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14. ABSTRACT

Hand and upper limb transplantation (a form of vascularized composite allotransplantation or VCA) is a new treatment option that aims to restore motor and mobility functions 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 that are sensitive to different levels of dysfunction, residual limbs, health literacy levels, 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.

During the last year, our website has been developed and refined based on feedback from telephone focus groups, with minor design and content changes left to incorporate. A total of n=11 videos were conducted with 1 UE VCA recipient, 1 UE VCA candidate, 3 upper limb amputees, 5 clinicians, and 1 prosthetist. Across all sites, we conducted: In-Depth Interviews (n=33), Online Focus Groups (n=2), Telephone Focus Groups (n=6), and Semi-Structured Interviews (n=6). A refined draft of the Question Prompt Sheet has been developed and is currently being reviewed by participants in the Semi-Structured Interviews. Preliminary analysis of the In-depth Interviews reveals a general preference for informing people about the option of upper limb transplantation close to the time of the amputation, and no undue pressure to pursue upper limb transplantation. Participants' reported information needs about upper limb transplantation including: the process of getting an upper limb transplant, the hand or arm functioning post-transplant, the appearance of the graft, the risks of having an upper limb transplant, the rehabilitation process, recipients' experiences with the transplant, and the status of the VCA field.

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 aims 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?

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), 10% (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, 68% complete (NU), 61% complete (JHU) 10% (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 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: UE amputees (n=25), VCA candidates (n=17), VCA participants (n=5), VCA recipients (n=3)
  Timeline: 12-18 months, 100% complete (NU, JHU), 35% complete (WR)

- Subtask 5: Conduct online focus groups with UE amputees (n=25)
  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), 35% complete (WR)
- Subtask 7: Conduct qualitative data analysis
  Timeline: 10-21 months, 25% complete
- Subtask 8: Co-author manuscript on Aim 1 findings
  Timeline: 18-24 months, 10% complete
- Milestone #2: Manuscript on informed consent, information needs for VCA
  Timeline: 18-24 months, 10% 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, 30% complete

- Subtask 1: Set up server, obtain web domain, establish ADA standards compliance
  Timeline: 12 months, 75% 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, 30% 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, 90% 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, 90% 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) 75% complete (WR)
- Subtask 6: Recruit and conduct 9 telephone focus groups
  Timeline: 19-24 months, 100% complete (NU, JHU) 0% complete (WR)
- Subtask 7: Transcribe telephone focus groups
  Timeline, 19-24 months, 33% complete (NU) 0% complete (JHU) 0% complete (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, 50% complete
- Subtask 9: Iteratively review and provide feedback on website design, instructional design, and functionality to Advantage Marketing website developers
  Timeline: 19-26 months, 75% complete
- Subtask 10: Revise website design and content
  Timeline, 19-26 months, 50% complete

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

- Subtask 2: Recruit and audition amputees for videotaping
  Timeline: 21-24 months, 73% complete
- Subtask 3: Videotape UE amputee and clinician testimonials
  Timeline: 21-24 months, 73% complete
- Subtask 4: Edit and link in video testimonials into website
  Timeline: 21-24 months, 15% 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), 0% complete (WR)

- Subtask 3: Recruit and conduct semi-structured interviews for feedback on and refinement of the QPS
  Timeline: 19-24 months, 10% complete (NU), 20% complete (JHU), 0% complete (WR)
- Subtask 4: Analyze semi-structured interviews to refine the QPS items for inclusion, exclusion, and wording
  Timeline: 19-24 months, 0% complete
- Subtask 5: Further refine QPS
  Timeline: 24-26 months, 0% complete
- Milestone #3: Complete VCA-QPS development
  Timeline: 26 months, 0% 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, 5% complete
- Milestone #4: Complete UE VCA website
- Timeline: 31-33 months, 0% complete
- Milestone #5: Manuscript on website development and usability testing for UE VCA,
- Timeline: 36 months, 0% 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
  - John's 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
  - Purchased and posted advertisements in:
    - On the Move e-newsletter, appeared in Quarter 3 and Quarter 4 2020 editions, and Quarter 1 and Quarter 2 2021 editions.
    - Amplitude e-newsletter, appeared in Oct. 2020, Dec. 2020, and Feb. 2021 editions
- 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
  - NU downloads updated EDW database bi-weekly – has identified n=29 potential participants to date
  - JHU obtained updated list on [8/25/2021] – has identified n=136 potential participants to date
  - WR obtained updated list on 09/10/2021 – has identified n=44 potential participants to date
- Subtask 3: Recruit participants and obtain informed consent by staff

- Over the last year:
  - NU obtained informed consent from n=10 patients for in-depth interviews
  - JHU obtained informed consent from n=20 patients for in-depth interviews
  - WR obtained informed consent from n=6 patients for in-depth interviews
  - NU obtained informed consent from n=12 patients for online focus groups
  - NU obtained informed consent from n=13 patients for telephone focus groups
  - JHU obtained informed consent from n=16 patients for telephone focus groups
  - NU obtained informed consent from n=5 patients for semi-structured interviews
  - JHU obtained informed consent from n=6 patients for semi-structured interviews

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 3: Submit revised in-depth interview guide for local IRB and HRPO review
  - JHU received IRB approval and HRPO approval
  - WR received IRB approval and HRPO approval
- Subtask 4: Conduct in-depth interviews with (n=50) participants: UE amputees (n=25), VCA candidates (n=17), VCA participants (n=5), VCA recipients (n=3)
  - Over the last year:
    - NU completed n=10 in-depth interviews with:
      - N= 9 UE amputees
      - N= 1 VCA participant
    - JHU conducted a total of n=17 in-depth interviews with:
      - N= 8 UE amputees
      - N= 3 VCA candidates
      - N= 2 VCA participants
      - N= 4 VCA recipients
    - WR conducted a total of n=6 in-depth interviews with: n=6 UE amputees
- Subtask 5: Conduct online focus groups with UE amputees (n=25)
  - NU conducted 2 online focus groups with n=7 total participants (100% complete)
- Subtask 6: Transcribe in-depth interviews and online focus groups
  - Over the last year:
    - N=2 of 2 online focus groups have been transcribed at NU
    - N=10 of 10 in-depth interviews have been transcribed at NU
    - N=17 of 17 in-depth interviews have been transcribed at JHU
    - N=6 of 6 in-depth interviews have been transcribed at WR
- Subtask 7: Conduct qualitative data analysis
  - Research team refined segmenting and coding approach
  - Research team completed refinement of codebook
  - NU and JHU research teams together held n=21 total inductive coding analytic retreats
  - NU research team held n=44 total inductive coding retreats and completed final coding of n=16 total in-depth interview transcripts
  - JHU research team held n=16 total inductive coding retreats and completed final coding of n=17 total in-depth interview transcripts
  - WR research team installed NVIVO coding software and participated in codebook training
  - NU and JHU conducted preliminary analysis of themes from NU and JHU participant in-depth interviews
- Subtask 8: Co-author manuscript on Aim 1 findings
  - Drafts of the Introduction and Methods sections have been prepared
- Milestone #2: Manuscript on informed consent, information needs for VCA

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 1: Set up server, obtain web domain, establish ADA standards compliance
  -
- 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
  -
- 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
  - Instructional design consultant and research team refined and edited website text to improve readability, comprehension, formatting, and identified sections to be enhanced with photos.
  - Reviewed website content against QPS to determine gaps of information needs from patient interviews
  - Wrote overviews/introductions for each website section
  - Edited, formatted, and confirmed list of website sources/references
  - Compiled and refined reference page
  - Refined website glossary
  - Wrote captions for potential photos on website
  - Website content was sent to website developer (Advantage Marketing)
- 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
  - Data tables, graphs, and diagrams were created to supplement website text
  - New drafts of the website logo were created based on focus group feedback
  - Research team obtained additional potential photos for website
  - Research team narrowed down list of potential photos for website
- Subtask 5: Submit website content and telephone focus group moderators guide to local IRBs and HRPO for review
  - Developed telephone focus group materials packet for participants that included portions of website text, terminology, diagrams, and photos.
  - Edited and refined telephone focus group moderator's guide to coincide with focus group materials packet
  - NU submitted the revised telephone focus group materials and moderator's guide to the IRB on 6-29-21, which was approved on 7-6-21.
  - JHU submitted the revised telephone focus group materials and moderator's guide to the IRB on 7-1-21, which was approved on 7-22-21.
- Subtask 6: Recruit and conduct 9 telephone focus groups
  - NU conducted n=3 telephone focus groups with n=11 UE amputees and n=1 previous VCA candidate
  - JHU conducted n=3 telephone focus groups with n=8 UE amputees, n=4 UE VCA candidates, and n=2 UE VCA Recipients
- Subtask 7: Transcribe telephone focus groups
  - N=1 focus group has been transcribed at NU
  - N=0 focus groups have been transcribed at JHU
- 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
  - NU and JHU held n=3 meetings to review focus group feedback and prioritize questions for the following focus groups
  - Revised graphs and tables based on focus group feedback and recommendations
- Subtask 9: Iteratively review and provide feedback on website design, instructional design, and functionality to Advantage Marketing website developers
  - Research team provided marketing team 3 rounds of website feedback based on telephone focus group feedback
- Subtask 10: Revise website design and content
  - Advantage Marketing has made various changes to website formatting and design over the course of several months based on research team edits and focus group feedback.

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

- Subtask 2: Recruit and audition amputees for videotaping
    - Over the last year, n=4 UE amputees and n=1 UE VCA Recipient were recruited for a video
- Subtask 3: Videotape UE amputee and clinician testimonials
    - Over the last year, n=11 videos were conducted with 1 UE VCA recipient, 1 UE VCA candidate, 3 upper limb amputees, 5 clinicians, and 1 prosthetist.
- Subtask 4: Edit and link in video testimonials into website
    - Research staff at all sites have continued selecting video segments for n=12 total videos obtained to date
    - N=2 videos have been sent to video editing team for final editing before being placed on the website

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

- Subtask 1: Prepare draft of QPS based on Aim 1 results
    - Extracted questions from all in-depth interviews conducted at NU and JHU (n=33) and online focus groups (n=2) to populate the initial QPS draft
        - Initial set of QPS items were identified (n=130)
        - Reading grade levels were obtained for each item
    - Research team refined the initial QPS draft:
        - Initial feedback from internal research team was consolidated and the QPS items were reduced to (n=74) items
        - Revised version of the QPS was sent to all PIs and consultants for their input to ensure clinical accuracy on 6-25-21.
        - Research team further refined QPS according to clinician feedback and QPS items were reduced to (n=52) items
- Subtask 2: Submit draft QPS and semi-structured interview guide to local IRBs and HRPO for review
    - NU submitted draft of QPS to IRB, which was approved on [8-23-21]
    - JHU submitted draft of QPS to IRB, which was approved on [8-31-21]
    - NU submitted IRB-approved draft of QPS to HRPO, which was approved on [8-26-21]
    - JHU submitted IRB-approved draft of QPS to HRPO, which was approved on [9-2-21]
- Subtask 3: Recruit and conduct semi-structured interviews for feedback on and refinement of the QPS
    - NU obtained consent from n=5 UE amputees for semi-structured interviews
    - NU completed n=2 semi-structured interviews
    - JHU obtained consent from n=6 UE amputees for semi-structured interviews
    - JHU completed n=4 semi-structured interviews

- **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
        - Research team held brainstorming session about which task scenarios should be asked based on first draft of website

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

Brianna Kuramitsu, Research Coordinator, Sr. and Jessica Gacki-Smith, Research Project Manager, attended and each presented posters at the American Transplant Congress (ATC) annual virtual conference June 4-9, 2021

Melissa Hewitt, Research Assistant, prepared and submitted an abstract to AMSUS 2021 on 10/04/2021. The team is currently pending an acceptance response.

The study team at Johns Hopkins was trained in qualitative research methods, including the design and facilitating of focus groups and the analysis of qualitative data.

How were the results disseminated to communities of interest?

- 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. 10/15/20
- An abstract titled "Patients' Psychosocial Perceptions, Information Needs, and Decision Making about Upper Extremity VCA was published in the journal of VCA in March 2021
- Brianna Kuramitsu presented a poster on UE VCA Decision Making at the American Transplant Congress virtual conference in June 2021
- Jessica Gacki-Smith presented a poster on a Question Prompt Sheet for UE VCA at the American Transplant Congress virtual conference in June 2021

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

During the next reporting period, we will:

- Continue to refine website content and materials based on focus group feedback
- Purchase photos for website prototype
- Continue to develop the navigation, formatting, and usability of the website
- Continue to hold weekly research team meetings
- Train WR research team on transcript segmenting/coding
- Post and share study recruitment fliers in clinics and support groups
- Continue conducting Semi-Structured interviews on the QPS at NU and JHU and begin at WR
- Refine the Question Prompt Sheet based on Semi-Structured Interviews
- Send refined QPS to Advisory Board and Consultants for feedback
- Prepare navigation questions for usability testing
- Send updated website to Advisory Board for their feedback before Usability Testing
- Continue conducting in-depth interviews at WR
- Begin coding in-depth interviews at WR
- Continue qualitative analysis of in-depth interviews and online focus groups at NU and JHU
- Develop and give presentation for TERMIS 2021 conference
- Develop and give presentation for ASRT 2021 conference
- Submit abstracts to ATC 2022 conference
- Continue preparing manuscript #1 on the in-depth interviews
- Continue preparing manuscript #2 on the QPS
- Film videos and edit them for testimonial segments

4. IMPACT:

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

In-depth interviews conducted thus far provide insights into UE amputees' information needs, psychosocial concerns, and decision-making processes for UE VCA. Psychosocial factors influencing decisions to pursue UE VCA include: regaining functionality and the associated independence, increasing social and physical confidence, and enabling more active parental involvement. Psychosocial factors and concerns influencing decisions to NOT pursue UE VCA include: health or limb function becoming "worse off" from UE VCA, the rigorous commitment required for undergoing UE VCA and rehabilitating, and having already adapted to life without upper limb(s). Preliminary findings suggest that people with upper limb amputations would ethically 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. Additionally, people with UE amputations desire information about upper limb transplantation, including the process for getting an UE VCA, expectations for recovery and functionality, and recipient experiences with UE VCA. These preliminary findings support the need for UE VCA programs to address patients' information needs and psychosocial concerns to facilitate decision-making and the informed consent process. Our next steps will be to continue conducting the in-depth interviews and telephone focus groups at Walter Reed to expand upon and identify other themes that may apply to active duty military individuals and veterans, and continue conducting semi-structured interviews at all sites to obtain feedback that will help us refine the question prompt sheet (QPS). We will leverage study findings to inform the development of all educational materials (website, videos, and QPS) to make UE VCA information more accessible to people with UE amputations in order to facilitate informed decision-making and the informed consent process in the future.

What was the impact on other disciplines?

Preliminary findings suggest a need to better inform and prepare patients in decision making and the informed consent process for UE VCA. 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.

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report

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

COVID clinical trials: (JHU)
JHU's study team members for DoD-Ethics are involved in kidney transplant research as well, so they were asked to help with the clinical trial and with another observational study for the 3rd Dose COVID-19 Vaccine. JHU's kidney transplant center began conducting a 3rd Dose COVID-19 vaccine clinical trial called "COVID-19 Protection After Transplantation (CPAT)" in August 2021 that pulled staff away from the DOD-Ethics study. An Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) was released on 8/12/2021, which allowed immuno-compromised people, including kidney transplant patients, to receive a 3rd dose of Modern/Pfizer-BioNTech at local pharmacies due to low antibodies from the first 2 doses. Since patients could now receive a 3rd dose independently from this clinical trial, help was needed urgently to recruit and consent as many patients as possible to the NIH-funded clinical trial. If a potential participate already received their 3rd dose outside of JHU, then they would become ineligible for this study. Study members from JHU were onboarded onto this project and observational COVID study in the week of 8/16/2021-8/20/2021 and participation in these studies continued through 9/29/2021.

Staff shortage: (JHU)
JHU is encountering challenges with hiring new research staff. In the US in general, there is a shortage of people applying for jobs. Part-time research assistants were hired (under a non-DoD grant) and trained to help with recruitment for this study and other studies at JHU.

Delay in transcription program approval: (WR)
WR has been transcribing in-depth interviews by hand while looking for a secure platform which can auto-transcribe. After extensive research among multiple departments, the team unfortunately came to the conclusion that no platform is available to the study team. As such, the team is examining the center's available personnel and bandwidth for alternative solutions.

IRB delays: **(WR)**
Walter Reed initially submitted a modification to the IRB enumerating a number of changes including staffing changes, updated interview guides, and requesting the use of Zoom to auto-transcribe interviews on 08-04-2021. The team received stipulations on 08-11-2021. The main stipulation was that Zoom is not an approved platform for research and use of PHI. Over the next month and a half, the team worked diligently with multiple departments, including the Department of Research Programs, IRB analysts, and Engineering and Research. After examining seven different platforms, the team ultimately came to the conclusion that no platform met all necessary criteria (approved by the DoD, secure for PHI transfer, auto-transcription, recording features, and available for use by external partners). As such, the team resubmitted the modification on 10/06/2021, with a few additional stipulations addressed such as the update to the telephone focus group materials. The modification is currently pending approval by the WRNMMC IRB. Once this submission has also been approved by the WR IRB, the WR team will send all materials to HRPO for record keeping purposes. Although administrative delays are partly outside the team's control, the staff works diligently to complete tasks quickly and follow-up with the IRB and other administrative entities until tasks are completed.

Recruitment challenges: (JHU, NU)

At JHU, initial recruitment call response rates were similar to other studies. After recruiting, consenting, and scheduling participants, it was difficult to follow-up with the patient for data collection despite multiple phone and email reminders. For this reason, there is a higher number of consented individuals than actual participants for each data collection activity. Given the difficulty following-up, we over-recruited for each focus group to ensure that we would meet our target participant number.

At NU and its partner Shirley Ryan, all potentially eligible patient participants have been contacted to request study participation. Additionally, advertisements about the study have been posted in several social media venues including Reddit, and in purchased online newsletters. This year we also tried posting advertisements on Facebook, but that effort yielded no participants. We are primarily relying on past participants to participate in future data activities. In order to get new participants, in the next period we plan to reach out to past participants to push more for snowball sampling, that is personal recommendations of people with upper limb amputations that we can reach out to about participating in our study.

Changes that had a significant impact on expenditures

- At NU and JHU, transcriptions for focus groups have been more expensive than expected due to increased time allotted for the focus groups (IRB approval for 2 hours for each focus group).
- At NU, we spent less money on participant compensation for the online focus groups. We compensated n=7 participants out of the anticipated n=25. We conducted 2 instead of 5 online focus groups because the platform was not conducive to gathering quality focus group feedback particularly from people with amputations due to the time it takes to type responses.
- Due to IRB and HRPO delays and study participant delays, fewer participants have been recruited than expected. Thus, expenditures are lower than expected. However, as soon as all IRB and HRPO approvals are obtained, we expect to complete all data collection activities, which is draw down upon the budget.

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.

Nothing to report

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

Nothing to report

Other publications, conference papers and presentations.

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.

Kuramitsu B, Berumen C, Sung HC, Ferzola A, Cooney C, Brandacher G, Henderson M, Tintle S, **Gordon EJ**. Paper presented on the panel, "VCA Ethics: How do we determine flourishing in VCA transplantation?" (EJ Gordon, Panel Organizer), at the American Association of Bioethics and Humanities Virtual Annual Conference, October 15, 2020.

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.

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.

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.

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. Abstract accepted for oral presentation at Tissue Engineering and Regenerative Medicine International Society (TERMIS) virtual World Congress in Maastricht, The Netherlands, November, 2021.

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. Abstract presented as a poster presentation at the Military Health Systems Research Symposium (MHSRS), August 23-26, 2021.

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.

Website(s) or other Internet site(s)

www.WithinReach.info

This website is still being built, and is thus not yet open to the public.
This website will serve as a neutral decision aid that provides a wealth of information about upper limb VCA designed to help people make informed decisions about upper limb transplantation.

Technologies or techniques

Nothing to report

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

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

Name:	Dr. Elisa Gordon
Project Role:	Initiating Principal Investigator
Researcher Identifier (e.g. ORCID ID):	0000-0003-0969-1998
Nearest person month worked:	2.55
Contribution to Project:	No Change

Name:	Brianna Kuramitsu
Project Role:	Research Study Coordinator, Sr.
Nearest person month worked:	6.15
Contribution to Project:	No Change

Name:	Jessica Gacki-Smith
Project Role:	Research Project Manager
Nearest person month worked:	4.25
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:	0.28
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:	0.6
Contribution to Project:	No Change

Name:	Dr. Macey Levan (Henderson)
Project Role:	Partnering Principal Investigator
Researcher Identifier:	0000-0002-4239-1252
Nearest person month worked:	0.90
Contribution to Project:	No Change

Name:	Dr. Dorry Segev
Project Role:	Co-Investigator
Researcher Identifier:	0000-0002-1924-4801
Nearest person month worked:	0.24
Contribution to Project:	No Change

Name:	Dr. Gerald Brandacher
Project Role:	Partnering Principal Investigator
Researcher Identifier:	0000-0001-7790-441X
Nearest person month worked:	1.00
Contribution to Project:	No Change

Name:	Karen Vanterpool
Project Role:	Qualitative Research Data Analyst
Nearest person month worked:	1.20
Contribution to Project:	No Change

Name: Carisa Cooney
Project Role: Co-Investigator, Psychologist
Researcher Identifier: 0000-0002-5475-206X
Nearest person month worked: 0.49
Contribution to Project: No Change

Name: Max Downey
Project Role: Research Assistant
Nearest person month worked: 12.00
Contribution to Project: Overtook research coordinator roles from Alex Ferzola as of 5/17/2021 as primary point of contact for JHU. Moderated all focus groups and conducted all semi-structured interviews. Made IRB modifications and HRPO approval requests for focus group and semi-structured interview materials. Completed qualitative coding for in-depth interviews. Helped to draft focus group materials, QPS, and website content.

Name: Dr. Scott Tintle
Project Role: Partnering Principal Investigator at WRNMMC
Nearest person month worked: 1.4
Contribution to Project: No Change

Name: Michelle Nordstrom, OTR/L
Project Role: Registered Occupational Therapist
Nearest person month worked: 0.3
Contribution to Project: No change

Name: Melissa Hewitt
Project Role: Research Assistant
Nearest person month worked: 1.38
Contribution to Project: No Change

Name: Derek Soloway
Project Role: Program Manager
Nearest person month worked: 0.31
Contribution to Project: No change

Name: Lauren Dodd
Project Role: Program Coordinator
Nearest person month worked: 0.27
Contribution to Project: Assisted in the protocol management and submissions to WRNMMC IRB as needed; replaced Megan Tsui.

Name: Tiffany Riggleman
Project Role: Research Certified Occupational Therapist Assistant
Nearest person month worked: 0.13
Contribution to Project: No Change

Name: Kalyn Jannace
Project Role: Lead Data Manager
Nearest person month worked: 0.03
Contribution to Project: No Change

Name: Rebecca Shultz
Project Role: Data Analyst II
Nearest person month worked: 0.45

Contribution to Project: Assisted Dr. Jannace with the study protocol review and recommendations, submitted both DSAs, provided relevant knowledge and guidance to the WRNMMC study team regarding data management concerns.

Name: Megan Tsui
Project Role: Clinical Research Coordinator
Nearest person month worked: 0.02
Contribution to Project: Assisted in the protocol management and submissions to WRNMMC IRB as needed.

Name: Julie Tran
Project Role: Regulatory Affairs Assistant
Nearest person month worked: 0.09
Contribution to Project: Assisted and answered questions related to the regulatory requirements at WRNMMC for this study.

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

Julie Tran, Andrea Schultheis, Christina Kunkle, and Megan Tsui are no longer supporting the protocol at the WR site.

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: Abstract accepted for publication in journal VCA (ASRT 2020), and for oral presentation at ASRT 2021

Appendix 2: Decision Making abstract accepted for oral poster presentation at ATC 2021

Appendix 3: QPS abstract accepted for poster presentation at ATC 2021

Appendix 4: Abstract accepted for oral presentation at TERMIS 2021

Appendix 5: Abstract accepted for poster presentation at MHSRS 2021

Appendix 1:

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 2:

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.

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 3:

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 4:

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. Abstract accepted for oral presentation at Tissue Engineering and Regenerative Medicine International Society (TERMIS) virtual World Congress in Maastricht, The Netherlands, November, 2021.

BACKGROUND
The informed consent process for upper extremity (UE) Vascularized Composite Allotransplantation (VCA) has not been standardized. Information provided to patients varies, which may contribute to individuals being inadequately informed and under-prepared for decision making. Therefore, this study examined psychosocial factors affecting decision-making about UE VCA.

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, 18 people completed in-depth interviews (82% participation rate), including 3 undergoing UE VCA evaluation. 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. Fifty percent were 'completely' or 'a lot' willing to pursue VCA. Psychosocial factors influencing decisions to pursue VCA included: regaining functionality and the associated independence; increasing social and physical confidence; and enabling more active parental involvement in childrearing. Psychosocial factors and concerns influencing decisions not to pursue VCA included: health or limb function becoming "worse off" from UE VCA; the rigorous commitment required for undergoing UE VCA and rehabilitating; and having already adapted to life without upper limb(s). Participants would ethically 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 concerns that diminish enthusiasm for UE VCA. Addressing psychosocial concerns may foster informed decision making about UE VCA.

Appendix 5:

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. Abstract presented as a poster presentation at the Military Health Systems Research Symposium (MHSRS), August 23-26, 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.[1] 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.[2,3] Individuals with UE amputations may face challenges related to engaging in activities of daily living, their physical environment, employment, social life, transportation, and more.[4] Many also experience psychosocial complications including depression, anxiety, employment challenges, social isolation, body image disturbance, and military concerns over honor.[5-7] 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.[8,9,10] 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.[11]

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 <u>not</u> 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.

Ethical Factors Impacting Patients Decisions to Pursue VCA

RT180041
W81XWH-19-2-0033

PI: Elisa Gordon, PhD, MPH **Org:** Northwestern University **Award Amount:** $721,150

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.

Timeline and Cost

Activities CY	19-20	20-21	21-22	
Prepare regulatory documents, hire and train staff				
Conduct interviews, focus groups				
Develop website, videos, QPS				
Conduct usability testing				
Estimated Budget ($K)	**$239K**	**$251K**	**$232K**	

Updated: September 29, 2021

Image source:
https://www.hopkinsmedicine.org/transplant/news_events/double_arm_transplant.html

Accomplishments: NU conducted 3 telephone focus groups and 2 semi-structured interviews. The entire team contributed to the website design and content, QPS refinement, video segmenting, MHSRS poster presentation, and AMSUS abstract submission.

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
☐ Usability testing of website
☑ Prepare manuscripts and presentations

Comments/Challenges/Issues/Concerns

- HRPO and CRADA/DSA delays study advancement at WR

Budget Expenditure to Date

Projected Expenditure: $382,017 cumulative as of 9/29/21 (Yr2)
Actual Expenditure: $366,347 cumulative as of 09/29/21