

Award Number: W81XWH-18-1-0676

AD_____

TITLE: Potential VCA Candidates, Caregivers, and
Providers Motivations, Expectations, and Shared Decision-Making in VCA

CONTRACTING ORGANIZATION:

Mayo Clinic
Rochester MN 55906-0002

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REPORT DATE: Oct 2019

TYPE OF REPORT: Annual

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

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14. ABSTRACT Our most significant finding in the last year is related to the barriers to engaging caregivers in the qualitative research process. Our recruiting has led to a number of VCA recipients and upper amputee eligible patients willing to be interviewed, but the subjects note that they do not feel that their caregiver has played enough of a role in their day-to-day activities to warrant their interest in being interviewed. We have acquired a number of provider and patient subject interviews and will continue to analyze these data as we enter year two. We have begun to consider the longitudinal nature of the care subjects receive at the time of injury and the logistical challenges of observing their decision-making process. This has led to discussions about introducing journaling for subjects in Aim 2 of the study to better understand their decision-making process and will be submitting a modification to reflect this and other ways of gathering longitudinal information that informs the values and expectations of the subjects.					
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AWARD NUMBER: W81XWH1810676
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PRINCIPAL INVESTIGATOR: Sheila Jowsey-Gregoire
CONTRACTING ORGANIZATION: Mayo Clinic
REPORT DATE: Oct. 22 2019
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1. INTRODUCTION

The Potential VCA Candidate, Caregivers and Provider's Motivations, Expectations and Shared Decision Making in VCA Study began one year ago with the aim to understand the motivations, preferences and values of individuals with upper limb loss and significant facial disfigurement who may be candidates for hand or face transplant. This research is critical to the success of the field of vascularized composite transplantation (VCA) because—although the world experience in VCA is small with only approximately 35 face transplants and 150 upper extremity transplants performed—some transplant recipients have been significantly dissatisfied with the outcome, in some cases leading to noncompliance and graft loss. Improved patient selection and communication about the risks and benefits of VCA is needed to provide this treatment option to those most suited and most likely to succeed. To this end, our study is utilizing qualitative research techniques to understand the perceptions, hopes, and expectations of upper limb loss and facially disfigured patients, their caregivers and their providers. Following completion of the qualitative discovery of themes that emerge from these interviews, we will further our investigation of strategies to improve communication between potential VCA candidates and providers in considering treatment options. We believe that improving the communication of choices, understanding the possible outcomes, and considering the potential life style and side effect profile of treatment options will facilitate decision making and improve outcomes in VCA.

2. KEYWORDS

Vascularized Composite Transplantation, qualitative research, hand and face transplantation, motivation and preferences

3. ACCOMPLISHMENTS

What were the major goals of the project?

Major Task 1

Subtask 1: Prepare Regulatory documents and Research Protocol for local and other recruitment centers.

Subtask 2: Submit the Mayo IRB approval and necessary documents for HRPO approval.

Subtask 3.1: Recruit, consent, and enroll 5 patients and caregivers with VCA.

Subtask 3.2: Recruit and consent patients with upper extremity amputations or facially disfigured patients and their caregivers who are evaluated for transplantation.

Subtask 3.3: Recruit and consent patients and caregivers who are potentially eligible for transplantation.

Subtask 4: Conduct in-depth interviews with VCA transplant patients and caregivers.

Subtask 4.1 Conduct in-depth interviews with upper extremity amputees and facially disfigured patients and their lay caregivers.

Subtask 5: Transcribe and de-identify interviews and analysis, and report interview of VCA transplant recipients and caregivers and subjects from subtasks 3.2 and 3.3.

Subtask 6: Conduct in-depth interviews of the transplant team providers.

Subtask 8: Transcribe and de-identify interviews and analysis of provider interviews.

Major Task 2: Ethnographic observation.

Major Task 3: Manuscript preparation.

What was accomplished under these goals?

Specific Aim 1 Accomplishments

Subtask 1: IRB approval was received from the Mayo Clinic and HRPO for a modification that involved self-referral (snowball sampling) of non-Mayo subjects including veteran populations and transplant recipients transplanted at other institutions. HRPO approval was obtained for the study. Modifications are pending approval with HRPO. 100% accomplished for the initial preparation of documents.

Subtask 2: IRB approval was received for the study; 100% accomplished for initial IRB and HRPO study approval.

Subtask 3.1: We have recruited 2 VCA patients and 0 caregivers (2 of 5, 40% accomplished of recipients; 0 of 5, 0% for caregivers). We anticipate consenting and interviewing more now that we have the snowball sampling for the non-Mayo patients. We have 1 pending consent with a non-Mayo transplant recipient and will continue to use snowball sampling to acquire additional subjects. Dr. Simon Talbot, Harvard University, is sharing our recruitment flyer with his transplant population.

Subtask 3.2: We have recruited and consented 1 Mayo subject and his/her caregiver (1/15 or 6% for transplant evaluated patients and 6% for caregivers). We will continue to recruit through word of mouth, self-referral, and snowball sampling. We have contacted a number of transplant providers and prosthetic centers and anticipate further recruitment of this population.

Subtask 3.3: We have recruited and consented 6 patients eligible for VCA (6/15, 40% accomplished). We have recruited and consented 2 caregivers of eligible patients (2/15, 13% accomplished).

Subtask 4: We have conducted 2 interviews with a VCA patients (40% accomplished, 0% with caregivers).

Subtask 4.1: Conduct in-depth interviews with upper extremity amputees and facially disfigured patients and their caregivers. We have conducted 1 interview with a transplant candidate and 1 interview with a caregiver (6 % accomplished, 6% for caregivers).

Subtask 4.2: We have completed 5 interviews with transplant eligible subjects (5/30 or 16% accomplished) 2 caregivers have been interviewed, 13% transplant eligible caregivers interviewed.

Subtask 5: Transcribe and de-identify interview and analysis and report on interviews.

2 recipient interviews

- 2 transcribed or 2/5
- 1 has been reviewed with the KERN and the KER team
- 1 interview has been open coded

1 candidate interview

1 candidate caregiver interview

- Both transcribed 1/15 and 1/15, 6%
- Reviewed with the KERN and the KER team
- 2 interviews have been open coded

4 “eligible” patients, 2 bilateral, 2 unilateral

2 eligible caregivers

- Four transcribed, 4/30 or 13%
- 1 patient, 1 caregiver have been open-coded

(See Appendix 1 for enrollment table)

Subtask 6: We have completed 8 in-depth provider interviews (8/12, 66% interviews accomplished).

Subtask 7: This subtask was deleted during the revision process prior to final DOD approval.

Subtask 8: Transcriptions are completed on the Mayo providers: 6 Mayo providers transcribed and 4/6 open coded. 2 Non-Mayo providers transcribed, not coded. 8/12 transcribed or 66% transcribed.

Major Task 2: Ethnographic observation will begin in year 2 (0 % completed).

Major Task 3: Manuscript preparation will begin in year 2 and 3 (0 % completed).

Aim 2: Activities will commence in Year 2

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

We have been able to provide training and professional development in the following venues: The American Transplant Congress, The National Center for Medical Rehabilitation Research (NCMRR), National Institute of Child Health and Human Development (NICHD) Limb Loss and Preservation Registry Meeting, and the International Society of Vascularized Composite Transplantation. We have recruited PhD candidate, Marisa Suchyta, to participate in recruitment as part of her research training at the Mayo Clinic.

How were the results disseminated to communities of interest?

We have utilized speaking engagements to share information, and anticipate continuing to do so in the coming year, with planned presentations at the Chauvet Workshop, the American Transplant Congress, and the American Society of Reconstructive Transplantation.

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

We will continue to recruit patients with upper extremity limb loss and facial disfigurement who may be eligible for transplantation, as well as complete our interviews with hand and face transplant patients and their caregivers and finish interviewing providers. We will begin our Aim 2 activities related to the development of a conversation aid for facilitating the discussion about treatment options including transplantation for individuals who have experienced upper extremity limb loss of severe facial disfigurement.

4. IMPACT

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

Due to the ongoing nature of the research, we believe that the impact of our findings will continue through the next two years as we analyze the qualitative data results and utilize this information to develop a conversation aid to facilitate decision making for transplant eligible individuals.

What was the impact on other disciplines?

This will occur once we have developed the conversation aid, which may result in new communication strategies for a variety of transplant team members as well as other individuals who provide care for patients with upper extremity limb loss and facial disfigurement. We have had interest from physiatrists and prosthetists about how this research could aid them in their interactions with individuals who might be interested in hand or face transplantation.

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

We changed our recruitment approach to snowball sampling, word of mouth, and self-referral due to changes in the Minneapolis Veteran Affairs willingness to serve as a site for research recruitment. We also could not reconcile our IRB requirements with the Leeds Spire NHS Trust Ethics Board requirements for recruiting patients from their hand transplant practice. We have had success in recruiting patients through word of mouth, snowball sampling and self-referral and are actively sharing information about our study with a number of groups who either provide services to potential subjects or to caregivers.

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

We anticipate the recruitment will continue to be a challenge due to the nature of the population who are often receiving care in prosthetic settings and may not be as accessible in medical settings where we have strong relationships with a number of medical providers. We also anticipate that recruitment of caregivers will continue to be a challenge. This may be related to a perception by the subjects that they are not impacted by their condition in a way that makes them reliant on caregivers. The approval process from HRPO, which was unexpectedly lengthy, delayed initiation of recruitment by snowball sampling and referral methods in recruitment which now have significantly improved our recruitment in the last few months and we expect a busy second year.

Changes that had a significant impact on expenditures.

Nothing to report.

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

Nothing to report.

Significant changes in use or care of human subjects.

Nothing to report.

Significant changes in use or care of vertebrate animal.

Nothing to report.

Significant changes in use of biohazards and/or select agents.

Nothing to report.

6. PRODUCTS

Publications, conference papers, and presentations

Publications: None

Abstracts: Abstract will be submitted the American Transplant Congress Meeting 2020, Philadelphia, PA
Title: Provider perspectives: Early results of Qualitative Research on Caregivers Perceptions in VCA

Presentations:

Session Title: Unlocking Concepts of VCA vs. Solid Organ Transplant

Presentation Title: How Qualitative Research Informs Clinical Decision Making in VCA

Date: June 5, 2019

Venue: American Transplant Congress, Boston, MA

This presentation reviewed key concepts in the role that qualitative research can play in assisting the VCA scientific community in understanding the preferences, values and motivation of affected individuals who may be interested in pursuing VCA as a treatment option.

Presentation title: Hand transplantation and presentation on the DOD Funded Research Project” Potential VCA Candidates, Caregivers and Provider’s Motivations, Expectations and Shared Decision-making in VCA”

Date: September 12, 2019

Venue: The National Center for Medical Rehabilitation Research (NCMRR), national Institute of Child Health and Human Development (NICHD) Limb Loss and Preservation Registry Meeting, Rochester MN

Presentation Title: Progress Report (Chauvet Working Group) – Psychological Aspects in VCA

Date: October 1, 2019

Venue: International Society of Vascularized Composite Allotransplantation

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

Nothing to report.

Technologies or techniques.

We are utilizing qualitative research strategies in Year 1 and anticipate the creation of a conversation aid as a result of our research plan for years 2 and 3.

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?

Name: Sheila Jowsey-Gregoire

Project Role: Principal Investigator

Researcher Identifier: orcid.org/0000-0003-2597-3987

Nearest person month worked: 2

Contribution to the Project: Planning, leading, and establishing the communication line between several organizations. Overseeing research activities and IRB submission process.

Name: Adam Miller

Project Role: Study Coordinator

Researcher Identifier:

Nearest person month worked: 3

Contribution to the Project: Under the direction of PI, followed through with several coordinating tasks to set up the trial at our site. Began recruitment of study subjects. Maintaining the study binders.

Name: Katrina Schaefer

Project Role: Research Protocol Specialist

Researcher Identifier:

Nearest person month worked: 2

Contribution to the Project: Under the direction of PI, was involved in setting up the IRB, submitting to IRB documents to HRPO and submitting modifications to the IRB and HRPO.

Name: Joan Griffin

Project Role: Co-investigator

Research identifier: orcid.org/0000-0001-8120-3229

Nearest person month worked: 1

Contribution to the project: Helped revise interview guides and the study protocol and helped to establish collaborations with VA clinicians and investigators and organizations that support veterans.

Name: Karen Schaepe

Project Role: Research Analyst

Research Identifier:

Nearest person month worked: 2

Contribution to the project: Collected background research material to facilitate the development of interview guides and developed the research interview guides. Conducted qualitative research interviews and began analyzing the transcribed interviews.

Name: Dawn Finnie

Project Role: Research analyst and Qualitative research coordinator

Research Identifier:

Nearest person month worked: 1

Contribution to the project: Assisted in the development of the interview guides and provided content to support the IRB submission process. Assisted in research analysis of qualitative research activities.

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

What other organizations were involved as partners?

None

8. SPECIAL REPORTING REQUIREMENTS

See appendix 2 for Quad Report.

9. Other achievements

Invitation to participate in the DOD funded RTRP FY19 Stakeholders Meeting in Washington DC. *This is a follow-on effort to the Request for Information that was released by the RTRP in the Spring of 2019, which solicited input regarding the most important quality of life (QoL) and psychosocial questions that need to be addressed in the field of vascularized composite allotransplantation. The intent of this meeting is to delve*

deeper into these critically important issues through discussion among stakeholders, and gather information that can be used by the program to develop a plan of action going forward.

Participation in the Chauvet Steering Group planning for Chauvet 2020, tentatively planned for May 1-2 in Bethesda Maryland with plans for a DOD Funded research symposium highlighting our currently funded research as well as the research of colleagues who have been the recipient of CDMRP Qualitative Research funding for DOD Reconstructive Transplant Research Program, Qualitative Research Award.

9. APPENDICES

Appendix 1. Enrollment Table

	Screened	Approached	Consented	Enrolled	Interviewed	Withdrew
Transplanted	4	4	2	2	2	
Transplanted Caregiver	2	0	0	0	0	
Candidate	6	5	1	1	1	
Candidate Caregiver	5	1	1	1	1	
Eligible	37	12	7	5	5	1
Eligible Caregiver	5	3	2	2	2	1
Provider	27	9	8	8	8	
Totals	86	34	21	19	19	2

Potential VCA Candidates, Caregivers and Provider’s Motivations, Expectations and Shared Decision-making in VCA

Year 1 Quarter 4

Award Number: W81XWH1810676

PI: Dr. Sheila Jowsey-Gregoire

Org: Mayo Clinic Rochester

Award Amount: \$999,284.00



Study/Product Aim(s)

- To determine, through in-depth interviews, the motivations, values, preferences, and expectations of VCA candidates and their caregivers
- To incorporate the psychosocial and situational factors from Aim 1 in a Conversation Decision Aid to support military personnel and their care teams choose the appropriate treatment choice for their upper limb amputation and/or facial disfigurement.

Approach

1. Obtain IRB approvals from our designated centers
2. Conduct interviews that will help us better understand the motivations and values of the VCA patients.
3. Use our information gathered to develop a Conversation Decision Aid to support the military VCA patients.

- *Received approval for flyer use on social media.*
- *Using the snowball sampling to help enroll.*
 - *Enrollment and interviews continue.*

Accomplishment: Place a description of the latest scientific accomplishment here. Limit the comments to three lines or less to make them fit; be succinct. These comments are valuable since they show progress.

Timeline and Cost

Activities	CY	18	19	20	21
Obtain Mayo Clinic IRB approval		█			
Obtain approval from HRPO			█		
Enroll and interview subjects, complete analysis of those interviews)				█	
Text (Major aim/study/milestone)					█
Estimated Budget (\$K)		\$80	\$306	\$000	\$000

Updated: (10/16/2019)

Goals/Milestones

CY18 Goal – Start getting Approval from IRB

Mayo IRB

CY19 Goals – Attain Approvals and enroll subjects

Obtain approval from HRPO

Start enrolling providers

Receive approval from HRPO on modification with self referral

Continue enrollment of subjects

Start the interviewing of Subjects

CY20 Goal – Get a start on AIM 2

Continue enrollment and interviewing of subjects

CY21 Goal –

Comments/Challenges/Issues/Concerns

- Balancing the approval timespan between submitting and approval.

Budget Expenditure to Date

Projected Expenditure: \$321,848

Actual Expenditure: \$199,024