepare draft of QPS based on Aim 1 results  
Timeline: 12-18 months, 100% complete
- Subtask 2: Submit draft QPS and semi-structured interview guide to local IRBs and HRPO for review  
Timeline: 19 months, 100% complete (NU, JHU, WR)
- Subtask 3: Recruit and conduct semi-structured interviews for feedback on and refinement of the QPS  
Timeline: 19-24 months, 100% complete (NU, JHU, WR)
- Subtask 4: Analyze semi-structured interviews to refine the QPS items for inclusion, exclusion, and wording  
Timeline: 19-24 months, 100% complete
- Subtask 5: Further refine QPS  
Timeline: 24-26 months, 100% complete
- Milestone #3: Complete VCA-QPS development  
Timeline: 26 months, 100% complete

**Specific Aim 3. Formatively evaluate the educational materials through usability testing**

- Subtask 1: Prepare 6 task scenarios of topics or sections to find on the website during usability testing  
Timeline: 25-26 months, 100% complete
- Subtask 2: Submit screenshots of developed website and task scenarios to local IRBs and HRPO for review  
Timeline: 26 months, 100% complete
- Subtask 3: Recruit and conduct website usability testing among (n=21) participants: UE amputees (n=10), VCA candidates (n=8), VCA participants (n=2), and VCA recipients (n=1), prioritizing VCA candidates, participants, recipients when possible  
Timeline: 27-30 months, 100% complete
- Subtask 4: Data entry of survey data and demographics  
Timeline 27-30 months, 100% complete
- Subtask 5: Analyze usability testing qualitative and quantitative data  
Timeline: 28-31 months, 100% complete
- Subtask 6: Revise website design, functionalities, and content, as needed, based on usability testing results  
Timeline: 28-31 months, 100% complete
- Milestone #4: Complete UE VCA website
- Timeline: 31-33 months, 100% complete

- Subtask 7: Co-author manuscript on Aims 2-3 findings  
Timeline 31-33 months, 100% complete
- Milestone #5: Manuscript on website development and usability testing for UE VCA  
Timeline: 36 months, 100% complete
- Subtask 8: Obtain Creative Commons website licensing  
Timeline: 31-33 months, 100% complete
- Subtask 9: Report to NU, JHU, and WR/USU intellectual property departments to report development of intellectual property  
Timeline: 31 months, 100% complete, (only NU was necessary to lead this process)
- Subtask 10: Develop brochure on website and disseminate  
Timeline: 31-33 months, 100% complete

## What was accomplished under these goals?

### Specific Aim 1: Qualitatively assess the informed consent process for upper extremity-VCA transplantation.

#### Major Task 1: Submit IRB documents for local IRB review

- Subtask 2: Submit IRB approval and necessary documents for initial HRPO review
  - Northwestern IRB submitted: 6/9/19
  - Northwestern IRB approved: 7/10/19
  - Johns Hopkins IRB submitted: 10/22/19
  - Johns Hopkins IRB approved: 1/29/20
  - Walter Reed IRB submitted: 11/19/19
  - Walter Reed IRB (administrative review) approved: 4/27/2020
    - CRADA approved 2-19-2021
    - WR drafted the data sharing agreement application (DSAA), which was submitted 3-10-2021 and has been approved for the following two DSAs:
      - 1st DSA approved 6-10-21
      - 2nd DSA approved 6-24-21
      - Command start letter received on 6-28-21
- Milestone #1: HRPO approval
  - Northwestern HRPO approved: 1-8-20
  - Johns Hopkins HRPO approved: Dr. Levan: 6-5-20, Dr. Brandacher: 3-30-20
  - Walter Reed HRPO approved: 11-30-20

#### Major Task 2: Recruit and consent human subjects

- Subtask 1: Place advertisements in newsletters and fliers in clinics
- Subtask 2: Submit internal requests, and contact collaborators and community clinics to obtain lists of eligible potential participants for recruitment, by research staff at all sites
- Subtask 3: Recruit participants and obtain informed consent by staff

#### Major Task 3: Conduct cognitive interviews, in-depth interviews, and online focus groups to assess: UE amputees' information needs, understanding of VCA risks, benefits, alternatives, and procedures, perceptions of voluntariness for UE VCA, candidates' perceptions of the informed consent process, and decision-making about UE VCA

- Subtask 4: Conduct in-depth interviews with (n=50) participants:
- Subtask 5: Conduct telephone focus groups with UE amputees (n=25)
- Subtask 6: Transcribe in-depth interviews and online focus groups
- Subtask 7: Conduct qualitative data analysis
- Subtask 8: Co-author manuscript on Aim 1 findings
- Milestone #2: Two planned manuscripts on decision making and informed consent; and information needs for VCA and the QPS development; and additional manuscripts
  - We published the planned paper on Information Needs about UE VCA and the QPS in the journal *Frontiers in Psychology* in a special issue dedicated to VCA

- The Informed Consent and Decision Making for UE VCA qualitative planned manuscript has been submitted to the journal *American Journal of Transplantation*
- The qualitative additional manuscript on Patients' Definitions of VCA Success is nearly complete; final manuscript preparation is underway
- The qualitative additional manuscript on Patients' Perceptions of Patient Selection Criteria for UE VCA is nearly complete; final manuscript preparation is underway
- The PI (Dr. Gordon) collaborated with other VCA researchers and published an unplanned scoping review paper on psychosocial and bioethical challenges and developments in VCA in *Frontiers in Psychology* in a special issue dedicated to VCA

**Aim 1 summary:** By completing the interviews and focus groups, we gained insights into the psychosocial and ethical factors influencing decision making about UE VCA among individuals with UE amputations and the experience of informed consent among UE VCA candidates, participants, and recipients.

**Specific Aim 2: Develop educational materials (video, website, question prompt sheet) that provide patient-centered information about upper extremity VCA.**

**Major Task 1:** Develop the website

- Subtask 3: Write initial draft of website content, create and revise prototypes and wireframes of website design and functionality for review in phase 1 telephone focus groups
- Subtask 4: Create graphics, logo, website name, and illustrations, purchase photographs, based on phase 1 focus groups, and for review in phase 2-3 focus groups
- Subtask 5: Submit website content and telephone focus group moderators guide to local IRBs and HRPO for review
  - NU submitted on 11-9-21, approved on 11-16-21
  - JHU submitted on 07-01-21, approved on 07-22-21
  - WR submitted for IRB acknowledgement on 1-18-22, Acknowledged on 3-7-22
  - NU submitted to NU IRB on 6-21-22, approved on 6-22-22
  - WR submitted for IRB acknowledgement on 6-23-22, Acknowledged on 7-19-22
  - NU submitted to HRPO on 6-22-22, but because this was a non-substantive modification, our program officer informed us that we did not require HRPO review.
- Subtask 9: Iteratively review and provide feedback on website design, instructional design, and functionality to Advantage Marketing website developers
  - Research team members reviewed each website page and provided extensive revisions to content, formatting, video placement, video captioning, photo captions, reference lists for each website page, superscript citations throughout website, and webpage ordering within the site
- Subtask 10: Revise website design and content
  - PAO approved the website on 11-4-22

**Major Task 2:** Create Video Testimonials (n=15)

- Subtask 2: Recruit and audition amputees for videotaping
- Subtask 3: Videotape UE amputee and clinician testimonials
- Subtask 4: Edit and link in video testimonials into website

**Major Task 3:** Develop the Question Prompt Sheet (QPS)

- Subtask 1: Prepare draft of QPS based on Aim 1 results
- Subtask 2: Submit draft QPS and semi-structured interview guide to local IRBs and HRPO for review
- Subtask 3: Recruit and conduct semi-structured interviews for feedback on and refinement of the QPS (n=60) among UE amputees (n=35), VCA candidates (n=17), VCA participants (n=4), VCA recipients (n=4), prioritizing VCA candidates when possible
- Subtask 4: Analyze semi-structured interviews to refine the QPS items for inclusion, exclusion, and wording
- Subtask 5: Further refine QPS by:
  - Drs. Gordon & Levan: Prepare questions in <6 grade reading level
    - Research team used the Flesch Kincaid readability test to ensure all QPS items were below a 6<sup>th</sup> grade reading level

- Drs. Brandacher and Tintle: Ensured questions cover VCA psychosocial issues, accurately reflect VCA concepts
- Scientific Advisory Board: Ensured questions cover VCA ethics issues, military perspectives, and disability rights
  - o The SAB and research team clinicians reviewed the QPS rankings from semi-structured interviews and provided feedback
  - o The QPS was finalized after feedback was reviewed and incorporated as appropriate
- *Milestone #3: Complete VCA-QPS development*
  - o The QPS was completed, and uploaded to the Within Reach website

**Aim 2 summary:** Through in-depth interviews, focus groups, and semi-structured interviews, we gained insights into the UE VCA information needs among individuals with UE amputations to inform the website content and develop a patient-centered Question Prompt Sheet, as well as insights into the format and design of a patient-centered website.

### **Specific Aim 3. Formatively evaluate the educational materials through usability testing**

- Subtask 1: Prepare 6 task scenarios of topics or sections to find on the website during usability testing
  - o Research team finalized 5 task scenarios for usability testing as 6 would have been too burdensome to complete during interviews
- Subtask 2: Submit screenshots of developed website and task scenarios to local IRBs and HRPO for review
  - o NU submitted for IRB review on 4-2-22, approved on 5-16-22
  - o NU submitted for HRPO review on 5-16-22, approved on 5-20-22
  - o WR submitted for IRB acknowledgement on 5-18-22, Acknowledged on 6-8-22
- Subtask 3: Recruit and conduct website usability testing among (n=21) participants: UE amputees (n=10), VCA candidates (n=8), VCA participants (n=2), and VCA recipients (n=1), prioritizing VCA candidates, participants, recipients when possible
  - o Usability testing was performed among n=14 participants (n=7 at NU, n=7 at WR). JHU was unable to complete this task due to delays in single IRB processing and concurrent unavailable staffing given Dr. Levan's move to NYU. However, we reached saturation with the sample of n=14 to support final revisions to the website
- Subtask 4: Data entry of survey data and demographics
- Subtask 5: Analyze usability testing qualitative and quantitative data
- Subtask 6: Revise website design, functionalities, and content, as needed, based on usability testing results
- *Milestone #4: Complete UE VCA website, and post URL links to it on other transplant-related websites (e.g., ISVCA)*
- Subtask 7: Co-author manuscript on Aims 2-3 findings
  - o The manuscript is 100% complete
- Milestone #5: Manuscript on website development and usability testing for UE VCA
  - The manuscript is under re-review by *JMIR Formative Research*
- Subtask 8: Obtain Creative Commons website licensing
  - o This has been completed and the Creative Commons logo is in the website footer
- Subtask 9: Report to NU, JHU, and WR/USU intellectual property departments to report development of intellectual property
  - o NU has already, and WR, and JHU will reach out to their respective intellectual property departments as soon as the website is approved by PAO and DOD
- Subtask 10: Develop brochure on website and disseminate
  - o The brochure was completed and uploaded onto the website

**Aim 3 summary:** Through Usability Testing, we gained insights into the website navigation preferences of individuals with UE amputations to refine the website content, format, and design, and make the website more user-friendly for this population.

Total number of participants recruited by data collection activity across study sites is shown in the table below:

|                              | WR        | NU        | JHU       | Total Recruited Participants | Target Enrollment |
|------------------------------|-----------|-----------|-----------|------------------------------|-------------------|
| Cognitive Interviews         | 0         | 5         | 0         | 5                            | 12                |
| In-Depth Interviews          | 17        | 16        | 17        | 50                           | 50                |
| 2 Online Focus Groups        | 0         | 7         | 0         | 7                            | 25                |
| 9 Telephone Focus Groups     | 11        | 12        | 14        | 37                           | 45                |
| Semi-Structured Interviews   | 18        | 19        | 19        | 56                           | 60                |
| Usability Testing Interviews | 7         | 7         | 0         | 14                           | 21                |
| <b>TOTAL</b>                 | <b>53</b> | <b>66</b> | <b>50</b> | <b>169</b>                   | <b>228</b>        |

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

Overall, this project has offered the research team many opportunities for training and professional development over the past year including:

- Learning how to recruit study participants and obtain informed consent
- Learning how to develop REDCap survey databases
- Learning how to track participants, perform data entry, and manage datasets
- Learning how to financially process participant compensation
- Learning how to conduct in-depth interviews
- Learning how to conduct semi-structured interviews
- Learning how to conduct and moderate focus groups
- Learning how to conduct usability testing
- Learning how to perform rapid qualitative analysis
- Learning how to perform thematic qualitative analysis and writing code summaries
- Learning how to use NVIVO qualitative analysis computer data analysis software
- Learning how to prepare a poster or a paper presentation
- Learning how to present a poster or a paper presentation at a national professional conference
- Learning how to prepare and write manuscript drafts
- Learning how to disseminate research findings beyond presentations and publications
- Learning how to collaborate with a research team across multiple study sites
- Learning how to complete work according to a timeline

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

To date, we disseminated results and the website to communities of interest via multiple strategies:

- We published **3** peer-reviewed papers.
- We submitted **1** manuscript for publication that pertains to informed consent and decision making.
- We are three-fourths complete in preparing **3** manuscripts for submitting for publication. These manuscripts should be ready to submit by January 31, 2023.
- We gave **8** paper presentations and **7** poster presentations across **7** different professional conferences.
- The website went live on November 6, 2022.
- The URL link to Within Reach was posted on the websites for:
  - American Society of Reconstructive Transplantation (in the Resources tab on the home page)

- American Society of Transplantation's on the Educational Resources page
- News of the website was distributed via Walter Reed's newsletters
- We emailed prior study participants to inform them of the website's completion and provide the URL
- We disseminated electronic versions of the Within Reach website brochure to online and in-person support groups throughout the US and through a Walter Reed email distribution list.
- We emailed and posted information about the Within Reach site on Reddit (3 subreddits: r/amputees, r/prosthetics, and r/disabilities) and to amputee community organizations, including the North American One Armed Golfers Association.
- The website developers taught the Northwestern research team how to make minor content changes to the website for future edits as need be. Dr. Gordon established a Google Analytics account to enable monitoring of website visits. From 11-6-22 to 4-11-23, there have been 6,158 visits to *Within Reach*. The most commonly visited pages with the longest duration of being viewed included: Who is eligible, functional outcomes, and patient experiences. Eight viewers downloaded the QPS, and 5 downloaded the pamphlet. Viewers came from the US and 18 other countries.

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

Nothing to Report

## **4. IMPACT:**

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

Our study findings revealed novel ethical and psychosocial considerations about when and how patients are informed about UE VCA, perceptions of limited treatment alternatives, and potential sources of undue influence, which may impact patients' autonomous treatment decision-making. Our findings indicated that psychosocial factors influencing decisions to pursue UE VCA included: dissatisfaction with current treatment options and the desire to regain hand functioning, improve appearance, and regain independence. Psychosocial factors and concerns influencing decisions to NOT pursue UE VCA included: concerns about jeopardizing current health and numerous psychosocial factors regarding commitment to rehabilitation, logistical burdens, and interrupting family and work life. Addressing patients' psychosocial concerns may help facilitate informed treatment decisions.

We developed patient-centered resources—a UE VCA Question Prompt Sheet (QPS) and an educational website ("Within Reach")—for individuals with UE amputations, their families, and healthcare professionals to support informed treatment decision making.

The UE VCA QPS supports patient-centered care by empowering patients to ask questions important to them, promoting patient-provider communication, and increasing patient knowledge.

The educational "Within Reach" website (which includes 188 videos of clinicians, UE VCA recipients, and individuals with UE amputations; 29 photos, and 7 graphics), addresses upper limb amputees' UE VCA information needs and psychosocial concerns in a patient-centered, neutral manner, that is neither "for" nor "against" UE VCA. Additionally, the UE VCA QPS and a brochure about the "Within Reach" website are available for download from the website.

We recommend integrating "Within Reach" into clinical practice as a supplement to patient-provider education. Healthcare professionals, including hand/upper limb surgeons, prosthetists, hand therapists, and UE VCA teams, should inform individuals with UE amputations about the website as a useful educational resource prior to scheduled amputations or in the rehabilitation period after traumatic amputations. Healthcare professionals could download the Within Reach brochure from the website to distribute in the clinic setting. The UE VCA-QPS could be provided to patients in advance of their first

visit to the VCA clinic, or handed to them for review while waiting in the clinic to see their provider so that they can identify questions they find important and become more engaged during their visit.

The Within Reach website, website brochure, and UE VCA QPS address the information needs of people with UE amputations and makes UE VCA information more accessible in order to facilitate informed decision-making and the informed consent process for those considering UE VCA.

### **What was the impact on other disciplines?**

Our findings suggest a need to better inform and prepare patients in decision making and in the informed consent process for UE VCA. Healthcare professionals who manage individuals with UE amputations should adjust their clinical practice to provide more education about UE VCA.

Providing patient-centered educational resources, such as our educational website, Within Reach, and the UE VCA-QPS, prior to or soon after undergoing UE amputation may provide an opportunity for patients to make more informed treatment decisions. Findings from this research may inform future research in other types of VCA organ programs to identify information needs and improve the decision-making process for patients. Our findings revealed patient-centered UE VCA treatment goals, which can inform the development of patient reported outcome measures for UE VCA and inform clinical practice. Our findings also revealed ways to engage individuals with UE amputations in research and to make online resources more accessible for these individuals.

### **What was the impact on technology transfer?**

Nothing to report

### **What was the impact on society beyond science and technology?**

The results from this project are likely to make an impact on society by:

- Improving public knowledge and attitudes about UE VCA among individuals with UE amputations, their families, and health care professionals
- We anticipate that with greater knowledge and understanding of UE VCA information needs and treatment decision making factors among individuals with UE amputations, healthcare professionals will more comprehensively inform individuals with UE amputations about their treatment options to foster informed treatment decision-making. Healthcare professionals should also inform individuals closer to their amputation surgery so that they can make more timely decisions.
- We anticipate that our findings regarding information needs about UE VCA will be leveraged to inform OPTN/UNOS policy about informed consent provisions for patients seeking UE VCA.

## **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**

We encountered several types of delays throughout the project period:

- IRB and Data Use Agreement delays arose throughout the study period. This project involved required IRB review of different data collection materials which compounded the time frame. HRPO reviews also compounded the delays.

- Public Affairs Office (PAO) reviews of abstracts, posters, paper presentations, manuscripts, and the website lasting 1-4 weeks in duration contributed to delays in dissemination.
- Institutional level policies restricting the use of transcription services and transcription software presented delays to completing the data analysis process.

### **Changes that had a significant impact on expenditures**

- Because NYU did not have sIRB approvals, they did not complete the Usability Testing interviews. Thus, expenditures are lower than expected.

### **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.**

1. Gacki-Smith J, Kuramitsu B, Downey M, Vanterpool K, Nordstrom MJ, Luken M, Rigglesman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, **Gordon EJ**. Information needs and development of a question prompt sheet for upper extremity vascularized composite allotransplantation: A mixed methods study. Frontiers in Psychology: Special Issue 2022; Sep 5;13:960373. doi: 10.3389/fpsyg.2022.960373.
2. Vanterpool KB, Gacki-Smith J, Kuramitsu B, Downey M, Nordstrom MJ, Luken ML, Rigglesman T, Fichter SC, Altema WM, Brucker JB, Cooney CM, Dumanian G, Jensen SE, Levan M, Tintle SM, Brandacher G, **Gordon EJ**. Within Reach -- A Patient-Centered Website to Foster Informed Decision Making about Upper Extremity Vascularized Composite Allotransplantation: Development and Usability Testing. JMIR Formative Research 2022. In Press.
3. Kumnig M, Jowsey-Gregoire SG, **Gordon EJ**, Werner-Felmayer G. Psychosocial and Bioethical Challenges and Developments for the Future of Vascularized Composite Allotransplantation: A Scoping Review and Viewpoint of Recent Developments and Clinical Experiences in the Field of VCA. Frontiers in Psychology: Special Issue 2022; Dec 15;13:1045144. doi: 10.3389/fpsyg.2022.1045144.

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

Nothing to report

## Other publications, conference papers and presentations.

4. Kuramitsu B, Berumen C, Sung HC, Ferzola A, Brandacher G, Henderson M, **Gordon EJ**. Informed Consent and Decision Making for Upper Extremity VCA. Poster presented at the American Transplant Congress. Philadelphia, PA. [D-234] June 2, 2020.
5. Kuramitsu B, Berumen C, Sung HC, Ferzola A, Cooney C, Brandacher G, Henderson M, Tintle S, **Gordon EJ**. Decision Making and Informed Consent for Upper Extremity VCA. Paper presented on the panel, "VCA Ethics: How do we determine flourishing in VCA transplantation?" at the American Society of Bioethics and Humanities, Virtual Annual Conference. October 15, 2020.
6. **Gordon EJ**, Kuramitsu B, Berumen C, Ferzola A, Sung HC, Scarton D, McHugh T, Schultheis A, Riggleman T, Taylor J, Cooney C, Henderson M, Tintle S, Brandacher G. Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA. American Society for Reconstructive Transplantation Conference Abstracts 2020. Vascularized Composite Allotransplantation 2021;9(March):6. doi:10.1177/20503121211003534.
7. Gacki-Smith J, Kuramitsu B, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney CM, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Development of a Question Prompt Sheet for Upper Extremity Vascularized Composite Allotransplantation. Poster presented at the American Transplant Congress Virtual Meeting. June 4, 2021.
8. Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney CM, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Psychosocial Factors Influencing Patients' Decision Making about Upper Extremity VCA. Live poster presented at the American Transplant Congress Virtual Meeting. June 6, 2021.
9. Hewitt M, Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Downey M, Kunkle C, Schultheis A, Riggleman T, Taylor T, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon E**. Treatment Options for Upper Extremity Limb Loss: Ethical and Psychosocial Factors Affecting Patients' Decision Making about Vascularized Composite Allotransplantation. Poster presented at the Military Health Systems Research Symposium (MHSRS) virtual meeting. August 23, 2021.
10. **Gordon E**, Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney C, Tintle S, Brandacher G, Levan M. Psychosocial and Ethical Factors Affecting Patients' Decision Making about Upper Extremity Vascularized Composite Allotransplantation. Paper accepted for oral presentation at Tissue Engineering and Regenerative Medicine International Society (TERMIS) virtual World Congress in Maastricht, The Netherlands, November 17, 2021.
11. B. Kuramitsu, C. Berumen, A. Ferzola, H. Sung, D. Scarton, T. McHugh, A. Schultheis, T. Riggleman, J. Taylor, C. Cooney, M. Henderson, S. Tintle, G. Brandacher, **E. Gordon**. Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA. Paper accepted for a 5-minute Podium Presentation at the American Society for Reconstructive Transplantation Meeting in Bethesda, MD. Hybrid meeting. November 18, 2021.
12. Hewitt M, Riggleman T, Nordstrom M, Dodd LD, Kuramitsu B, Gacki-Smith J, Vanterpool K, Downey M, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon E**. Awareness and Perceptions of Vascularized Composite Allotransplantation (VCA) Among Military Personnel with Upper Extremity Amputations: A Qualitative Approach. Poster presented at the Association of Military Surgeons of the United States (AMSUS), February 22, 2022.

13. Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Rigglesman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Poster presented at the American Transplant Congress (ATC) meeting, Boston, MA, June 5, 2022.
14. Levan M. Psychosocial Factors in the Decision Making and Informed Consent Process for Upper Extremity VCA. Paper (Invited) presented at American Transplant Congress (ATC) meeting in Boston, Massachusetts, on June 7, 2022.
15. Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Rigglesman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Mini-oral paper presented (virtually) at The Transplantation Society (TTS) meeting in Buenos Aires Sept. 10<sup>th</sup>-14<sup>th</sup>, 2022.
16. M. Nordstrom, M. Luken, M. Hewitt, T. Rigglesman, S. Fichter, B. Kuramitsu, J. Gacki-Smith, K. Vanterpool, M. Downey, C. Cooney, G. Dumanian, S. Jensen, S. Tintle S, G. Brandacher, M. Levan, **EJ. Gordon**. Treatment Options for Upper Extremity Limb Loss: Ethical and Psychosocial Factors Affecting Patients’ Decision Making about Vascularized Composite Allotransplantation. Poster presented at the Military Health Systems Research Symposium (MHSRS) meeting, Kissimmee, FL. September 13, 2022. Abstract # MHSRS-22-07470.
17. Gacki-Smith J, Kuramitsu BR, Downey M, Vanterpool KB, Nordstrom MJ, Luken M, Rigglesman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, **Gordon EJ**. Empowering Patients with Upper Extremity Amputations to Communicate with Providers about VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 4, 2022.
18. **Gordon EJ**. Moderator (**Invited**), Session III: Psychologists. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 4, 2022.
19. **Gordon EJ**. *Informed Consent in VCA*. (**Invited**) Session III: Psychologists. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 4, 2022.
20. Downey M, Gacki-Smith J, Kuramitsu BR, Vanterpool KB, Nordstrom MJ, Luken M, Rigglesman T, Fichter S, Altema W, Langlee W, Cooney CM, Jensen SE, Dumanian GA, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 5, 2022.

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

[www.WithinReach.info](http://www.WithinReach.info)

We developed the *Within Reach* website to educate people about hand/arm transplantation. *Within Reach* is designed to be neutral (neither in favor of, nor against, hand/arm transplantation) so that people with hand or upper limb amputations, their families, and their healthcare providers can make informed treatment decisions. The website went live on November 6, 2022.

### Technologies or techniques

Nothing to report

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

Nothing to report

## **Other Products**

1. We developed the UE VCA Question Prompt Sheet (QPS), which is available to download from the Within Reach website. We intend for VCA transplant programs to send the QPS to VCA candidates expressing interest in initiating UE VCA evaluation, and to VCA participants who initiated UE VCA evaluation, to empower them to ask questions about UE VCA.
2. We developed a brochure/pamphlet that showcases the Within Reach website features, which is available to download from the Within Reach website. We intend for health care professionals treating individuals with UE amputations (e.g., prosthetists, surgical hand clinics, UE VCA programs) to provide the pamphlet in patient waiting rooms to ensure that patients can learn about the website.

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

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

*Note: Calendar Months for Northwestern collaborators is presented in cumulative effort*

|                                        |                                   |
|----------------------------------------|-----------------------------------|
| Name:                                  | Dr. Elisa Gordon                  |
| Project Role:                          | Initiating Principal Investigator |
| Researcher Identifier (e.g. ORCID ID): | 0000-0003-0969-1998               |
| Nearest person month worked:           | 7.95 months                       |
| Contribution to Project:               | No Change                         |

|                              |                                 |
|------------------------------|---------------------------------|
| Name:                        | Brianna Kuramitsu               |
| Project Role:                | Research Study Coordinator, Sr. |
| Nearest person month worked: | 16.75 months                    |
| Contribution to Project:     | No Change                       |

|                              |                          |
|------------------------------|--------------------------|
| Name:                        | Jessica Gacki-Smith      |
| Project Role:                | Research Project Manager |
| Nearest person month worked: | 12.6 months              |
| Contribution to Project:     | No Change                |

|                              |                               |
|------------------------------|-------------------------------|
| Name:                        | Dr. Greg Dumanian             |
| Project Role:                | Co-Investigator, Hand surgeon |
| Researcher Identifier:       | 0000-0002-0389-5191           |
| Nearest person month worked: | 0.74 months                   |
| Contribution to Project:     | No Change                     |

|                              |                               |
|------------------------------|-------------------------------|
| Name:                        | Dr. Sally Jensen, PhD         |
| Project Role:                | Co-Investigator, Psychologist |
| Researcher Identifier:       | 0000-0002-2078-3263           |
| Nearest person month worked: | 1.8 months                    |
| Contribution to Project:     | No Change                     |

|                              |                                                                                                                               |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| Name:                        | Jefferson Uriarte                                                                                                             |
| Project Role:                | Research Project Coordinator                                                                                                  |
| Nearest person month worked: | 2.16 months                                                                                                                   |
| Contribution to Project:     | Assisted with Research Coordinator role, including contributing to website development and processing financial transactions. |
|                              |                                                                                                                               |
| Name:                        | Cindy Berumen                                                                                                                 |
| Project Role:                | Research Project Coordinator                                                                                                  |
| Nearest person month worked: | 3.85 months                                                                                                                   |
| Contribution to Project:     | Assisted with Research Coordinator role, recruitment, including contributing to website development.                          |
|                              |                                                                                                                               |
| Name:                        | Dr. Macey Levan (Henderson)                                                                                                   |
| Project Role:                | Partnering Principal Investigator                                                                                             |
| Researcher Identifier:       | 0000-0002-4239-1252                                                                                                           |
| Nearest person month worked: | 2.00 at JHU; 1.00 avg. at NYU                                                                                                 |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Dr. Dorry Segev                                                                                                               |
| Project Role:                | Co-Investigator                                                                                                               |
| Researcher Identifier:       | 0000-0002-1924-4801                                                                                                           |
| Nearest person month worked: | 1.04 at JHU                                                                                                                   |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Dr. Gerald Brandacher                                                                                                         |
| Project Role:                | Partnering Principal Investigator                                                                                             |
| Researcher Identifier:       | 0000-0001-7790-441X                                                                                                           |
| Nearest person month worked: | 3.10 at JHU                                                                                                                   |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Dr. Daniel Warren                                                                                                             |
| Project Role:                | Partnering Principal Investigator                                                                                             |
| Nearest person month worked: | 0.12 at JHU                                                                                                                   |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Karen Vanterpool                                                                                                              |
| Project Role:                | Senior Research Scientist                                                                                                     |
| Nearest person month worked: | 0.70 at JHU                                                                                                                   |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Carisa Cooney                                                                                                                 |
| Project Role:                | Co-Investigator, Psychologist                                                                                                 |
| Researcher Identifier:       | 0000-0002-5475-206X                                                                                                           |
| Nearest person month worked: | 1.70 at JHU                                                                                                                   |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Max Downey                                                                                                                    |
| Project Role:                | Senior Research Coordinator                                                                                                   |
| Nearest person month worked: | 5.50 at JHU; 6.75 avg. at NYU                                                                                                 |
| Contribution to Project:     | No Change                                                                                                                     |
|                              |                                                                                                                               |
| Name:                        | Alexander Ferzola                                                                                                             |
| Project Role:                | Research Coordinator                                                                                                          |
| Nearest person month worked: | 7.50 at JHU                                                                                                                   |
| Contribution to Project:     | No Change                                                                                                                     |

|                              |                                                         |
|------------------------------|---------------------------------------------------------|
| Name:                        | Dr. Scott Tintle                                        |
| Project Role:                | Partnering Principal Investigator at WRNMMC             |
| Nearest person month worked: | 5.85                                                    |
| Contribution to Project:     | No Change                                               |
| Name:                        | Michelle Nordstrom, OTR/L                               |
| Project Role:                | Registered Occupational Therapist                       |
| Nearest person month worked: | 3.90                                                    |
| Contribution to Project:     | No change                                               |
| Name:                        | Derek Soloway                                           |
| Project Role:                | Program Manager                                         |
| Nearest person month worked: | 1.04                                                    |
| Contribution to Project:     | No change                                               |
| Name:                        | Lauren Dodd                                             |
| Project Role:                | Program Manager                                         |
| Nearest person month worked: | 1.39                                                    |
| Contribution to Project:     | No change                                               |
| Name:                        | Shannon Fichter                                         |
| Project Role:                | Clinical Research Coordinator                           |
| Nearest person month worked: | 1.86                                                    |
| Contribution to Project:     | No change                                               |
| Name:                        | Michelle Luken                                          |
| Project Role:                | Sr. Clinical Research Associate                         |
| Nearest person month worked: | 0.87                                                    |
| Contribution to Project:     | No change                                               |
| Name:                        | Tiffany Riggleman                                       |
| Project Role:                | Research Certified Occupational Therapist Assistant     |
| Nearest person month worked: | 2.11                                                    |
| Contribution to Project:     | No Change                                               |
| Name:                        | Withney Altema                                          |
| Project Role:                | Clinical Research Assistant II                          |
| Nearest person month worked: | 3.06                                                    |
| Contribution to Project:     | No Change                                               |
| Name:                        | Kalyn Jannace                                           |
| Project Role:                | Epidemiologist                                          |
| Nearest person month worked: | 0.15                                                    |
| Contribution to Project:     | No Change                                               |
| Name:                        | Rebecca Schulz                                          |
| Project Role:                | Data Analyst                                            |
| Nearest person month worked: | 0.48                                                    |
| Contribution to Project:     | No Change                                               |
| Name:                        | Andrea Schultheis                                       |
| Project Role:                | Occupational Therapist                                  |
| Nearest person month worked: | 0.48                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 06/2021 |

|                              |                                                         |
|------------------------------|---------------------------------------------------------|
| Name:                        | Christina Kunkle                                        |
| Project Role:                | Program Coordinator                                     |
| Nearest person month worked: | 0.55                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 06/2021 |
| Name:                        | Christopher Kim                                         |
| Project Role:                | Clinical Research Assistant                             |
| Nearest person month worked: | 1.41                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 07/2020 |
| Name:                        | Dylan Scarton                                           |
| Project Role:                | Research Associate                                      |
| Nearest person month worked: | 0.19                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 08/2021 |
| Name:                        | Jerika Taylor                                           |
| Project Role:                | Program Manager                                         |
| Nearest person month worked: | 0.35                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 04/2021 |
| Name:                        | Joshua Reini                                            |
| Project Role:                | Data Manager                                            |
| Nearest person month worked: | 0.26                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 01/2021 |
| Name:                        | Julie Tran                                              |
| Project Role:                | Regulatory Affairs Coordinator                          |
| Nearest person month worked: | 0.60                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 07/2021 |
| Name:                        | Megan Tsui                                              |
| Project Role:                | Program Coordinator                                     |
| Nearest person month worked: | 0.64                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 07/2022 |
| Name:                        | Melissa Hewitt                                          |
| Project Role:                | Clinical Research Assistant                             |
| Nearest person month worked: | 3.18                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 11/2021 |
| Name:                        | Terrence McHugh                                         |
| Project Role:                | Clinical Research Assistant                             |
| Nearest person month worked: | 0.59                                                    |
| Contribution to Project:     | No Change; No longer supporting the study after 03/2021 |

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

No changes to report.

**What other organizations were involved as partners?**

Shirley Ryan AbilityLab (SRAL)  
Chicago, IL

Contribution to the project: NU collaborates with an SRAL clinician to assist with recruitment. NU posts fliers advertising the study for opt-in recruitment in the SRAL library.

David Rotter Prosthetics  
Joliet, IL

Contribution to the project: David Rotter (prosthetist) shares fliers advertising the study to his clients to aid with recruitment, participated in a video.

Advantage Marketing  
Chicago, IL

Contribution to the project: Assist with hosting, the design, and the development of the educational website "[WithinReach.info](#)"

**8. SPECIAL REPORTING REQUIREMENTS:**

**COLLABORATIVE AWARDS:**

**QUAD CHARTS:**

## 9. APPENDICES:

### Appendix 1.

- Gacki-Smith J, Kuramitsu B, Downey M, Vanterpool K, Nordstrom MJ, Luken M, Riggleman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, Gordon EJ. Information needs and development of a question prompt sheet for upper extremity vascularized composite allotransplantation: A mixed methods study. Frontiers in Psychology: Special Issue 2022; Sep 5;13:960373. doi: 10.3389/fpsyg.2022.960373.

Available at: [www.frontiersin.org/articles/10.3389/fpsyg.2022.960373/full](http://www.frontiersin.org/articles/10.3389/fpsyg.2022.960373/full)

## Appendix 2.

- Vanterpool KB, Gacki-Smith J, Kuramitsu B, Downey M, Nordstrom MJ, Luken ML, Riggleman T, Fichter SC, Altema WM, Brucker JB, Cooney CM, Dumanian G, Jensen SE, Levan M, Tintle SM, Brandacher G, **Gordon EJ**. A Patient-Centered Website (Within Reach) to Foster Informed Decision-making About Upper Extremity Vascularized Composite Allotransplantation: Development and Usability Study. JMIR Formative Research 2023 Feb 7;7:e44144.

Available at: <https://formative.jmir.org/2023/1/e44144>

### Appendix 3.

- Kumnig M, Jowsey-Gregoire SG, **Gordon EJ**, Werner-Felmayer G. Psychosocial and Bioethical Challenges and Developments for the Future of Vascularized Composite Allotransplantation: A Scoping Review and Viewpoint of Recent Developments and Clinical Experiences in the Field of VCA. Frontiers in Psychology: Special Issue 2022; Dec 15;13:1045144. doi: 10.3389/fpsyg.2022.1045144.

Available at: [www.frontiersin.org/articles/10.3389/fpsyg.2022.1045144/full](https://www.frontiersin.org/articles/10.3389/fpsyg.2022.1045144/full)

## **Appendix 4.**

- Kuramitsu B, Berumen C, Sung HC, Ferzola A, Brandacher G, Henderson M, **Gordon EJ**. Informed Consent and Decision Making for Upper Extremity VCA. Poster presented at the American Transplant Congress. Philadelphia, PA. [D-234] June 2, 2020.

### **Background**

The field of upper extremity (UE) Vascularized Composite Allotransplantation (VCA) continues to advance with more patients undergoing the informed consent process each year. However, the informed consent process for UE VCA has not yet been standardized, and has not been empirically examined for its adequacy. Consequently, the amount, type, and personalization of information provided to patients about UE VCA likely varies. Such variation may potentially contribute to UE amputees being inadequately informed, under-prepared, and feeling undue pressure when considering this option.

### **Problem Statement**

This paper examines the little known topic of UE amputees' and VCA candidates', participants', and recipients' perceptions of the informed consent and decision-making processes about UE VCA, as part of a broader Department of Defense-funded study. Patients' narratives have been an underutilized resource in shaping the informed consent process.

### **Approach**

We will have conducted in-depth interviews among UE amputees, UE VCA candidates, participants, and UE transplant recipients (n=5-20) at three geographically distinct transplant and/or rehabilitation centers. Interviews will focus on participants' information needs, comprehension of information disclosed, perceptions of undue influence, and psychosocial factors affecting decision making for UE VCA. This paper will highlight informed consent elements distinct to UE VCA, as compared to other VCA organs and to solid organs.

### **Conclusions**

UE amputees' insights can enable the informed consent process for UE VCA to become more patient-centered, and thereby help VCA candidates and participants become better prepared to undergo UE VCA. Our findings will be used to develop educational resources (e.g., a website, videos), which will provide comprehensive, standardized information to help potential recipients, their families, and the general public learn about UE VCA. Future research should assess differences in the informed consent and decision making processes across VCA organs.

## Appendix 5.

- Kuramitsu B, Berumen C, Sung HC, Ferzola A, Cooney C, Brandacher G, Henderson M, Tintle S, **Gordon EJ**. Decision Making and Informed Consent for Upper Extremity VCA. Paper presented on the panel, “VCA Ethics: How do we determine flourishing in VCA transplantation?” at the American Society of Bioethics and Humanities, Virtual Annual Conference. October 15, 2020.

This panel session examines the ethics of Vascularized Composite Allotransplantation (VCA), which involves transplants comprised of skin, muscle, nerve, tendon and/or bone as a functional unit to replace non-reconstructible tissues to restore function, quality of life, and social engagement, rather than promote survival. Examples include: face, arm, and uterus.

VCA challenges the ethical principles of non-maleficence, respect for persons, and voluntariness because: it is unclear if benefits outweigh risks to healthy individuals; few available data on functional and psychosocial outcomes limit patient’s ability to provide informed consent; and patients’ desperation may compromise voluntary decision-making.

This multidisciplinary panel involves clinicians, ethicists, behavioral scientists, and health policy experts from five institutions to examine these ethical issues and perceptions of “flourishing” among patients considering or receiving a uterus, face, or hand transplant and the public.

The first presentation examines public perceptions and misconceptions of VCA based on six focus groups (n=44), suggesting that public education is needed to enable family authorization for deceased donation.

The second presentation examines uterus transplant recipients’ (n=20) process of treatment decision making and critically examines social assumptions about reproductive autonomy.

The third presentation examines preliminary interview data on upper limb amputees’ (n=5) perceptions of factors that would influence decision-making, information needs for consent, and voluntariness.

The fourth presentation examines potential face transplant candidates’ (n=6) perceptions of risks and benefits of face transplant versus alternative treatments, suggesting candidate information access and receptivity.

Each panelist and moderator will present in 13 minutes. The remaining 10 minutes will entail moderated discussion.

## Appendix 6.

- **Gordon EJ**, Kuramitsu B, Berumen C, Ferzola A, Sung HC, Scarton D, McHugh T, Schultheis A, Riggleman T, Taylor J, Cooney C, Henderson M, Tintle S, Brandacher G. Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA. American Society for Reconstructive Transplantation Conference Abstracts 2020. Vascularized Composite Allotransplantation 2021;9(March):6. doi:10.1177/20503121211003534.

### BACKGROUND

Little is known about the informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA). Consequently, the amount and type of information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed, under-prepared, and feeling unduly pressured when considering this option. This study examines the decision-making process, psychosocial concerns, and information needs about UE VCA among people with UE amputations.

### METHODS

We conducted cognitive and in-depth interviews among people with UE amputations at one academic medical center and one rehabilitation clinic. Interviews focused on psychosocial factors affecting decision making for UE VCA, information needs about UE VCA, and perceptions of undue influence to pursue UE VCA. Thematic analysis was used to analyze qualitative data.

### RESULTS

Eight individuals participated (50% rate). Most were male (75%), had a mean age of 48.5 years. Most participants had a unilateral transradial amputation (62.5%) at a mean of 5 years prior. Psychosocial factors influencing decision making about UE VCA included: having the "right mindset," concerns about immunosuppressants, and maintaining support of caregivers. Most participants reported the best time to be informed about UE VCA is near the time of amputation, i.e., before the scheduled surgery (n=4), or within the first couple weeks or months thereafter (n=7), because they would be less receptive to it after adapting to their amputation. Participants desired information about the process of getting an UE VCA, expectations for functionality and recovery, and recipient experiences of getting an UE VCA. Most unilateral participants believed that people with bilateral amputations should be prioritized in patient selection for UE VCA, whereas bilateral participants did not believe unilateral versus bilateral should matter. While participants reported no undue influence to pursue UE VCA, some identified the need for a job, unavailable prosthetic device, and case worker or family member enthusiasm as potentially exerting undue influence on them.

### DISCUSSION and CONCLUSION

Preliminary findings suggest that people with UE amputations have limited knowledge about UE VCA. Addressing patients' information needs and psychosocial concerns may enhance decision-making and informed consent.

## Appendix 7.

- Gacki-Smith J, Kuramitsu B, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney CM, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Development of a Question Prompt Sheet for Upper Extremity Vascularized Composite Allotransplantation. Poster presented at the American Transplant Congress Virtual Meeting. June 4, 2021.

**Purpose:** Upper extremity (UE) vascularized composite allotransplantation (VCA) is an innovative option for people with UE amputations. Individuals with limb loss commonly receive little information about treatment options and have limited communication with healthcare providers about their condition. Making informed treatment decisions can be difficult when information needs are unmet. Question prompt sheets (QPS) are structured lists of questions that can facilitate communication with providers by empowering patients to ask questions and acquire relevant information. No QPS is available for VCA. This study aimed to develop an UE VCA-specific QPS.

**Methods:** We conducted in-depth interviews among people with acquired UE amputations. Participants were asked about information needs about UE VCA to inform the initial QPS draft. A qualitative thematic approach was used to analyze open-ended responses. The multidisciplinary research team reviewed the QPS draft to improve organization, clarify question wording, and remove repetitive items.

**Results:** Thus far, 12 individuals completed an in-depth interview (75% participation rate). Most were male (71%), with a mean age of 49 years, and had a unilateral amputation (75%). Most participants (75%) reported being 'completely' or 'a lot' likely to use a QPS if they were considering UE VCA. The initial QPS draft included 77 items grouped into 16 topics. UE VCA topics and sample questions included: Eligibility (What makes a good candidate?); Matching (How does the donor matching process work?); Surgery (How is the hand or arm surgically connected to my body?); Function (How much hand function can I regain?); Risks (What happens if my body rejects the hand/arm? Is it removed?); Appearance (Will the new hand look noticeably different from my arm?); and Rehabilitation (What does rehabilitation involve?).

**Conclusions:** Preliminary findings suggest people with UE amputations desire information about VCA. The UE VCA-QPS draft will be refined via semi-structured interviews and team review for content validity, comprehensiveness, and readability. Future research should assess the impact of the UE VCA-QPS on communication and informed decision making about UE VCA.

## Appendix 8.

- Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggelman T, Taylor J, Cooney CM, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Psychosocial Factors Influencing Patients' Decision Making about Upper Extremity VCA. Live poster presented at the American Transplant Congress Virtual Meeting. June 6, 2021.

### BACKGROUND

The informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA) has yet to be standardized. Consequently, the information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed and under-prepared for decision making about UE VCA. This study examined decision making and psychosocial factors affecting decisions about UE VCA among people with UE amputations.

### METHODS

We conducted in-depth interviews among people with acquired UE amputations. Open-ended questions assessed psychosocial factors informing decision making about UE VCA. Thematic analysis was used to analyze qualitative data.

### RESULTS

To date, 12 people completed in-depth interviews (75% participation rate). Most were male (71%) and had a mean age of 49 years. Most had a unilateral amputation (75%) and had undergone amputation a mean of 8 years earlier. Forty-two percent of participants were 'completely' or 'a lot' willing to pursue VCA. Psychosocial factors influencing decisions to pursue VCA included: expecting an increase in social and physical confidence; seeking independence with activities of daily living; enabling more active involvement as a parent; family or friend enthusiasm; and prosthetic device problems. Psychosocial factors influencing decision making not to pursue VCA included: feeling mentally unprepared for a transplant; having already adapted to life without upper limb(s); concerns about the long-term commitment to taking immunosuppressants; discouragement from family or friends; concerns about the rigorous rehabilitation process; concerns about receiving a graft that appears mismatched in size or skin color; concerns that the transplant may be unsuccessful; concerns about health or limb function becoming "worse off" from the UE VCA; and concerns about logistical barriers to accessing transplant and rehabilitation services.

### CONCLUSION

Preliminary findings suggest that people with UE amputations hold concerns that diminish their enthusiasm for UE VCA. Addressing patients' psychosocial concerns may foster informed decision making about UE VCA.

## Appendix 9.

- Hewitt M, Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Downey M, Kunkle C, Schultheis A, Riggleman T, Taylor T, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon E**. Treatment Options for Upper Extremity Limb Loss: Ethical and Psychosocial Factors Affecting Patients' Decision Making about Vascularized Composite Allotransplantation. Poster presented at the Military Health Systems Research Symposium (MHSRS) virtual meeting. August 23, 2021.

### BACKGROUND

Limb loss is a common combat injury among United States military service members (SMs). From 2001 to 2017, US SMs sustained a total of 302 upper extremity (UE) amputations that were caused primarily by explosions, motor vehicle crashes, and penetrating gunshot wounds.<sup>1</sup> From 2001 to 2011, SMs with UE amputations were assigned an average disability rating of 75 (of 100), which indicates that they were unable to perform in many occupational or social settings, and only about 11% of all SMs with at least one amputation returned to duty.<sup>2,3</sup> Individuals with UE amputations may face challenges related to engaging in activities of daily living, their physical environment, employment, social life, transportation, and more.<sup>4</sup> Many also experience psychosocial complications including depression, anxiety, employment challenges, social isolation, body image disturbance, and military concerns over honor.<sup>5-7</sup> Restoring SMs' function and well-being, in addition to benefitting the individual's quality of life, benefits the military by increasing service readiness, improving return-to-duty rates, and reducing healthcare costs.

One possible treatment option for UE limb loss is hand or upper extremity transplantation as one form of Vascularized Composite Allotransplantation (VCA). Upper extremity VCA entails transplanting an entire hand/forearm/arm from a deceased organ donor onto a recipient. VCA has been used to treat multiple severe tissue defects due to trauma or infection with the goals of restoring function and improving quality of life. Overall, functional outcomes from UE VCA appear to be highly encouraging.<sup>8,9,10</sup> Despite the positive outcomes, there are also surgical, medical, and psychosocial risks. Allograft failure and rejection may require reconstruction or even limb removal. Additionally, VCA requires a lifelong commitment to anti-rejection medications and long-term rehabilitation regimens. Psychosocial adaptation and the accompanying financial costs will vary across individuals.<sup>11</sup>

Given the risks and potential benefits of this procedure, the informed consent process is extremely important before undergoing treatment. However, the informed consent process for UE VCA has yet to be standardized. Consequently, the information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed and under-prepared for decision making about UE VCA. This study examined decision making and psychosocial factors affecting decisions about UE VCA among people with UE amputations.

### METHODS

We conducted in-depth telephone interviews among people with acquired UE amputations to assess psychosocial factors informing decision making about UE VCA. Interviews were conducted by research staff at Northwestern University and Johns Hopkins University. Participants were recruited via medical record review, social media advertisements, advertisements by support groups across the country, and flyers posted in various clinics on site. Interview topics covered personal history, awareness and perceptions of UE VCA, information needs, the decision-making process, perceptions of voluntariness and patient selection, and interest in using educational materials such as a website, videos, and a question prompt sheet. Interviews lasted between one and two hours. Thematic analysis and a grounded theory approach were used to analyze qualitative data.

### RESULTS

To date, 18 people completed in-depth interviews (82% participation rate), including 3 undergoing UE VCA evaluation as VCA "participants" or "candidates". Most were male (78%), had a mean age of 48 years, had a unilateral amputation (78%), and had undergone amputation a mean of 10 years earlier.

Half (50%) were 'a lot' or 'completely' willing to pursue VCA. Psychosocial factors influencing decisions to pursue VCA included: expecting an increase in social and physical self-esteem; seeking independence with activities of daily living; enabling more active involvement as a parent; family or friend enthusiasm; and prosthetic device problems. Psychosocial factors influencing decision making not to pursue VCA included: feeling mentally unprepared for a transplant; having already adapted to life without upper limb(s); concerns about the long-term commitment to taking immunosuppressants; discouragement from family or friends; concerns about the rigorous rehabilitation process; concerns about receiving a graft that appears mismatched in size or skin color; concerns that the transplant may be unsuccessful; concerns about health or limb function becoming "worse off" from the UE VCA; and concerns about logistical barriers to accessing transplant and rehabilitation services. Participants would justify getting an UE VCA if the UE VCA success rate was high and risks were low, and if participants currently struggled with managing daily tasks.

## **CONCLUSION**

Preliminary findings suggest that people with UE amputations hold clinical and psychosocial concerns that diminish their enthusiasm for UE VCA. These findings are currently being used to inform the development of educational materials that aim to provide comprehensive, objective information to SMs and civilians with UE amputations, their families, and the general public. Addressing patients' psychosocial concerns may help to set appropriate expectations, and improve understanding of the risks and benefits associated with UE VCA, and ultimately foster informed decision making about UE VCA.

## Appendix 10.

- **Gordon EJ**, Kuramitsu B, Gacki-Smith J, Ferzola A, Vanterpool K, Kunkle C, Hewitt M, Schultheis A, Riggleman T, Taylor J, Cooney C, Tintle S, Brandacher G, Levan M. Psychosocial and Ethical Factors Affecting Patients' Decision Making about Upper Extremity Vascularized Composite Allotransplantation. Paper accepted for oral presentation at Tissue Engineering and Regenerative Medicine International Society (TERMIS) virtual World Congress in Maastricht, The Netherlands, November 17, 2021.

### Background

The informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA) has yet to be standardized. Consequently, the information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed and under-prepared for decision making about UE VCA. This study examined decision making and psychosocial factors affecting decisions about UE VCA among people with UE amputations.

### Methods

We conducted in-depth interviews among people with acquired UE amputations. Open-ended questions assessed psychosocial factors informing decision making about UE VCA. Thematic analysis was used to analyze qualitative data.

### Results

To date, 12 people completed in-depth interviews (75% participation rate). Most were male (71%) and had a mean age of 49 years. Most had a unilateral amputation (75%) and had undergone amputation a mean of 8 years earlier. Forty-two percent of participants were 'completely' or 'a lot' willing to pursue VCA. Psychosocial factors influencing decisions to pursue VCA included: expecting an increase in social and physical confidence; seeking independence with activities of daily living; enabling more active involvement as a parent; family or friend enthusiasm; and prosthetic device problems. Psychosocial factors influencing decision making not to pursue VCA included: feeling mentally unprepared for a transplant; having already adapted to life without upper limb(s); concerns about the long-term commitment to taking immunosuppressants; discouragement from family or friends; concerns about the rigorous rehabilitation process; concerns about receiving a graft that appears mismatched in size or skin color; concerns that the transplant may be unsuccessful; concerns about health or limb function becoming "worse off" from the UE VCA; and concerns about logistical barriers to accessing transplant and rehabilitation services.

### Conclusion

Preliminary findings suggest that people with UE amputations hold concerns that diminish their enthusiasm for UE VCA. Addressing patients' psychosocial concerns may foster informed decision making about UE VCA.

## Appendix 11.

- B. Kuramitsu, C. Berumen, A. Ferzola, H. Sung, D. Scarton, T. McHugh, A. Schultheis, T. Riggelman, J. Taylor, C. Cooney, M. Henderson, S. Tintle, G. Brandacher, **E. Gordon**. Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA. Paper accepted for a 5-minute Podium Presentation at the American Society for Reconstructive Transplantation Meeting in Bethesda, MD. Hybrid meeting. November 18, 2021.

### BACKGROUND

Little is known about the informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA). Consequently, the amount and type of information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed, under-prepared, and feeling unduly pressured when considering this option. This study examines the decision-making process, psychosocial concerns, and information needs about UE VCA among people with UE amputations.

### METHODS

We conducted cognitive and in-depth interviews among people with UE amputations at one academic medical center and one rehabilitation clinic. Interviews focused on psychosocial factors affecting decision making for UE VCA, information needs about UE VCA, and perceptions of undue influence to pursue UE VCA. Thematic analysis was used to analyze qualitative data.

### RESULTS

Eight individuals participated (50% rate). Most were male (75%), had a mean age of 48.5 years. Most participants had a unilateral transradial amputation (62.5%) at a mean of 5 years prior. Psychosocial factors influencing decision making about UE VCA included: having the "right mindset," concerns about immunosuppressants, and maintaining support of caregivers. Most participants reported the best time to be informed about UE VCA is near the time of amputation, i.e., before the scheduled surgery (n=4), or within the first couple weeks or months thereafter (n=7), because they would be less receptive to it after adapting to their amputation. Participants desired information about the process of getting an UE VCA, expectations for functionality and recovery, and recipient experiences of getting an UE VCA. Most unilateral participants believed that people with bilateral amputations should be prioritized in patient selection for UE VCA, whereas bilateral participants did not believe unilateral versus bilateral should matter. While participants reported no undue influence to pursue UE VCA, some identified the need for a job, unavailable prosthetic device, and case worker or family member enthusiasm as potentially exerting undue influence on them.

### DISCUSSION and CONCLUSION

Preliminary findings suggest that people with UE amputations have limited knowledge about UE VCA. Addressing patients' information needs and psychosocial concerns may enhance decision-making and informed consent.

## Appendix 12.

- Hewitt M, Riggleman T, Nordstrom M, Dodd LD, Kuramitsu B, Gacki-Smith J, Vanterpool K, Downey M, Cooney C, Dumanian G, Jensen S, Tintle S, Brandacher G, Levan M, **Gordon E**. Awareness and Perceptions of Vascularized Composite Allotransplantation (VCA) Among Military Personnel with Upper Extremity Amputations: A Qualitative Approach. Poster presented at the Association of Military Surgeons of the United States (AMSUS), February 22, 2022.

**Introduction:** Upper extremity (UE) vascularized composite allotransplantation (VCA) is a relatively new procedure with >130 performed worldwide.<sup>1</sup> To date, UE VCA has shown promising results: restoring motor function, touch, and improved quality of life to recipients.<sup>2</sup> However, UE VCA poses several risks including immunosuppressant side effects, rejection, and long-term rehabilitation.<sup>2</sup> From 2001-2017, US service members sustained a total of 302 upper limb amputations.<sup>3</sup> Therefore, it is important for military personnel to understand the UE VCA procedure, risks, and potential benefits as an option for restoring their quality of life.

**Methods:** We conducted qualitative interviews with Veterans with acquired UE amputations to assess their awareness and perceptions of VCA. All participants were receiving rehabilitation and treatment services at Walter Reed National Military Medical Center (WRNMMC).

**Results:** Four Veterans participated (100% participation rate). Participants were male (100%), white (75%), and Hispanic (50%). All participants had unilateral, above elbow amputations, and an average of 12 years since their amputation. All had heard of UE VCA. One individual had never discussed UE VCA with a provider, and had only heard about it through media resources (Internet, online article, etc.). The remaining three individuals all had conversations, of varying degree and depth, with providers in regard to UE VCA. The three individuals who spoke with providers were offered VCA, but expressed disinterest in pursuing it. No participant knew of others seeking UE VCA at the time of the interview. All participants perceived UE VCA as providing potentially better control over the UE than prosthetics could provide. The perceived benefits of UE VCA included the potential for two-handed activities and that fine motor skills would improve after UE VCA.

**Conclusion:** Our preliminary findings suggest that some US service members were aware of UE VCA. Clinicians seem to be an important resource for information. Next steps in this study will incorporate interview findings in conjunction with findings from Northwestern University and Johns Hopkins University in order to create educational materials including a website, videos, and a question prompt sheet.

## Appendix 13.

- Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Riggleman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Poster presented at the American Transplant Congress (ATC) meeting, Boston, MA, June 5, 2022.

**Purpose:** Little is known about how to measure “success” of upper extremity (UE) vascularized composite allotransplantation (VCA) given its relative novelty and low frequency. While providers define UE VCA “success” as survival, functional, and quality-of-life outcomes, patients’ definitions have been little examined. Our study assessed patients’ definitions of transplant “success.”

**Methods:** We conducted focus groups among people with acquired UE amputations and UE VCA candidates, participants, and recipients at two sites to assess transplant “success.” Focus group transcriptions were analyzed using thematic analysis. A post-focus group survey assessed demographics.

**Results:** We conducted 6 focus groups among 26 participants (90% participation rate), including people with acquired UE amputations (n=20), UE VCA candidates who did not pursue it (n=3), a waitlisted UE VCA participant (n=1), and UE VCA recipients (n=2). Most were male (62%), white (85%), and had a unilateral amputation (77%), with a mean age of 49. Transplant “success” was defined in 5 ways: 1) The surgical attachment of the donor limb without complication: “an arm has been transplanted onto your body without rejection”; 2) Restoring function and sensation in the transplanted limb to restore activities: “I can bring a glass to my lips and drink. I can open a door. Turn a doorknob. I can drive my car”; 3) Ensuring the transplant process (e.g., surgery, hand therapy, immunosuppression) ran smoothly: “you’re in rehab and moving forward and making the process work”; 4) Gaining greater function and quality of life with UE VCA compared to no treatment or prosthetics: “How many different tasks can I do with my new hand *versus* residuals?”; and 5) Ensuring that functional and quality-of-life benefits outweighed the risks (e.g., recovery, side effects, financial): “The addition of the functionality would have to outweigh... whatever other negatives there might be, like recovery time, and what the side effects of the anti-rejection drugs would be”.

**Conclusions:** Our findings suggest that people with UE amputations define transplant “success” based on desired treatment processes and outcomes, comparing UE VCA to alternatives. Patient-provider discussion about definitions of transplant “success” may help patients determine if UE VCA is the right treatment for them.

#### **Appendix 14.**

- Levan M. Psychosocial Factors in the Decision Making and Informed Consent Process for Upper Extremity VCA. Paper (**Invited**) presented at American Transplant Congress (ATC) meeting in Boston, Massachusetts, on June 7, 2022.

[no abstract available]

## Appendix 15.

- Downey M, Kuramitsu B, Gacki-Smith J, Vanterpool K, Luken M, Nordstrom M, Riggleman T, Cooney C, Levan M, Tintle S, Brandacher G, Jensen S, Dumanian G, **Gordon E**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Mini-oral paper presented (virtually) at The Transplantation Society (TTS) meeting in Buenos Aires Sept. 10<sup>th</sup>-14<sup>th</sup>, 2022.

**Purpose:** Little is known about how to measure “success” of upper extremity (UE) vascularized composite allotransplantation (VCA) given its relative novelty and low frequency. While providers define UE VCA “success” as survival, functional, and quality-of-life outcomes, patients’ definitions have been little examined. Our study assessed patients’ definitions of transplant “success”.

**Methods:** We conducted focus groups among people with acquired UE amputations and UE VCA candidates, participants, and recipients at two sites to assess transplant “success.” Focus group transcriptions were analyzed using thematic analysis. A post-focus group survey assessed demographics.

**Results:** We conducted 6 focus groups among 26 participants (90% participation rate), including people with acquired UE amputations (n=20), UE VCA candidates who did not pursue it (n=3), a waitlisted UE VCA participant (n=1), and UE VCA recipients (n=2). Most were male (62%), white (85%), and had a unilateral amputation (77%), with a mean age of 49. Transplant “success” was defined in 5 ways: 1) The surgical attachment of the donor limb without complication: “an arm has been transplanted onto your body without rejection”; 2) Restoring function and sensation in the transplanted limb to restore activities: “I can bring a glass to my lips and drink. I can open a door. Turn a doorknob. I can drive my car”; 3) Ensuring the transplant process (e.g., surgery, hand therapy, immunosuppression) ran smoothly: “you’re in rehab and moving forward and making the process work”; 4) Gaining greater function and quality of life with UE VCA compared to no treatment or prosthetics: “How many different tasks can I do with my new hand versus residuals?”; and 5) Ensuring that functional and quality-of-life benefits outweighed the risks (e.g., recovery, side effects, financial): “The addition of the functionality would have to outweigh... whatever other negatives there might be, like recovery time, and what the side effects of the anti-rejection drugs would be”.

**Conclusions:** Our findings suggest that people with UE amputations define transplant “success” based on desired treatment processes and outcomes, comparing UE VCA to alternatives. Patient-provider discussion about definitions of transplant “success” may help patients determine if UE VCA is the right treatment for them.

## Appendix 16.

- M. Nordstrom, M. Luken, M. Hewitt, T. Riggleman, S. Fichter, B. Kuramitsu, J. Gacki-Smith, K. Vanterpool, M. Downey, C. Cooney, G. Dumanian, S. Jensen, S. Tintle S, G. Brandacher, M. Levan, **EJ. Gordon**. Treatment Options for Upper Extremity Limb Loss: Ethical and Psychosocial Factors Affecting Patients' Decision Making about Vascularized Composite Allotransplantation. Poster presented at the Military Health Systems Research Symposium (MHSRS) meeting, Kissimmee, FL. September 13, 2022. Abstract # MHSRS-22-07470.

### Background

Limb loss is a common combat injury among United States military service members (SMs). From 2001 to 2017, US SMs sustained a total of 302 upper extremity (UE) amputations that were caused primarily by explosions, motor vehicle crashes, and penetrating gunshot wounds.<sup>1</sup> From 2001 to 2011, SMs with UE amputations were assigned an average disability rating of 75 (of 100), which indicates that they were unable to perform in many occupational or social settings, and only about 11% of all SMs with at least one amputation returned to duty.<sup>2,3</sup> Individuals with UE amputations may face challenges related to engaging in activities of daily living, their physical environment, employment, social life, transportation, and more.<sup>4</sup> Many also experience psychosocial complications including depression, anxiety, employment challenges, social isolation, body image disturbance, and military concerns over honor.<sup>5-7</sup> Restoring SMs' function and well-being, in addition to benefitting the individual's quality of life, benefits the military by increasing service readiness, improving return-to-duty rates, and reducing healthcare costs.

One possible treatment option for UE limb loss is hand or upper extremity transplantation as one form of Vascularized Composite Allotransplantation (VCA). Upper extremity VCA entails transplanting an entire hand/forearm/arm from a deceased organ donor onto a recipient. VCA has been used to treat multiple severe tissue defects due to trauma or infection with the goals of restoring function and improving quality of life. Overall, functional outcomes from UE VCA appear to be highly encouraging.<sup>8,9,10</sup> Despite the positive outcomes, there are also surgical, medical, and psychosocial risks. Allograft failure and rejection may require reconstruction or even limb removal. Additionally, VCA requires a lifelong commitment to anti-rejection medications and long-term rehabilitation regimens. Psychosocial adaptation and the accompanying financial costs will vary across individuals.<sup>11</sup>

Given the risks and potential benefits of this procedure, the informed consent process is extremely important before undergoing treatment. However, the informed consent process for UE VCA has yet to be standardized. Consequently, the information provided to patients about UE VCA varies. Such variation may contribute to people with UE amputations being inadequately informed and under-prepared for decision making about UE VCA. This study examined decision making and psychosocial factors affecting decisions about UE VCA among people with UE amputations.

### Methods

We conducted in-depth telephone interviews among people with acquired UE amputations to assess psychosocial factors informing decision making about UE VCA. Interviews were conducted by research staff at Northwestern University and Johns Hopkins University. Participants were recruited via medical record review, social media advertisements, advertisements by support groups across the country, and flyers posted in various clinics on site. Interview topics covered personal history, awareness and perceptions of UE VCA, information needs, the decision-making process, perceptions of voluntariness and patient selection, and interest in using educational materials such as a website, videos, and a question prompt sheet. Interviews lasted between one and two hours. Thematic analysis and a grounded theory approach were used to analyze qualitative data.

### Results

To date, 18 people completed in-depth interviews (82% participation rate), including 3 undergoing UE VCA evaluation as VCA "participants" or "candidates". Most were male (78%), had a mean age of 48 years, had a unilateral amputation (78%), and had undergone amputation a mean of 10 years earlier. Half (50%) were 'a lot' or 'completely' willing to pursue VCA. Psychosocial factors influencing decisions

to pursue VCA included: expecting an increase in social and physical self-esteem; seeking independence with activities of daily living; enabling more active involvement as a parent; family or friend enthusiasm; and prosthetic device problems. Psychosocial factors influencing decision making not to pursue VCA included: feeling mentally unprepared for a transplant; having already adapted to life without upper limb(s); concerns about the long-term commitment to taking immunosuppressants; discouragement from family or friends; concerns about the rigorous rehabilitation process; concerns about receiving a graft that appears mismatched in size or skin color; concerns that the transplant may be unsuccessful; concerns about health or limb function becoming “worse off” from the UE VCA; and concerns about logistical barriers to accessing transplant and rehabilitation services. Participants would justify getting an UE VCA if the UE VCA success rate was high and risks were low, and if participants currently struggled with managing daily tasks.

## **Conclusion**

Preliminary findings suggest that people with UE amputations hold clinical and psychosocial concerns that diminish their enthusiasm for UE VCA. These findings are currently being used to inform the development of educational materials that aim to provide comprehensive, objective information to SMs and civilians with UE amputations, their families, and the general public. Addressing patients’ psychosocial concerns may help to set appropriate expectations, and improve understanding of the risks and benefits associated with UE VCA, and ultimately foster informed decision making about UE VCA.

## Appendix 17.

- Gacki-Smith J, Kuramitsu BR, Downey M, Vanterpool KB, Nordstrom MJ, Luken M, Riggleman T, Altema W, Fichter S, Cooney CM, Dumanian GA, Jensen SE, Brandacher G, Tintle S, Levan M, **Gordon EJ**. Empowering Patients with Upper Extremity Amputations to Communicate with Providers about VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 4, 2022.

**Background:** Patient-provider communication can be ineffective because many patients feel intimidated or do not know what questions to ask providers. Many individuals with upper extremity (UE) amputations do not receive sufficient information about their treatment options, particularly vascularized composite allotransplantation (VCA). A question prompt sheet (QPS) is a list of questions that can empower patients to ask questions they find important, promote patient-provider communication, and increase patient knowledge, thereby fostering patient-centered care. This study developed a UE VCA-QPS and examined the UE VCA information needs among people with UE amputations.

**Methods:** We conducted a multi-site, cross-sectional, sequential mixed-methods study among people with acquired UE amputations. In-depth interviews were first conducted to examine patients' information needs about UE VCA, which were synthesized through qualitative content analysis into a list of items for the initial UE VCA-QPS draft. The initial draft UE VCA-QPS included 130 items across 18 topics. Thereafter, semi-structured interviews were conducted to rate the importance of each item for inclusion in the VCA-QPS and elicit qualitative rationales for each rating. Quantitative data were analyzed by descriptive statistics. The multidisciplinary research team reviewed the subsequent draft UE VCA-QPS to reduce the number of items, improve wording, remove repetitive items, and ensure that items were clinically relevant.

**Results:** Eighty-nine people participated (63.9% participation rate), including people who had not pursued UE VCA (85%), UE VCA candidates and participants (9%), and UE VCA recipients (6%). Most were male (73%), White (74%), and had a mean age of 46 years, had a unilateral (84%) and below-elbow amputation (56%). Participants expressed interest in learning about UE VCA eligibility, evaluation process, surgery, risks, rehabilitation, and functional outcomes. The final UE VCA-QPS included 35 items, organized into 9 topics. Items were written at a  $\leq$  6th grade reading level. Most semi-structured interview participants (86%) were 'completely' or 'very' likely to use a UE VCA-QPS.

**Conclusions:** Our findings suggest that people with UE amputations desire much information about myriad aspects of UE VCA. Future research should assess whether the UE VCA-QPS helps to meet patients' information needs and foster informed decision-making for UE VCA.

## Appendix 18.

- **Gordon EJ.** Moderator (**Invited**), Session III: Psychologists. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 4, 2022.

[no abstract available]

## Appendix 19.

- **Gordon EJ.** *Informed Consent in VCA.* (**Invited**) Session III: Psychologists. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 4, 2022.

[no abstract available]

## Appendix 20.

- Downey M, Gacki-Smith J, Kuramitsu BR, Vanterpool KB, Nordstrom MJ, Luken M, Riggelman T, Fichter S, Altema W, Langlee W, Cooney CM, Jensen SE, Dumanian GA, Levan M, Tintle S, Brandacher G, **Gordon EJ**. Patient Definitions of Transplant “Success” of Upper Extremity VCA. Paper accepted for a 6-minute Podium Presentation. American Society for Reconstructive Transplantation 7<sup>th</sup> Biennial meeting. Chicago, IL. November 5, 2022.

**Background:** Little is known about how to measure the “success” of upper extremity (UE) vascularized composite allotransplantation (VCA), an innovative treatment for people with UE amputations. While providers have defined UE VCA “success” by quantitative functional, clinical, and quality-of-life (QoL) metrics, patients’ definitions are lesser known. Our study assessed patients’ definitions of UE VCA “success.”

**Methods:** We conducted in-depth interviews and focus groups among people with acquired UE amputations and UE VCA candidates, participants, and recipients at three sites to assess transplant “success” and collect demographic data. Transcripts were analyzed using thematic analysis.

**Results:** We conducted 50 interviews (61.7% participation rate) and 9 focus groups among 37 participants (75.5% participation rate), including people with acquired UE amputations (83.3%), UE VCA candidates and participants (11.1%), and UE VCA recipients (5.6%). Most were male (73.6%), White (70.8%), had a mean age of 45 years, and had a unilateral (68.1%) and below-elbow amputation (51.4%). Transplant “success” was defined in 6 ways: 1) Restoring function and sensation to enable activities: “I can bring a glass to my lips and drink. I can open a door.... I can drive my car” (functional/QoL); 2) Accepting the transplanted limb into the recipient’s identity: “...if I can deal with living with it, knowing that it’s not actually my hand” (psychosocial); 3) Surgical attachment of the donor limb to the recipient without rejection: “I’m leaning towards, came out of the surgery, and all the systems are connected” (clinical); 4) Ensuring that the benefits outweigh the risks: “The addition of the functionality would have to outweigh... the side-effects of the anti-rejection drugs” (functional/QoL); 5) Attaining better outcomes compared to prosthetics: “...if you [are] just having basically a useless limb hanging there... it’d be worse than your prosthetic” (functional/QoL).

**Conclusions:** Our findings suggest that participants have multiple definitions of UE VCA “success” pertaining to improvements in the recipient’s daily living experience, compared to no treatment and/or prosthetics. Informed consent should address whether patients’ desired outcomes can be realized with UE VCA.

# Ethical Factors Impacting Patients Decisions to Pursue VCA

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W81XWH-19-2-0036



PI: CDR Scott Tintle, MD

Org: The Henry M. Jackson Foundation for the Advancement of Military Medicine

Award Amount: \$169,481

## Study/Product Aims

- Aim 1:** Qualitatively assess the informed consent process for upper extremity-VCA transplantation.
- Aim 2:** Develop educational materials (video, website, question prompt sheet) that provide patient-centered information about upper extremity VCA
- Aim 3:** Formatively evaluate the educational materials through usability testing

## Approach

The overall long-term objective of the proposed study is to optimize the informed consent process for upper extremity VCA candidates.



Image source:

[https://www.hopkinsmedicine.org/transplant/news\\_events/double\\_arm\\_transplant.html](https://www.hopkinsmedicine.org/transplant/news_events/double_arm_transplant.html)

**Accomplishments:** The entire team contributed to completing the QPS, finalizing website content,. We published 2 papers, and 3 are under review or re-review. video segmenting, data analysis, writing manuscript drafts, and poster and paper presentations

## Timeline and Cost

| Activities                                         | CY | 19-20                  | 20-21                  | 21-22                  |  |
|----------------------------------------------------|----|------------------------|------------------------|------------------------|--|
| Prepare regulatory documents, hire and train staff |    | <div><div></div></div> | <div><div></div></div> |                        |  |
| Conduct interviews, focus groups                   |    |                        | <div><div></div></div> | <div><div></div></div> |  |
| Develop website, videos, QPS                       |    |                        | <div><div></div></div> | <div><div></div></div> |  |
| Conduct usability testing                          |    |                        |                        | <div><div></div></div> |  |
| <b>Estimated Budget (\$K)</b>                      |    | <b>\$56.5K</b>         | <b>\$62.7K</b>         | <b>\$50.2K</b>         |  |

## Goals/Milestones

### CY19 Goal – Preparation

- ☒ Prepare regulatory documents
- ☒ Hire and train study staff

### CY20 Goals – Recruitment and analysis

- ☒ Conduct interviews and focus groups
- ☒ Analysis of interview and focus group transcriptions
- ☒ Develop educational materials: website and QPS

### CY21 Goal – Formative evaluation

- ☒ Prepare manuscripts and presentations
- ☒ Usability testing of website

## Comments/Challenges/Issues/Concerns

### Budget Expenditure to Date

Projected Expenditure: \$169,481 for Year 3

Actual Expenditure: \$167,647 as of October 2022

Updated: December 31, 2022