

AWARD NUMBER: W81XWH-18-1-0676

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

PRINCIPAL INVESTIGATOR: Sheila Jowsey-Gregoire MD

CONTRACTING ORGANIZATION: Mayo Clinic
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PREPARED FOR: U.S. Army Medical Research and Development Command
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14. ABSTRACT Information regarding the medical, surgical, and psychological issues associated with VCA has been gathered from clinicians and patient subjects and analyzed utilizing qualitative research methods and is being curated and incorporated into the conversation aid prototype, paying particular attention to presenting the information in a patient accessible way that facilitates discussion, reflection, and decision making. An oral presentation titled <i>"The Application of the Purposeful Shared Decision-Making Schema to Hand Transplant Conversations"</i> was given at the International Conference on Communication in Healthcare by Ian Hargraves PhD to introduce this concept to the scientific community. We believe that this prototype will serve as a first-in-world structured platform for supporting clinicians, candidates, and caregivers through the hand and face transplant decision-making process. Drawing on Mayo Clinic expertise in transplant medicine and psychiatry, immunosuppressive care, shared decision making, qualitative methods, and human-centered design, we are completing an initial prototype web-based tool that facilitates candidate-clinician hand transplant decision making that addresses the upsides and downsides of VCA, potentially conflicting desires of candidates and other stakeholders, the goals of VCA, the practicalities that need to be problem-solved, and the existential significance of limb-loss and transplant.					
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PRINCIPAL INVESTIGATOR: Sheila Jowsey-Gregoire
CONTRACTING ORGANIZATION: Mayo Clinic
REPORT DATE: Oct. 27, 2022
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1. INTRODUCTION

The Potential VCA Candidate, Caregivers and Provider's Motivations, Expectations and Shared Decision Making in VCA Study began three years 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 utilized 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 emerged from these interviews, we investigated strategies, by developing a decision aid prototype, 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 lifestyle 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?

Aim 1

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 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.

Aim 2

Major Task 1

Subtask 1: Enroll subjects, providers, and caregivers from Aim 1 for Aim 2.

Subtask 2: Enroll new patients at the time of their appointments.

Subtask 3: Conduct observations of treatment or treatment follow-up discussions.

Major Task 2

Subtask 1: Synthesize the learnings from Major Task 1 and develop prototypes.

Major Task 3

Subtask 1: Begin use of prototypes.

Major Task 4

Subtask 1: Synthesize the observations of conversation aid prototypes.

Subtask 2: Begin use of the reviewed prototypes and conduct observations and brief follow-up with clinicians and patients to determine the effectiveness of the prototype.

Major Task 5: Disseminate the prototype to participating clinicians and partnering sites.

Major Task 6: Manuscript describing the conversation aid development.

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 5 VCA patients and 0 caregivers (5 of 5, 100% accomplished for recipients; 0 of 5, 0% for caregivers).

Subtask 3.2: We consented 2 Mayo subjects and a total of 3 caregivers (2/15 or 13% for transplant evaluated patients and 3/15 or 20% for caregivers). The 2 additional candidates that we attempted to contact have still not returned calls to discuss the study.

Subtask 3.3: We have recruited and consented 14 patients eligible for VCA (14/15, 93% accomplished). We have recruited and consented 6 caregivers of eligible patients (6/15, 40% accomplished).

Subtask 4.: We have conducted 5 interviews with VCA patients (100% 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 10 interviews with transplant eligible subjects (10/30 or 33% accomplished) 6 caregivers have been interviewed (6/30 or 20% transplant eligible caregivers interviewed).

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

5 recipient interviews, transcribed and fully coded

1 candidate interview, transcribed and fully coded

1 candidate caregiver interview, transcribed and fully coded

10 eligible interviews—5 bilateral, 4 unilateral, 1 face, all transcribed and coded

6 eligible caregivers, all transcribed, all open coded, level 1

Subtask 6

We have completed 18 in-depth provider interviews. In our DOD grant narrative, we planned for 12 provider interviews and have completed 12/12 (100%). We subsequently received IRB/HRPO and DOD permission to expand this group to 30 and have completed 18 interviews.

- 10 Mayo providers have been interviewed
 - a. 10 have been transcribed
 - b. 10 have been fully coded
- 8 Non-Mayo providers have been interviewed
 - a. 8 transcriptions are completed
 - b. 8 have been fully coded

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

Subtask 8: Transcription of in-depth provider interviews is completed, and analysis is completed (100 % completed).

Major Task 2: Ethnographic observation. 10/10 100 % completed for the chart review.

Major Task 3: A paper on the qualitative interview analysis of 10 subjects with limb loss has been published; a paper on the outcomes provider qualitative interviews and how this influences team function and the provision of care has been published; a case series from our retrospective review of the findings from previous transplant candidates has been submitted for publication. Copies of the published manuscripts will be attached to this report. We also have two manuscripts in preparation including one on the qualitative findings of the provider interviews and one on the development of the shared decision making (SDM) prototype.

Specific Aim 2 Major Accomplishments

Major Task 1

Subtask 1: Enroll patients from Aim 1. We have enrolled one subject, their caregiver and provider (3/12, 25%).

Subtask 2: Enroll patients at the time of their appointments with providers. We have enrolled 3 subjects, 2 caregivers and 4 providers (9/12, 75%)

Subtask 3: We have observed 4 subjects, 3 caregivers and 5 different providers (12/12, 100%).

Major Task 2

Subtask 1: Development of the conversation aid prototype is completed (100%)

Major Task 3

Subtask 1: 0% completed. This task was not completed during the funding period due to lack of available transplant candidates. We will utilize the prototype with VCA candidate subjects and their caregivers as part of our ongoing Mayo IRB approved research.

Major Task 4:

Subtask 1: 0% completed. Not completed due to the lack of VCA transplant candidates. We have Mayo IRB approval to continue this research.

Subtask 2: 0% completed. Not completed due to the lack of VCA transplant candidates. We have Mayo IRB approval to continue this research.

Subtask 3: 0% completed. Not completed due to the lack of VCA transplant candidates. We have Mayo IRB approval to continue this research.

Major Task 5: 0% completed. Not completed due to the lack of VCA transplant candidates.

Major Task 6: 0% completed. Not completed due to the lack of VCA transplant candidates.

Other Achievements

Dr. Jowsey-Gregoire presented at the American Transplant Congress 2021 IMPACT Session: Psychosocial and Bioethical Aspects of VCA: An Update on Medical Decision Making for VCA Candidates and introduced the concept of purposeful shared decision making to the transplant community. An oral presentation by Ian Hargraves, PhD, titled “*The Application of the Purposeful Shared Decision-Making Schema to Hand Transplant Conversations*” was presented at the International Conference on Communication in Healthcare, October 20, 2021. See below in the section “Presentations” for additional presentations made in the last year.

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

Due to COVID, opportunities to present at national meetings and enlist trainees have been limited. We have included Briana Sanchez, Post Baccalaureate Program and Montserrat Leon Garcia, Visiting Predoctoral Graduate student as part of our research team.

How were the results disseminated to communities of interest?

Please see section 6. PRODUCTS: Presentations and Past Presentations.

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?

Due to the ongoing nature of the research, we believe that the impact of our findings will continue through the next year as we test the prototype of the conversation aid to facilitate decision making for transplant eligible individuals. We have received funding to continue the research initiated by the DOD grant and allow field testing of the prototype (Appendix 3: Obaid Grant Award Letter). Once the testing is completed and after notifying the CDMRP about the availability of the tool and requesting their permission to allow internet access to the tool, we will make the tool available to any interested VCA transplant team.

Our papers have helped elucidate the qualitative findings on the experience of limb loss, the desire for strategies to improve quality of life in effected individuals, and the transplant team’s perspective on the provision of transplant care. We have contributed novel research findings about the impact of aging on the perspective of potential VCA candidates considering transplantation. We have analyzed the complexity of the transplant team’s ability to provide care to candidates and how team communication evolves. VCA requires multiple teams from multiple disciplines to work interdependently. Teams engage in a complex process of communication, coordination, and innovative and timely problem solving. They must maintain a high level of respect, flexibility, and confidence in each other and in the patient. Our paper on team science explores the organization of these processes and their perceived influence on patients progressing through stages for transplant. The third paper is a case series focusing on the decision-making process of previous hand transplant candidates.

Our manuscript currently in development examines perceptions on treatment choices by key provider stakeholder groups, including providers at military and veteran facilities, prosthetists, and specialized transplant centers. It explores both formal and informal approaches for assessing patient needs, suitability for treatment, and attitudes and provider beliefs about available treatment options.

We have developed a prototype of a shared decision-making aid that can facilitate the conversation between providers and candidates that is web based and can be shared between the transplant team and the transplant candidates and their caregivers. The development of the shared decision making aid will be submitted for publication as we proceed with the field testing.

What was the impact on other disciplines?

Purposeful shared decision making is emerging as a unique way to assist patients with complex multimorbid conditions to engage in determining treatment choices. Dr. Hargraves has recently received funding from the NIH to continue research in this area with other complex medically ill populations, AHRQ R01 to develop a new measure of SDM based on Purposeful SDM, and this research will build upon the knowledge attained through the development of the prototype and may result in new communication strategies for a variety of complex medical conditions. 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.

AHRQ grant is: SDMo

Current approaches to the measurement of shared decision making (SDM), a process in which patients and clinicians work together to understand the patient's problematic situation and collaboratively develop a plan of care, are inadequate in determining whether SDM occurs when a patient and clinician make a decision together. Therefore, the objectives of this proposal are to develop a theoretically-based, expert-informed, user-tested, observer-based measure of whether SDM occurs ("SDMo") and to estimate its reliability and validity. The outcome of this work (led by a team of experts in SDM who measured development, validation, and user-centered design) will enable a more accurate assessment of how often SDM is used in the care of patients with multiple chronic health conditions and, in the long-term, will improve the quality and consistency of research on SDM in this priority population.

Purposeful SDM is being used as the theoretical foundation for the new observer measure of SDM, particularly for identifying and classifying SDM behaviors observed in clinical encounters.

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

Due to the COVID pandemic, recruitment was slower than expected and participation by the VA and the military centers was not realized. We were able to recruit candidates at our institution and plan to continue this research using philanthropic funds provided by the Mayo Clinic. We continue to have an active Mayo IRB protocol for this research. Due to the small numbers of transplant candidates, our current prototype focuses on upper limb loss candidates with the plan to modify this for use with facially disfigured candidates once we have had the opportunity to field test the version for hand candidates.

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

We anticipate that future research in this area will be challenging due to the small number of subjects available for research.

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 (Appendix 5)

Finnie D, Griffin JM, Kennedy CC, Schaepe K, Boehmer K, Hargraves I, Amer H, Jowsey-Gregoire S. Education for patients with limb loss or absence: Aging, overuse concerns, and patient treatment knowledge gaps. *Front Psychol.* 2022; 13:953113 Epub 2022 Sept 27 PMID: 36237690. PMCID: 9552948. DOI: 10.3389/fpsyg.2022.953113

Griffin JM, Kennedy CC, Boehmer KR, Hargraves IG, Amer H, Jowsey-Gregoire SG. Using team science in vascularized composite allotransplantation to improve team and patient outcomes. *Front Psychol.* 2022 Sep 6;13:935507. PMID: 36148132; PMCID: PMC9486538. DOI: 10.3389/fpsyg.2022.935507

Submitted for publication: “A Single-Center Retrospective Evaluation of Decision Making and Factors Motivating Hand Transplant Candidates” has been successfully submitted online and is presently being given full consideration for publication in *Progress in Transplantation*.

Abstracts

Development of a Shared Decision Making Tool to Assist in VCA Patient Selection, presented at the American Transplant Congress, Boston MA, June 7, 2022
Presenter: Ian G. Hargraves PhD

Development of a Shared Decision Making Conversation Aid for VCA, presented at the American Society of Reconstructive Transplantation, Chicago IL, November 5, 2022
Authors: Hargraves IG, Boehmer KR, Griffin JM, Kennedy CC, Finnie DM, Amer H, Smither FC, Miller AR, Schaepe K, Montori VM, Chokkalingam A, Jowsey-Gregoire S
Presenter: Ian G. Hargraves PhD

Presentations

Presentation Title: The Application of the Purposeful Shared Decision-Making Schema to Hand Transplant Conversations

Date: October 20, 2021

Venue: International Conference on Communication in Healthcare, Virtual

Presenter: Ian G. Hargraves, PhD

Session Title: Plenary Session III – What is Needed to Ensure Sustainability of the Field/What Does Sustainability of the Field Look Like?

Presentation Title: How to Quantify Outcomes after VCA

Date: November 18, 2021

Venue, American Society of Reconstructive Transplantation Annual Meeting, Virtual

Presenter: Sheila Jowsey-Gregoire MD

Presentation Title: participation, see below.

Date: December 15-17, 2021

Venue: AboutFace Policy Lab Meeting hosted by York University and the Policy Institute, King's College London, London UK

Presenter: Dr. Jowsey-Gregoire participated in this international meeting to develop a sustainable blueprint for face transplant policy and practice and discussed the role of purpose shared decision making as a key step in ensuring the understanding of the patients and their caregivers regarding the options, impact, and implications of face transplantation.

Session Title: IMPACT Session: Psychosocial and Bioethical Aspects of VCA: An Update on Medical Decision Making for VCA Candidates

Presentation Title: Development of a Shared Decision Making Tool to Assist in VCA Patient Selection

Date: June 7, 2022

Venue: American Transplant Congress, Boston, MA

Presenter: Sheila Jowsey-Gregoire MD

In our contribution to the symposium, we introduced the concept of purposeful shared decision making to the transplant community. We discussed the work that our team conducted on how to help patients, caregivers, and their clinicians work through making the challenging decision of whether to proceed with face or hand transplant. Through human-centered design methods, we developed a digital shared decision making (SDM) tool to assist with this process. We have found that traditional SDM models are not well equipped to handle the complex issues involved in VCA decision making. We presented elements of the SDM intervention that is based on a newly expanded SDM framework that accounts for many of the concerns that need to be addressed before making a final transplant decision.

Presentation Title: Innovations in Shared Decision Making for VCA, and
Development of a Shared Decision Making Conversation Aid for VCA
Date: November 4-5, 2022
Venue: American Society of Reconstructive Transplantation, Chicago, IL
Presenter: Ian G. Hargraves, PhD

Presentation Title: Transforming Shared Decision Making in VCA
Date: January 12, 2023
Venue: FY23 RTRP In Progress Review Meeting, Virtual (Appendix 6: Presentation Slides)
Presenter: Sheila Jowsey-Gregoire, MD

Past 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.
Presenter: Sheila G. Jowsey-Gregoire, MD

Presentation Title: Hand Transplantation 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
Presenter: Sheila G. Jowsey-Gregoire, MD

Presentation Title: Progress Report (Chauvet Working Group)—Psychological Aspects in VCA
Date: October 1, 2019
Venue: International Society of Vascularized Composite Allotransplantation, New Delhi, India
Presenter: Sheila G. Jowsey-Gregoire, MD

Session Title: IMPACT Session—Psychosocial and Bioethical Aspects of VCA: An Update on Medical Decision Making for VCA Candidates
Presentation Title: Medical Decision Making for VCA Candidates
Date: June 5, 2021
Venue: American Transplant Congress, Virtual
Presenter: Sheila G. Jowsey-Gregoire, MD

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

We have developed a website link for the prototype that is available at:
<https://41bzcn.axshare.com/prototype.html>. It is in beta testing mode currently. Further modifications to the content have been made since our last quarterly report and strategies for storing the clients’ recorded responses are being developed.

Technical improvements are being made to facilitate adding or modifying content at the time of use (to build a living document that is customized to the patient), and to allow patients to access and add to content at home. We

estimate that the prototype tool is currently 100% complete. Dr. Hatem Amer, Medical Director of the Mayo Clinic VCA Program provided a final review of the content.

Technologies or techniques.

We utilized qualitative research strategies for Aim 1 analysis; for Aim 2 we developed the digital Shared Decision-Making Tool, accessible through tablets or computers, intended to be used within patient-clinician interactions, as a means of structuring those conversations by calling attention to important decisive issues in VCA decision making. It is also intended to be used by candidates or potential candidates, with or without caregivers, at home as they consider and deepen their understanding of VCA and its implications and demands. Candidate-specific important topics that come up over the extended decision-making process can be added to the tool, expanded, and reflected upon.

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:
Nearest person month worked: 6
Contribution to the Project: no change

Name: Hatem Amer
Project Role: Co-Investigator
Researcher Identifier:
Nearest person month worked: 2
Contribution to the Project: Support in writing publications for the study

Name: Adam Miller
Project Role: Study Coordinator
Researcher Identifier:
Nearest person month worked: 1
Contribution to the Project: no change

Name: Joan Griffin
Project Role: Co-Investigator
Research identifier:
Nearest person month worked: 2
Contribution to the project: no change

Name: Kasey Boehmer
 Project Role: Co-Investigator
 Researcher Identifier:
 Nearest person month worked: 6
 Contribution to the Project: no change

Name: Ian Hargraves
 Project Role: Co-Investigator
 Researcher Identifier:
 Nearest person month worked: 7
 Contribution to the Project: no change

Name: Fantley (Clay) Smither
 Project Role: Co-Investigator
 Research Identifier:
 Nearest person month worked: 2
 Contribution to the project: no change

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. APPENDICES

Appendix 1. Enrollment Table

c	Screened	Approached	Consented	Enrolled	Interviewed	Withdrew
Transplanted	11	6	5	5	5	
Transplanted Caregiver	2	0	0	0	0	
Candidate	10	9	2	1	1	
Candidate Caregiver	7	4	3	1	1	
Eligible	56	32	14	10	10	1
Eligible Caregiver	9	8	7	6	6	1
Provider	38	27	22	22	18	
Totals	133	86	53	45	41	2

Appendix 2: Year 4, Quarter 4, Quad Report

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

Year 4 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

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

- Awaiting a suitable hand candidate/s for enrollment*
- Submissions of abstracts*
- Development of the decision-making tool progresses.*

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	22
Obtain Mayo Clinic IRB approval						
Obtain approval from HRPO						
Enroll and interview subjects, complete analysis of those interviews)						
Continue to develop a prototype decision aid						
Estimated Budget (\$K)		\$80	\$306	\$710	\$749	\$999

Updated: (12/12/2022)

Goals/Milestones

CY18 Goal – Start getting Approval from IRB

CY19 Goals – Attain Approvals and enroll subjects

CY20 Goal – Continue to activate AIM 2

CY21 Goal – Continue Enrollment and develop tool

CY22 Goal

□ Development and testing of the shared decision-making intervention.

Comments/Challenges/Issues/Concerns

- Being able to connect with Military and VA population.
- Obtained a no cost extension for another year
- Have a program that can be accessed by patients outside the clinic for journaling but also accessed in clinic for the providers.

Budget Expenditure to Date

Projected Expenditure: \$999,284 (Adjusted due to NCE)

Actual Expenditure: \$996,634

Appendix 3: Obaid Grant Award Letter



Date: November 23, 2021

To: Sheila Jowsey-Gregoire, M.D.

From: Julie Heimbach, M.D., Director, Transplant Center
Michael J. Krowka, M.D., Chair, Transplant Research Committee

On behalf of the Mayo Clinic Essam and Dalal Obaid Center for Reconstructive Transplant Surgery, we are pleased to inform you that your 2021 project "Advancing the pre-surgical VCA care model" was approved to be funded as an Obaid Vascularized Composite Tissue Award.

Description of Award

- The total award including indirect expenses is: \$74,300.
- The funding will be available once the research activity is set up by development. The new activity will be set up under your PAU,94302.
- The award should be utilized within the next 24 months.

Stewardship of Award

- You are asked to recognize benefactor support of your research by including the following statement in your publications/presentations:
 - *"This work is supported by a generous gift from Tarek E. Obaid."*
- You will be asked to author a thank-you letter to the Obaid Family in the next few weeks.
- You will be asked to provide a progress report later this year to account for how the Obaid Award has helped your program achieve its goals, including any publications resulting from the funding.
- You will be asked to present at Transplant Grand Rounds on your research work related to this award.

Congratulations and thank you for applying!

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'M. J. Krowka M.D.'.

Michael J. Krowka, M.D.
Chair, Transplant Research Committee

A handwritten signature in blue ink, appearing to read 'Julie Heimbach'.

Julie Heimbach, M.D.
Director, Transplant Center

Cc: David Dingli, M.D., Ph.D.
Lori Ewoldt
Carmen Keller
Mollie Luhman
Elizabeth Stanley

Appendix 4: Accepted Abstracts

Development of a Shared Decision Making Conversation Aid for VCA, presented at the American Society of Reconstructive Transplantation, Chicago IL, November 5, 2022

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Presenter: Ian G. Hargraves PhD

Development of a Shared Decision Making Conversation Aid for VCA

Ian G. Hargraves, Ph.D., Kasey R. Boehmer Ph.D., M.P.H., Joan M. Griffin Ph.D., Cassie C. Kennedy M.D., Dawn M. Finnie, M.P.A., Hatem Amer M.D., Fantley C. Smither M.D., Adam R. Miller, Karen Schaepe Ph.D., M.P.H., Victor M. Montori M.D., M.Sc., Avudaiappan Chokkalingam M.S., M.B.A., Sheila Jowsey-Gregoire M.D.,

Background

The decision to proceed, or not, with VCA for face or hand transplant is highly complex. Patients and their caregivers require support in thinking, feeling, and talking their way through this decision. A focus on clinical evaluation does not support this need.

Shared decision making (SDM) is a process by which patients, clinicians, and caregivers together work to reach a decision that makes sense intellectually, practically, and emotionally. Conversation SDM aids can enable SDM. Our team is developing an online conversation aid for use by hand transplant patients at home and in conversations with their clinicians.

Methods

A user-centered design process was used to develop prototype versions of the conversation aid. These prototypes were informed by IRB-approved:

1. Interviews with:
 - 5 VCA transplant recipients regarding their decision making experience
 - 10 potentially eligible VCA transplant recipients regarding perceptions and expectations of VCA
 - 21 VCA clinicians regarding VCA practice and patient evaluation
2. Review of the medical records of (10) patients evaluated for VCA candidacy at an American Academic Medical Center

Results

Medical (e.g., risks of immunosuppression) and nonmedical (e.g., caregiver willingness, practical barriers to undergoing transplant) issues contribute to VCA decisions. Legacy models of SDM are ill-equipped to account for these range of issue types. Purposeful SDM, a novel theoretical model for SDM, that addresses distinct decisional issue types (pros/cons, intra/inter-personal conflicts, problematic situations, and existential matters), guided prototype development.

Conclusion

A prototype online conversation aid has been developed for field testing with patients considering hand transplant (figure).

349/350 words (figure counts as 75 of these words)



The kinds of things that we need to talk through

As we discuss the possibility of hand transplant, there are four kinds of topics that we'll return to



Your situation, problems, and the feasibility of transplant

Before making a decision we need to be sure that transplant is the right fit for your life and any problems that you are experiencing



Upsides and Downsides

There are a lot of pros and cons to transplant that need careful weighing before making a decision



People

It is important that you, those who care about you, and your care team are committed to transplant before proceeding



Meaning

We also need to consider what limb loss and transplant means for you as a person, how you see yourself, and your larger life's story

Appendix 5: Published Manuscripts

Finnie D, Griffin JM, Kennedy CC, Schaepe K, Boehmer K, Hargraves I, Amer H, Jowsey-Gregoire S. Education for patients with limb loss or absence: Aging, overuse concerns, and patient treatment knowledge gaps. *Front Psychol.* 2022; 13:953113 Epub 2022 Sept 27 PMID: 36237690. PMCID: 9552948. DOI: 10.3389/fpsyg.2022.953113

Griffin JM, Kennedy CC, Boehmer KR, Hargraves IG, Amer H, Jowsey-Gregoire SG. Using team science in vascularized composite allotransplantation to improve team and patient outcomes. *Front Psychol.* 2022 Sep 6;13:935507. PMID: 36148132; PMCID: PMC9486538. DOI: 10.3389/fpsyg.2022.935507



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Education for patients with limb loss or absence: Aging, overuse concerns, and patient treatment knowledge gaps

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The goals of vascular composite allotransplantation (VCA) for hand are to maximize functional status and psychosocial wellbeing and to improve quality of life. Candidates are carefully vetted by transplant programs through an extensive evaluation process to exclude those patients with contraindications and to select those that are most likely to attain functional or quality of life benefit from transplant. Patient choice for any treatment, however, requires that candidates be able to understand the risks, benefits, and alternatives before choosing to proceed. This study aimed to understand patients' knowledge and perceptions about treatment options for hand loss, including hand transplant. This study will be used to inform a standardized education approach and develop conversation aids for use by clinicians and patients throughout the treatment decision process. Ten individuals who had experienced hand amputation or had congenital limb loss were interviewed to better understand previous and current decisions about treatment, experiences in adjusting to their treatment, and perceptions about hand VCA. From this qualitative interview data, four findings emerged: (1) knowledge and education around VCA as a treatment option; (2) adaptation of individuals with limb loss; (3) fear of risk associated with transplantation; (4) issues of aging and overuse injuries to existing limbs. Results suggests that there is opportunity for expanding education about all treatment options for patients with new loss, long-term loss, and congenital limb loss. Establishing a baseline of knowledge about all options—prosthetics, rehabilitative strategies, and VCA—can help patients evaluate their values and goals of treatment. Issues associated with aging, including overuse and injury, and adaptability over the life course should be included in considerations about treatment choices. Data indicate the need for routinely assessing patient preferences about treatment choice so patients can plan for their future as they adapt

and age and as technology for treatments change. To assure that thorough information is provided for current and future decision-making, education about treatment choices and selection procedures for VCA should be standardized.

KEYWORDS

vascularized composite allotransplantation, education, qualitative interviews, standardized tools for evaluation, VCA

Introduction

In 2005, the worldwide prevalence of limb amputations was 1.6 million, and projections suggest that number may double by 2050 (Ziegler-Graham et al., 2008). Treatment options for upper extremity amputations include prosthesis, replantation, and vascular composite allotransplantation (VCA), with prosthesis the most common treatment option. VCA is still rare but is becoming a feasible surgical alternative to replantation and prosthesis for some amputees.

The first hand transplant was performed in 1998 (Dubernard et al., 1999). Since then, more than 113 VCA hand procedures have been performed worldwide on 76 patients, some unilateral and some bilateral (Alolabi et al., 2017). Primary goals of hand transplantation are to maximize functional status, emotional status, and quality of life. Patient selection for hand transplant is complex and requires a thorough evaluation to assess the impact, risks, and benefits for each individual and to understand if hand transplantation will improve their quality of life. Developing standardized tools for identifying, evaluating, and assessing potential candidates and standardized approaches for patient education are key to assuring that selected candidates will benefit from transplant (Kumnig et al., 2014; Jowsey-Gregoire and Kumnig, 2016).

As an alternative to replantation and prosthesis, VCA can offer the potential for better sensation outcomes than prosthetics (Pasquina et al., 2006; Schuind et al., 2007). Data from all hand transplant recipients suggests improved protective sensibility of the recipients assessed, with 91% having tactile sensibility, and 82% regaining partial two-point discrimination sensibility. This improved function enabled independent living and, for some, return to full-time occupation (Shores et al., 2017). However, in a study comparing functional and psychological outcomes of hand transplant versus prosthetic users, no significant differences were found in functional outcomes between the two, but transplant patients did have higher scores in psychological areas of “role-physical,” “vitality,” “role-emotional,” and “mental health” (Salminger et al., 2016).

While the option of VCA may provide functional, psychological, social, and even cosmetic benefits for some, there are significant risks associated with lifelong immunosuppression (Dubernard et al., 1999; Hautz et al., 2020). Challenges also exist for VCA candidates around financial burden, missed work, and insurance coverage (Chung et al., 2010; Alolabi et al., 2015, 2017). An economic analysis of hand transplants indicated hand transplant to be significantly more costly than prosthesis and concluded that a unilateral hand transplant would not be considered cost-effective (Chung et al., 2010; MacKay et al., 2014). The decision-making process for treatment options for people with amputation is a balance between weighing risks, burdens, and benefits for all treatments. Seeking to improve functionality is a universal goal across treatment choices, but the broad aspects of quality of life are less frequently assessed. Hand transplant may improve quality of life, but VCA also includes a complex set of life-long risks. Understanding the broad spectrum of quality of life issues is critical for being able to weigh the risks and benefits. Patient satisfaction, for example, is one aspect of quality of life that is significantly related to function (Hautz et al., 2020), but other aspects, such as psychosocial function, wellbeing, and meaning making, are less commonly assessed. Bahler (2019) has commented on factors essential to quality of life that are currently not included in most patient assessments: “...our capacity to make meaning, particularly in relation to temporality, embodiment, and intersubjectivity. Without attention to these features of the human condition, assessment of hand transplant recipients’ functional capacity and psychological sense of satisfaction will remain incomplete” (Bahler, 2019).

With the expected increase in prevalence of limb loss and the complexity of risks and benefits for treatment options, data are needed to inform the development of standardized tools to assess a broad set of quality of life factors and develop patient education materials that can promote shared decision making. In this study, we aim to fill this gap by utilizing qualitative research methods to better understand the values, attitudes, and expectations of treatment for people with limb loss that may be associated with future quality of life and address patient education needs.

Materials and methods

Study design

To understand factors integral to treatment decision-making and education for potential VCA-eligible individuals (age range = 38–72), we conducted semi-structured interviews between March 2019 and March 2021 with ten individuals with upper extremity loss who were potentially eligible for upper limb transplantation. Interviews were conducted with participants from a variety of backgrounds, and great variation in their path to extremity loss, including congenital loss, active-duty military loss, and loss due to hospital-acquired sepsis.

Source of participants

Purposeful sampling was initially used to identify participants through medical record review of patients with limb absence. Snowball sampling was used for further recruitment as was outreach to amputee advocacy organizations. Participants were contacted *via* recruitment letter or email by the study coordinator to explain the study purpose and request participation. If no response to the initial contact was received, a follow-up contact was made. A study coordinator contacted interested participants to schedule interviews with one of three interviewers (KS, JG, and DF). Interviewers included two experienced Ph.D. trained qualitative researchers and one experienced Master's degree trained qualitative researcher. Recruitment and data collection concluded when thematic saturation was reached.

Source of data

The semi-structured interview guide was created to capture the lived experience of individuals with limb absence, quality of life, and how they approach healthcare decisions. It included questions on how they came to have an upper limb extremity loss, discussed their life without an upper limb(s), their experience or knowledge of prosthetics, and thoughts and interest around hand transplantation. The guide was iteratively adjusted to fit each individual's unique situation and to gather the most detailed and pertinent data from each participant. For example, questions were modified to capture the lived experience of an individual with congenital limb loss and modified again for a person with a military injury resulting in limb loss, as the treatment options and decision-making process may also be different.

All interviews were digitally recorded, transcribed verbatim, and de-identified (removing names and other identifiable

features). Recorded interviews were stored on a secure server for analysis in Nvivo (Qi Li Group Pty Ltd, 2020).

Data analytic approach

The qualitative research team (DF and JG) reviewed each transcript as they became available and listened to the interview audios. They independently read the interviews multiple times and listened to the audios to become immersed in the data. Initial key concepts were captured from the data and supported by the interpretive qualitative framework of medical anthropology (Lambert and McKeivitt, 2002; Bernard, 2011), emphasizing the lived experience of individuals through the narrative they share about their healthcare journey. Interviews were semi-structured but allowed for flexibility to probe new or emerging issues.

Descriptive coding of interview transcripts ran concurrently with data collection, consistent with iterative thematic analysis (Corbin and Strauss, 2015). After each new interview, DF, a qualitative research analyst, and JG, a health services researcher, with qualitative and mixed methods expertise, independently read and analyzed each transcript and met regularly to reflect on the data and discuss the concepts, themes, and codes. With the review of each transcript and constant comparison across transcripts, a deeper understanding of the themes was reached. Concurrent analysis with data collection allowed for iterative interaction between data and analysis in order to enhance reliability (Morse et al., 2002). Codes and themes were then organized and analyzed through interpretive thematic analysis (Corbin and Strauss, 2008), and each transcript was entered into Nvivo. Data were organized by code and theme.

We concluded data collection after ten interviews because no new themes emerged.

Results

As shown in Table 1, three women and seven men, ranging in ages from 38 to 72 were interviewed. Participants were individuals with varying amounts of time since initial extremity loss, from 1 to 64 years. Five had unilateral limb loss and five had bilateral limb loss. None were VCA recipients.

As common concepts and ideas emerged through the interview and coding process, four themes were identified: (1) awareness and knowledge of transplantation; (2) aging with amputation and/or VCA and overuse and injuries of existing limbs; (3) fear of risk associated with transplantation; and (4) contentment and adaptability to limb absence in long-term amputees. Themes included factors impacting knowledge about VCA and treatment decision making. Each subsequent interview helped to explore more depth into initial themes.

TABLE 1 Hand absence interview demographics.

	Gender	Age (years)	Years with amputation	Cause of extremity loss
1	F	64	4	Sepsis/bilateral.
2	M	50	22	Work injury/unilateral.
3	M	64	64	Congenital/partial bilateral.
4	M	38	2	Infection/bilateral.
5	M	65	40	Farm accident.
6	M	71	15	Arm shot off in active duty and reattached.
7	M	49	49 (additional wrist amputation 2 years)	Born without hand but had a bit of wrist. Two years ago, had squamous cell cancer and removed wrist.
8	F	72	1	Sepsis-bilateral. Lost all toes.
9	F	67	64	Gunshot accident as a child. Arm amputated about 1" below elbow.
10	M	59	1	Skin cancer. Amputation of both arms. Skin cancer removed from ear, face, back.

Adaptability to limb absence

Participants living successfully with upper extremity loss/absence identified ways they have adapted their jobs, hobbies, and lives, and continue to adapt as they age.

These individuals have been living successfully with various forms of prosthetics and have adapted their routines. Participants living for longer than 15 years ($n = 6$) with an upper extremity absence also noted that they had adapted their lives to incorporate their limb loss. They had completed education and degrees, changed careers and started businesses, incorporated adaptations to their hobbies and outside activities, maintained family and social relationships, and spoke about their resilience and adaptability as assets. Interestingly, none of the participants interviewed referred to themselves as disabled or handicapped, and some rejected the terms when used in reference to themselves.

"...you know, if you've maybe got just a couple of fingers, there have been many times I wish I had just one finger on the end of my arm, just one, to be able to do something. That's a frustration of mine. They're saying, 'Well don't you want the whole hand?' Not necessarily. The way I do things now, a lot of times, all I need is that one damn finger." (male, 64, congenital loss of one arm).

"Yeah. I've got stuff. I mean we go kayaking. I got stuff to hold the paddle. I've got stuff for the ATV. I got some things that hold guns when I shoot that will hold the forearm. Yeah cause that's what I do at work. So once in a while, I'll make something that I

can't buy somewhere, and I'll just make my own, you know. Like even for like when we go deer - for cleaning deer, I got one with a knife on the end I can hold and skin it, you know, and stuff - just weird, different - I got one of the big vice grips so I can clamp things and heat 'em with a torch, just different things." (male, 65, lost hand 40 years prior in farming accident).

"I learned how to put screws in my cutting board, put the chicken on it, and that holds it. I have attachments to open bottles with if I need to. I have a one-handed syringe with the CO2 to open a wine bottle, everything adaptive." (male, 71, arm shot off in active duty 15 years prior and reattached).

"I do mechanic work my whole life. I was born without my hand originally. So, I guess I've learned to adapt very well. I did have a prosthetic when I was younger and grew up through the Shriners. But then, as I got older and started to do more, I found - I was very fortunate I had the left arm all the way down, including the wrist. So, milking cows, driving equipment and stuff, I found that I could do better without the prosthetic just because I had the skin, I had the length, I could reach and do everything. I could balance the milkers better. I could drive the equipment better without the big rigid hook being in the way. I know technology has changed, obviously, quite a bit in 30 years [laughs]." (male, 49, congenital hand, additional wrist amputation 2 years prior due to cancer).

"I've gotten so used to living without my arm, my prosthesis almost gets in the way. It almost gets in the way because I've learned how to do so much in my armpit and holding my stump down and all kinds of stuff. . . I've learned how to do stuff so much without my arm, now my arm is like - I'm learning how to re-use my arm and keep it out of the way. When I need it, I need it. I haven't needed it for nothing yet." (male, 59, skin cancer led to arm amputation one year prior).

Lack of awareness or knowledge of vascular composite allotransplantation as an option

Participants' knowledge about upper limb transplantation was varied. Some were aware of cases of upper extremity transplantation but had little knowledge about details of eligibility. Some had an understanding the risk and benefits but did not consider it an option for themselves due to age or the burden of immunosuppression. Some had no knowledge at all. Some variation in knowledge was attributed to time since amputation. Participants that were either born without a limb or lost a limb as a child ($n = 3$) (current ages 64, 49, 67) and prior to the advent of VCA, for example, considered themselves adapted to their circumstances. Their discussions about transplantation suggested that they had some knowledge about hand transplantation but had not taken time to investigate transplant as an option for themselves because they did not see it as relevant to their situation.

Participants suggested that the challenges associated with insurance coverage for treatment or loss of work due to time needed for rehabilitation and recovery was also a concern with any treatment and may contribute to a lack of seeking information about transplant. Communicating with insurance for coverage of prosthetics was identified as an ongoing challenge and worry about insurance coverage for any treatment was discussed. For individuals that see themselves as productive and capable, the loss of work time and rehabilitation burden on family was also identified as a transplant consideration.

“... it takes me back to when people would come to the bedside to talk to me about, ‘Wanna transplant this, wanna transplant that, and we can take your thumb, and we can take your fingers, and we can take ligaments from the other side,’ you know all these conversations. And anybody else that came into the room was speaking the same language as they were. And I wanted to hear an advocate for the prosthetics, when that was a possible action, and an advocate for all the other options, not somebody who was presenting [all] the options under the umbrella of the one choice...” (male, 71, arm shot off in active duty 15 years prior and reattached).

“I guess this is all a part of like, making the justification for me to get a better hand or arm, and I guess we just have to keep doing this and going through these processes and adjusting what I have so the insurance will see that we’ve tried because I - I guess there are arms out there now that you can control grasp. I’ve seen it online - stuff where they actually do implants where they can implant sensors into your arm so like if you open a hand or close a hand or move your index finger, you could do all of that with a prosthetic. So, like I guess if it were ever to get that advanced, and my insurance would pay for it. . . I’ve been denied everything, and it was like jumping through hoops just to get me that myoelectric arm that I have. . . Everything’s been just so hard.” (male, 38, bilateral loss to infection 2 years prior).

Aging of patient and caregivers and overuse injury worries

When asked about concerns participants had about transplantation, participants organically shared their worries about their age or about aging. They voiced concerns about their own aging and their caregivers aging. With over half the study participants being over the age of 60, many expressed they felt the complexity of the VCA surgery, the recovery time, and the risks associated with lifelong immunosuppression were too much for them at their current age. Three individuals, however, felt they may have considered transplantation if they were younger. Fears of growing older, overuse injuries, and aging primary caregivers are also prevalent.

“I guess the only thing is the fear of aging. Right now, I’m able to do this stuff, and I have a husband who’s gonna do this stuff. But what happens when he can’t or isn’t around. As I get older,

I’m not sure - now I’ve certainly thought a lot about it and looked at a few different things, and my mother is gonna be 90 next year, and she and I have been visiting some senior care facilities, and that’s probably where I’ll end up. But it’s still very unnerving where really, up until this happened, I wasn’t that scared of retiring or even living in a senior facility. But now I’m like well - somebody else is gonna have to dress me and help me and all - do all that stuff.” (female, 64, sepsis, bilateral 4 years prior).

“Missing the limb, yep. . . I’m 50 now, and the thing I gotta think about is I don’t wanna wear this one out. My biggest fear is I tear a rotator cuff and then your arm is immobilized for three months, and who knows what the outcome is gonna be. What do I got to use?” (male, 50, accident - lost limb at age 28).

“If they actually get to the point where they are doing transplants, if it’s not an issue and insurance covers it, I definitely would get on the list. I’d be interested in doing it. I’d check it out just because thinking down the road, you know, like when I get older and I’m not as active or as strong as I am now, life’s probably gonna get a little harder... That’s the only thing that I really think of is just when I get older and if I’m gonna be able to do the things that I’ve learned or that I’m able to do now.” (male, 38, bilateral lost to infection 2 years prior).

“It’s just it eventually comes up—‘Okay, I’m getting carpal tunnel.’ I go, ‘Gee, imagine that. Only have one hand and you type all day. What do you think you’re going to get?’ Well, part of it being, you have to look at my age. Do I need something that’s that complicated at this stage in my life? So, that’s how I looked at it. Now, had I been 30 years old, that would have been a whole different ball game, you know?” (female, 67, gunshot accident as a child).

Perceptions of risks and benefits of vascular composite allotransplantation

Participants described added functional use and dexterity as possible benefits of hand transplantation, but also specified that they would only consider VCA if the function was above and beyond the function gained from their current state or with current prosthetics. Some valued the potential for sensation which can only be gained with VCA, including the greater ability to express emotion and care for others (e.g., hugging their grandchildren). Others described the benefits of social perceptions of having a hand, including looking “normal.” Participants also voiced concern about having the transplant rejected and the potential suffering of having to go through amputation again.

“And it’s like I can’t imagine being able to do most things for myself to go back to being bedridden and needing all that help from everyone until you can actually use your arms” (male, 38, bilateral lost to infection 2 years prior).

“I mean when you’ve been through the rejections stuff and, basically, the therapy and how long it would take to recover,

that was probably the biggest thing for me, where they're talking, and you could be down for a year just trying to let it heal and rehabilitate. I have a young daughter. I'm not going to be out of anything for a year. That can't happen. I mean I've got to be there for her, and that's the #1 thing I'm going to do, and I can't walk away from my farm" (male, 49, congenital hand, add'l wrist amputation 2 years prior due to cancer).

"Do you want to do this for the rest of your life? And what happens if—I mean I don't know much about this immunosuppressant-type drugs or anything like that; but if you have to take them for the rest of your life, what happens if you can't take them for the rest of your life? Does your hand fall off?" (female, 67, gunshot accident as a child).

Discussion

In this qualitative study of people living with limb loss, participants had adapted to their loss, finding creative ways to modify their activities of daily living and reducing their reliance on others to assist. They discussed their adaptations using prostheses and their knowledge about different treatment options, including VCA. They had variable degrees of seeking out knowledge about VCA and its requirements. We found that some participants had not explored other treatment options, such as VCA, because of concerns about financial burden or lack of insurance coverage. Our findings are consistent with Talbot et al. (2019) who found that adjustment to amputation (limb loss) was inversely related to an interest in transplantation and concluded this may help explain the difficulty in identifying and selecting candidates for VCA. One possible solution for addressing concerns about financial burden or insurance coverage is to have clearer communication early in the evaluation or treatment process about financial burdens and what insurance will and will not cover. This communication should include all options, including VCA and prosthetics, so fully informed decisions can be made.

Our data indicate that there is worry and concern around aging as well as overuse and injury of existing limbs. Other studies have also shown issues related to overuse injury in the population of people with amputation (Jones and Davidson, 1999; Burger and Vidmar, 2016; Cancio et al., 2021), however, our study adds to this literature by addressing how VCA is perceived in relation to issues of aging and overuse. Future research should explore how incorporating issues of aging and overuse into shared decision making about treatment choices and throughout the healthcare journey affects patient satisfaction and quality of life.

This study identifies the need for ongoing education throughout the healthcare journey of individuals with limb absence. Throughout their lives, as needs change with age,

injury, and caregiver access, there needs to be changing and adapting education provided to facilitate decision-making. Clinically, healthcare providers can routinely incorporate information about healthcare options and the self-care needed to maintain their treatment choice. Discussing overuse injuries, aging for themselves, and aging of caregivers should begin early, even if the individual is not actively considering transplantation. Included in education should be information for patients that considers adaptations to their limb absence and how those adaptations may be impacted by aging or overuse. Opportunities may also exist for education and mentoring for individuals eligible for upper extremity transplantation. Peer mentorship of new amputees may help individuals see the potential for having productive and capable lives, regardless of treatment option chosen. These conversations may also include topics such as loss of work time and rehabilitation burden on family that some may or may not consider when discussing treatment options.

With increased attention on the importance of standardized evaluation for amputees and VCA recipients, our results also suggest that routine assessment of quality of life for treatment options may be useful. Ability to adapt and contentment of current treatment option are additional factors that may be especially important in this population and may impact decision-making and help to capture concerns about aging and overuse. Furthermore, to assure that thorough information is provided for current and future decision-making, education about treatment choices should be standardized. Routine standardized psychosocial assessment and education should support current and future decision-making about treatment choices, including VCA, for all individuals with limb loss.

Limitations

Noted limitations for this study are its small sample size, which is typical of some qualitative interview studies, especially in unique populations such as this convenience sample of individuals that are difficult to find and recruit from the general population. Nonetheless, this sample of ten participants represents unique perspectives from a broad range of amputees that can be considered experts on their own healthcare needs and decision making; and the goal of this study was discovery of new information, which can be achieved through small sample size. Future studies that ethnographically capture the changes and trajectory of quality-of-life issues over time or the impact of educational interventions to reduce ambiguity of treatment decision choices would be important next steps for understanding the interconnectedness of treatment choice, selection criteria, assessment of psychosocial health and quality of life and patient functional outcomes.

Conclusion

Although VCA may be a life-changing option for individuals with loss of an upper extremity, this study highlights individuals who have lived with upper extremity loss for an extended period of time and have adapted their lives around their limb absence as well as individuals who are older and may be less motivated or less interested in limb transplantation. It also indicates the low level of VCA knowledge among these individuals. Lack of awareness and knowledge for this study population indicates an opportunity for education about transplantation earlier. With an increased need to develop evidence-based standardized protocols to evaluate hand transplant candidates, this study suggests the need to include in standardized evaluation: assessment of knowledge base; concerns and insight around aging for amputees; and evaluation of those highly adapted individuals who may be content in their life and may not consider their quality of life improved with a hand transplant. This study identifies the need for ongoing education throughout the healthcare journey of individuals with limb absence. Throughout their lives, as needs change with age, injury, and caregiver access, education should be adapted to support individuals' decision making around VCA and other treatment options.

Data availability statement

The datasets presented in this article are not readily available. Due to the nature of this qualitative study, the participants are recruited from a small population sample. De-identified transcripts may contain contextual information on the participant, their lived experience, and their care that could be inadvertently identifiable. To protect these human subjects, these datasets will not be made available. Requests regarding the datasets should be directed to DW, finnie.dawn@mayo.edu.

Ethics statement

The studies involving human participants were reviewed and approved by Mayo Clinic IRB. The patients/participants provided their written informed consent to participate in this study.

Author contributions

KS, DF, and JG collected the interview data. JG and DF performed the qualitative analysis. DF wrote the first draft of the manuscript. JG wrote sections of the manuscript. All authors contributed to conception and design of the study and manuscript revision, read, and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Using team science in vascularized composite allotransplantation to improve team and patient outcomes

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Reconstructive allografts using Vascularized Composite Allotransplantation (VCA) are providing individuals living with upper limb loss and facial disfigurement with new opportunities for a sensate, esthetically acceptable, and functional alternative to current treatment strategies. Important research attention is being paid to how best to assess and screen candidates for VCA, measure optimal patient outcomes, and support patient adherence to lifelong behaviors and medical regimens. Far less attention, however, has been dedicated to the team science required for these complex VCA teams to form, prepare, and provide the highest quality clinical and psychosocial care to those receiving VCA. VCA teams are unique in that they require specialized team members whose scope of practice may not otherwise overlap. The team also needs to constantly negotiate balancing patient safety with multiple risks throughout the transplant process. This study aimed to elucidate the team science needed for this highly innovative and complex area of medicine. Using in-depth qualitative interviews with 14 VCA team members and observations at team meetings, we found that careful consideration of team composition, team structure, and organizational commitment (e.g., local culture and team values; investment of resources) influences team performance and patient outcomes, but that to be efficient and truly effective, teams need to commit to developing processes that foster collaboration. These processes are action-oriented (e.g., communication, leadership), strategic (e.g., planning, training) and interpersonal (e.g., conflict management, trust building). Dedication and commitment to team science allows teams to manage conflict under stress and exercise ways to leverage

strengths to provide optimal performance or patient psychosocial and clinical outcomes. This study can provide insight into quality improvement efforts for VCA teams and guidance for other transplant programs that wish to consider expansion into VCA.

KEYWORDS

vascularized composite allograft (VCA), team science, qualitative study, case study, transplant

Introduction

The first reported hand transplantation was performed in Lyon, France in 1998 (Dubernard et al., 1999). Since then, more than 120 hand transplants in 76 patients and 37 face transplants have been performed, with reasonable functional and esthetic outcomes for optimally selected patients (Thuong et al., 2019). These reconstructive transplants, using Vascularized Composite Allografts (VCA), are providing some persons living with upper limb amputation and facial disfigurement with new opportunities for a sensate, esthetically acceptable, and functional alternative to current treatment strategies (Kaufman et al., 2019). With advances in immunosuppression, surgical and medical techniques, and technology, these transplants while complex and associated with long term risks of immunosuppressive medications, are no longer considered experimental, but feasible. The field, therefore, is at a juncture. These procedures are possible, but they are not yet part of the standard options routinely presented to eligible patients. The psychosocial and ethical challenges associated with VCA and how those challenges are translated into VCA care models and treatment standards are persistent questions. These challenges include how best to identify and select ideal candidates, communicate short- and long-term consequences, support short- and long-term rehabilitation goals, and define and attain optimal clinical and psychosocial outcomes. To optimize patient outcomes and satisfy requirements likely needed for insurance coverage and regulatory needs, clear methods to overcome these challenges are required. Further, these strategies must be considered within the ethical context and assumptions of VCA improving quality of life, not, like other transplants, to save or sustain life (Caplan et al., 2019).

With VCA opportunities still limited to relatively few academic health centers—18 hand and 17 face transplant programs as of 2019—much of the research to fill these gaps is underway with the highly specialized teams that currently have VCA programs (Henderson, 2019). One important area of inquiry with less attention, however, is the team science required to form these complex, transdisciplinary VCA teams and programs that develop and shape models of care and influence the local approach to transplant. Cultural understanding of these highly specialized teams is important, as it is a shaping factor in the ways in which patient-level concerns and challenges noted above are met. Such an understanding can provide insight as

other transplant programs consider expansion into VCA and more generally, to advance the understanding of barriers and facilitators required for transdisciplinary teams practicing in highly innovative and complex areas of medicine, areas where the benefits for a patient's quality of life needs to be constantly evaluated with safety and risks.

We interviewed healthcare providers as part of a larger study aimed at understanding the values, attitudes, and expectations of treatment for people with facial disfigurement and upper extremity limb loss. These members of the healthcare team were engaged in discussions about possible treatment options, candidate selection, VCA preparation, surgery, patient recovery and rehabilitation, and in VCA team meetings. One major theme that emerged in the interviews was consistent with definitions of team science: how team members organically formed and came to work collaboratively toward a common goal of establishing a VCA center and providing optimal outcomes for patients. Using a case study approach, we examined this “team science” theme.

Materials and methods

Study case

This study uses a qualitative case study methodology. Yin (2003) defines a case study as an empirical research activity that examines a specific situation within a real-life context. Case studies typically include a limited number of informed individuals with detailed understanding of the case or the context of the case. Qualitative methods for team science have been endorsed because they allow for identification of essential factors, a close proximity to processes (Yin, 2003). When conducted with teams in extreme settings or exceptional circumstances, such as VCA, they provide in-depth findings that can inform other teams in similar circumstances on models of best practice (Solis et al., 2016).

For this case we focused on a VCA team that has successfully completed one VCA transplant, but is actively assessing potential candidates for future procedures.

Study design

From March 2019 to March 2021, we conducted 14 unstructured interviews with the transdisciplinary team

that included surgeons, transplant physicians, a psychiatrist, transplant nurse coordinator, social worker, ethicist, and prosthetists. This study was approved as minimal risk by the Institutional Review Board (IRB 18-006889) and oral consent was obtained from all study participants.

Source of participants

We used a purposeful “maximum variation” sampling strategy to capture differences between providers (Patton, 2002). Figure 2 shows the composition of the VCA team. Spheres in green represent clinical team members, and spheres in blue represent institutional or administrative team members. Representatives from each of the clinical team spheres were included in interviews.

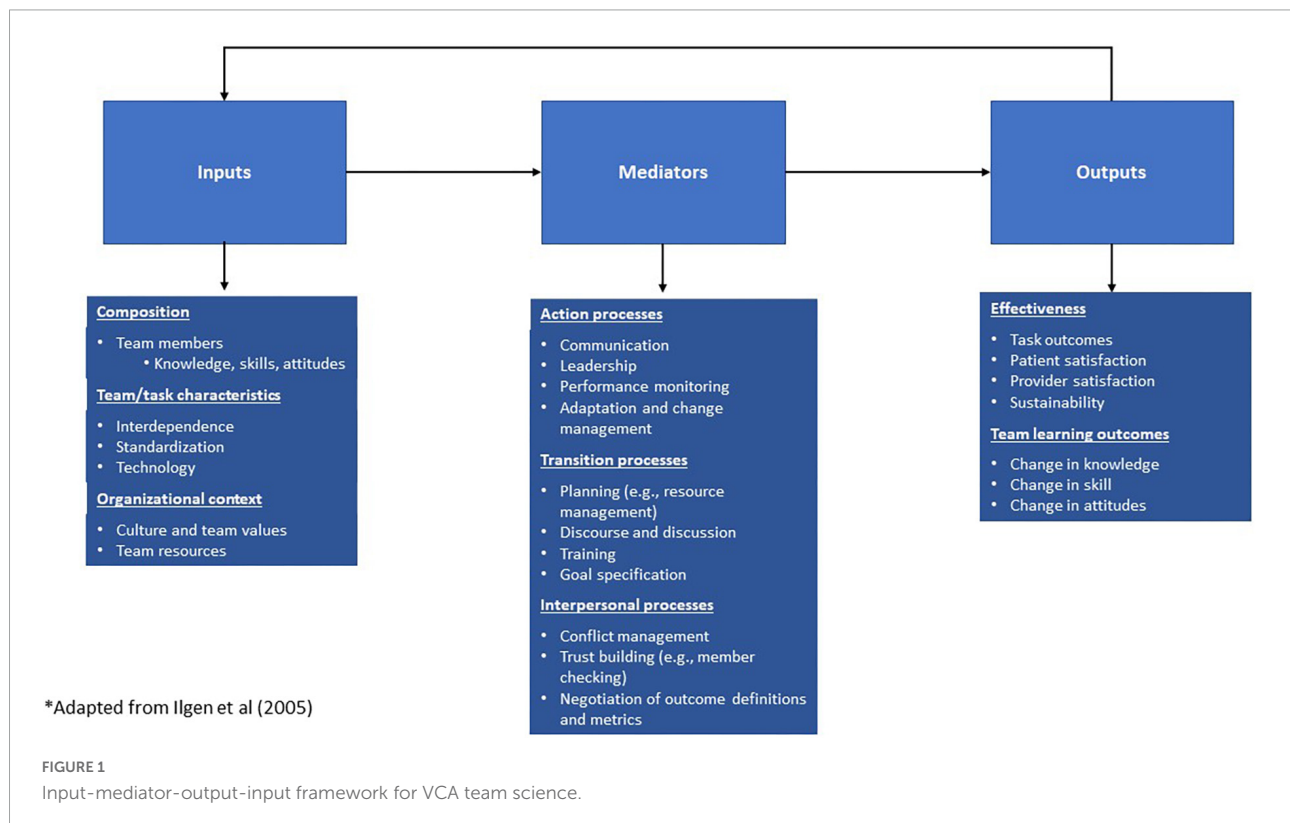
VCA team leaders representing the surgical team, transplant team and bioethics (indicated by the overlapping green spheres at the center in Figure 2), were interviewed. They identified additional key stakeholders for interviews from other spheres. These included physicians and nurses, social workers, physical therapists, transplant coordinators, and prosthetists and prostheses fitters involved in the VCA team. Names and contact information for additional key stakeholders were obtained through the VCA team leadership and through snowball sampling. Participants were contacted by either the study coordinator or the principal investigator *via* email to explain the study purpose, consent script, and to request participation. If no response to the initial email was received,

one additional follow-up email was sent. A study coordinator contacted interested providers to schedule interviews with one of two interviewers. Both interviewers were experienced Ph.D. trained researchers who had not previously worked with any of the providers. All team members approached ($n = 14$) agreed to be interviewed and completed interviews. Recruitment continued until saturation of information on treatment options, candidate selection, and VCA preparation.

Source of data

The interview guide was initially unstructured, but aimed to understand the team’s interactions and perspectives on VCA education, candidate selection, and once a candidate was listed, the pre- and post-VCA preparation and treatment discussions with patients and families. With every subsequent interview, the guide was modified to become semi-structured, and reflected new areas of inquiry or greater concentration on topics that were emerging as critical points for understanding. For example, with little prompting, those interviewed early in the process discussed at length the importance of collaboration and the development of the study team as it related to patient education and outcomes. Probes about team science, therefore, were integrated into the interview guide over time.

All interviews were digitally recorded and transcribed verbatim and then de-identified (removing names and other identifiable features). After each interview, case-based memos were created that captured ideas and compared accounts



with other participants. Recorded interviews were transcribed verbatim and stored on a secure server for analysis in NVivo (2020).

For team meeting observations, qualitative analysts attended meetings and took notes. Notes were uploaded into Nvivo for analysis. Meetings included 63 invited team members, with attendance varying depending on the case and agenda.

Data analytic approach

The research team used a three-phased thematic content analysis to understand provider attitudes, beliefs, and experiences about the VCA process (Patton, 2002;

Bradley et al., 2007). First, three research team members (JG, KS, and CK) independently read the interviews multiple times to become immersed in the data and then began an initial set of codes that captured key concepts from the data (e.g., team collaboration). Second, JG, a health services researcher with qualitative and mixed methods expertise, and CK, a solid organ transplant physician with qualitative research experience, further analyzed the transcripts, met regularly to expand, and refine code development, and create definitions for each code. With the review of each subsequent transcript, codes were refined (e.g., defining roles, coordination, program investment) to reflect a deeper understanding of the team

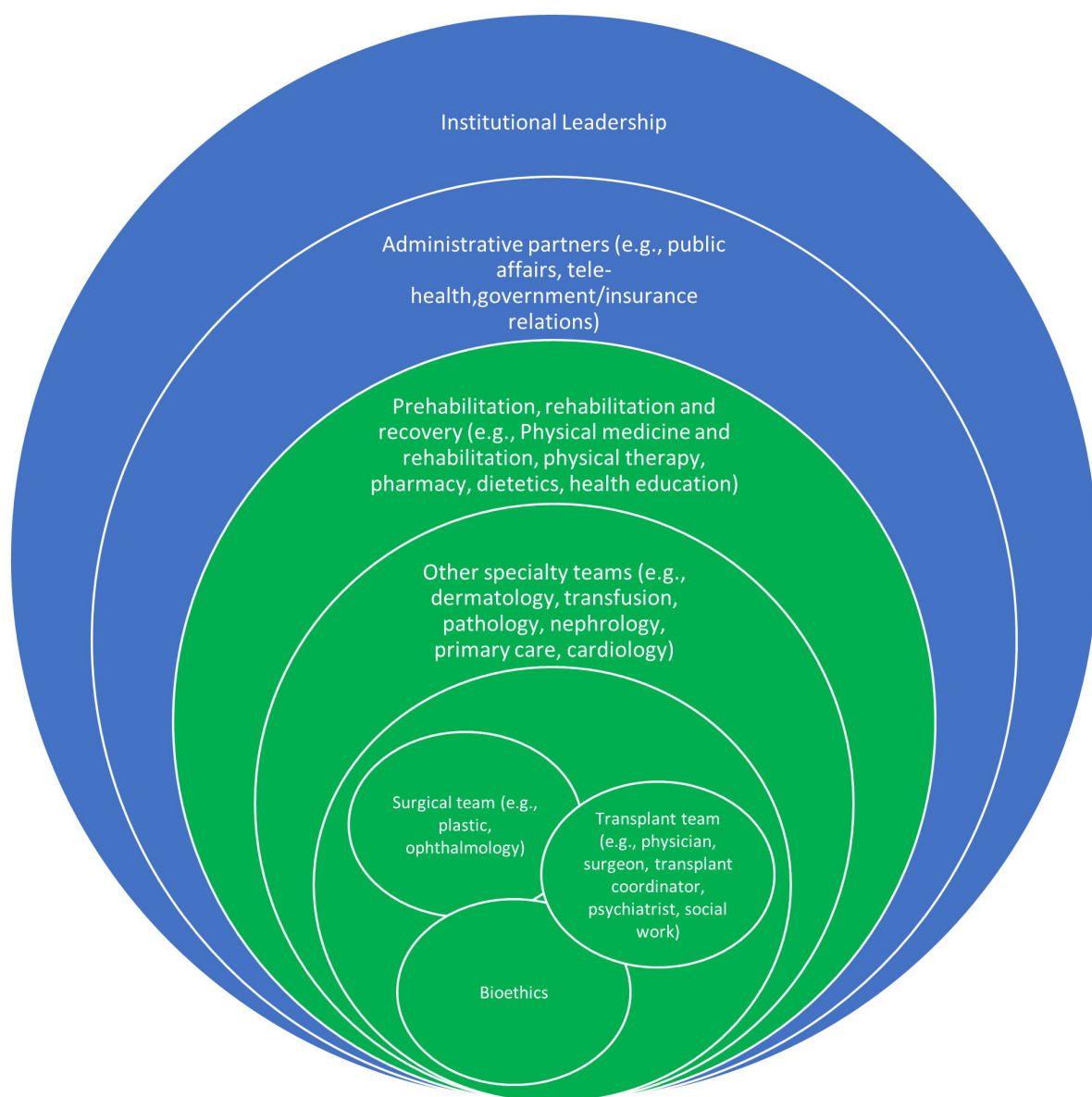


FIGURE 2
VCA team composition.

science theme. Coding decisions were developed by consensus and documented to provide a clear audit trail on the origin of the codes. After finalizing the code book, JG and CK then coded each transcript and applied codes line by line back to the transcripts. Third, codes were then organized into sets of codes specific to team science and analyzed for relationships across that set of codes.

Results

One major theme across interviews and observation data was how providers worked together to develop and create an environment to promote successful outcomes when stakes are high, and surgeries are infrequent. As shown in [Figure 1](#), we coded this theme as “team science” and as we analyzed sub-codes, we recognized the alignment of our subcodes with the constructs from the Input-Mediator-Output-Input framework, the dominant framework in team science that describes dynamic, causal relationships. It details affective, cognitive, and behavioral processes that affect team performance, where inputs and mediators explain variability in team output and viability, and output, in turn, affects the next iteration of inputs ([Ilgen et al., 2005](#)). Using this framework assists in helping to better understand the team’s experiences and their intentional and unintentional strategies that form the transdisciplinary team and refine team processes for VCA transplants.

Inputs

Inputs included team organizational commitment (e.g., local culture and team values; investment of resources), team structure, and composition, all of which are considered to influence team performance and patient outcomes. Participants described teams by their level of engagement and their unique skills. More often, participants described their role on the “teamlet” ([Bodenheimer and Willard-Grace, 2016](#)) or the smaller core teams. There was a deep understanding, however, that the teamlet was part of a larger integrated team and a commitment to that team. Participants considered their organization’s cultural values as a key element of how and why the team formed. Institutional and departmental leadership financially invested in developing and sustaining the program, encouraged learning from existing external programs, provided resources that allowed for leaders in transplant and plastic surgery—teams that typically do not share cases—to collaborate and initiate a new model of care. [Figure 2](#) is a synthesis of team roles and the described levels of team participation, with the inner circle having primary leadership roles, greatest number of responsibilities, and most interdependence.

The VCA team was led by transplant and surgical leaders who drew from existing teams and resources. Notably, the VCA program did not maintain any personnel whose sole

employment duties pertained to the VCA program. Salary and benefits were maintained by their primary position and a proportion of their time and expertise was allotted to the VCA program. Further, the VCA team used space in an established solid organ transplant center. Thus, the VCA program did not require infrastructure funds at its inception.

The team members entered the VCA program with established training and expertise in their field and adapted this experience to serve the VCA program. Some of the team members worked in multidisciplinary solid organ transplant teams but many were new to transplantation. Team members without transplant experience reported seeking out workshops or shadowing opportunities elsewhere to build familiarity with transplant practice. Similarly, team members with transplant backgrounds sought opportunities to understand the needs of patients cared for by the reconstructive surgery practices.

Team composition evolved with purpose over time. Leaders chose members for their teamlets based on previous experience, knowledge about transplant or surgical processes, and team members were added as needs emerged. For example, bioethicists were brought on early to help dissect ethical issues of offering non-life saving transplants, navigate candidate selection issues (e.g., ethics of offering bilateral vs. unilateral hand transplantation), and as additional selection and evaluation issues emerged, the bioethicists were integral members of the core VCA team.

“The transplant center has an integrated transplant practice, and although all are solid organs or BMT [bone marrow transplant], they are under the same roof, so we should try to merge those [areas of expertise] together’. . . And if you look at it, you need surgeons to be able to do the procedures. You need physical therapy, like a hand therapist, and we need physiatry because physiatry helps with the rehabilitation. Then you have the amputee clinic because the amputee clinic manages individuals who are amputees, so their expertise was important. . . So what you’re doing there is trying to make sure that, for the normal entities that take care of a particular population, you have representation.” (VCA team member, #1)

“[From conversations with another VCA team]. . . they viewed their team as like a spider web, and there were all these nodal points of information that then would go up through the web. They felt in their team, there was one person who kind of was the spider who caught all the information. And they proposed that with every team, there’s one person who kind of functions in that role. . . in our team, it isn’t one single person who does that. I think because of a shared electronic medical record and the [institutional] tradition of us all working in a very close fashion, team meetings, frequent consultations, we’re not all separated. . .” [VCA team member, #2]

“...I recall that the VCA team began to form as more and more prospects for transplantation began to develop. My primary involvement was to be a part of all of those meetings. I attended all of the VCA meetings and, as a result of that, my council was often solicited with respect to clinically relevant issues related to VCA.” (VCA team member, #3)

Mediators

Mediators included the development of action-oriented (e.g., communication, leadership), strategic (e.g., planning, training) and interpersonal (e.g., conflict management, trust building) processes. These processes shaped how the team considers potential candidates, functioned, and managed conflict under stress, leveraged individual strengths, and prepared for optimal performance. Participants highlighted two key strategies that helped to establish and sustain a highly functional and prepared team. The first strategy was the structure of scheduled meetings for assessment and evaluation of potential VCA candidates. The primary purpose for these ongoing meetings was to review a potential candidate's case by evaluating the medical criteria for transplant, psychological assessments, and a patient's psychosocial well-being and available social support. Team members presented evaluation reports for potential candidates. Although evaluation of medical and transplant criteria were relatively straightforward, the psychological and psychosocial evaluations were more challenging and ambiguous. Team leaders welcomed differing opinions about the evaluation conclusions from any team member and when concerns were raised, the team had a thorough and deliberate discussion. If deemed appropriate, additional information about that concern was collected or new team members with expertise about that concern were included. Based on participant interview data and observation notes, the unintentional consequence of these meetings was action-oriented and interpersonal processes that built trust, collaboration, and conflict resolution among the team. Team meetings led to frank discussions about selection criteria for candidacy, especially the psychosocial readiness of candidates both before and after listing them for transplant. These meetings continued even when there was not an active candidate listed for transplant or when surgery preparation or performance was imminent, allowing teams to continue to form and develop cohesion. All disciplines involved in VCA were included and participants remarked that leaders flattened hierarchies, thus reinforcing a sense of each discipline's critical contribution to the overall team and trust across disciplines. They emphasized individual expertise and the mutual contribution that each expert brought to the process. After a candidate was listed these thorough and candid discussions promoted a collective commitment and reinforced the team's belief that VCA was

a viable, safe, and reasonable option that would benefit the selected candidate.

[regarding leadership in team meetings] “...taking turns in speaking so that everybody contributes about the same number of minutes to the discussion. It's this very egalitarian way, so everybody feels comfortable enough to say something. There's no top-down leadership style...it's easy within medicine for there to be a hierarchy. But this just doesn't feel that way. It really feels like you are truly all equal contributors to a team.” (VCA team member, #4)

[team processes regarding selection and evaluation] “...we began early on, I believe, as a group to formulate a sense of what risk meant to us and what risk meant to those that we assumed were so vulnerable. These terms all began to take on different shades. I think, prior to my involvement [on the VCA team], I would have never had problems articulating what I thought was consistent with the word “risk,” but that changed substantially over time, and I believe it did for my colleagues, too. So, we were actively growing together and juggling these very abstract terms, all of which were superimposed on a very intense sense of beneficence and commitment to the welfare of potential recipients.” (VCA team member, #2)

[challenges with selection] “...if there were a patient who you felt some conflict with or some incompatibility up front that that would be very difficult to work through as a team and to have that patient have a good outcome. (VCA team member, #4)

“[the team process for VCA preparation]. . .it really is like launching a space rocket, that you have to have many, many, many, many, many, many checks and balances. And if the safety light is lighting up, you gotta stop everything, and you've gotta go back and check and not proceed until all systems are go. And if all systems aren't go, then you shouldn't go. I think [the recipient] did get that message, that that's how we would proceed because it's such an enormous responsibility to [the recipient] to do it right. . . . You've gotta have everybody kind of matched and moving in a concerted way together, and all your harnesses have to be buckled up and secured before you can really proceed safely. (VCA team member, #2)

The second key strategy was VCA team practice sessions in preparation for when a suitable VCA candidate was selected. Team members volunteered their time over 50 Saturdays to create protocols, practice transplant techniques, safety plans, hand-offs, and transitions in the transplant process (Amer et al., 2018). These practice sessions helped form strategic, action-oriented, and interpersonal processes for the team. The team developed a commitment to creating and refining

optimal procedures and built trust and cohesion. They formed a collective belief in their skill and efficacy, along with a shared mental model of the VCA process. Practice sessions led to better role clarification, development of contingency plans, and strategies for addressing interpersonal conflicts and administrative barriers. They simulated interpersonal and leadership communication patterns and highlighted areas where additional team coordination was needed. They also informed the need for additional team training, administrative task planning (e.g., blocking operating rooms at short notice), and clarification of necessary procedures outside of the specific VCA procedure (e.g., media relations, communication with and support of donor family). Practice sessions were adapted to the VCA candidate's case once selected.

(“Interviewer: Were the Saturday sessions everyone just saying “I want to be a part of this” or was it volunteer? How did that happen?” “I mean it was just actually building the team over time. At first it was a small group, two, three people going into the cadaver lab for maybe five or six times or seven times. Trying to decide. . .trying to figure out the basics. And then saying, ‘You know what, here’s the patient’s defect, let’s think through how we would do it’, and then we thought through that and then once we decided, you know this is a pretty reasonable protocol for this particular defect for our patient. Then we started building the team and rehearsing and of course, still during the rehearsal you are still modifying and improving things.” (VCA team member, #5)”)

“...they [the VCA team] practiced and practiced and practiced on cadavers until they almost could do it by memory. They knew every step, every part of step, and it still took, I think he said it took 52 hours, but like an orchestra, everybody came in. I like the analogy of an orchestra. You may be the first violinist but when it’s the oboe part, you sit there quietly and let the oboist play. And you can’t just say ‘Well, I’m the first violinist, you’ve got to be quiet. I’m going to play.’ You play when it’s your turn. You come in and do your job and back off and let somebody else do their job. Everybody knows their part. That’s what the team’s all about. There’s nothing special about anyone of us. But as a team we do a pretty good job” (VCA team member, #6)

“I’ve become interested in how do you build a successful team. . .it is like kind of lightning in a bottle. When you have it, it’s great. Trying to recreate it is really difficult. Certainly the anatomy lab sessions help tremendously, spending so many Saturdays together working together on this common project. . . . So I think a huge amount of the credit goes to [the

surgical leader] and then, yeah, forming those bonds in the anatomy lab, working towards that common goal. And then it also helps when you have a great outcome, too. It just bonds the team further together.” (VCA team member, #4)

Outputs

Outputs included team learning, patient selection and transplant outcomes, and sustainability of the team and its processes. As noted, team participants had a collective commitment to assuring optimal patient outcomes, regardless of whether a potential candidate progressed to VCA. In addition to the overall success of the transplant, each teamlet had their own individual markers of success for VCA that were associated with their assigned task and area of expertise.

“...afterwards he was able to smile on both sides. Because that’s – that’s success. Success is getting the smile to – you know it’s not perfect but to look like a smile. And he’s able to close his mouth.” (VCA team member, #5)

“...as surgeons, we would wanna see function, you know. We would wanna see sensation. (VCA team member, #7)

“If I was to talk to a new team forming. . .[I] would suggest to them that they get a sense of the rapport-building abilities of the other team members. How do the physician, medical director, and the key physical therapy staff. . .they have to be people who are experienced and known to be able to work well with patients. This is something you’ve gotta really have some years of clinical experience to do and be vetted by your surgical departments before you move forward. (VCA team member, #2)

More elusive to the team, however, was building consensus on the optimal approach for determining at each step of the VCA process (assessment/evaluation, procedure, recovery, and rehabilitation) how the expectations and goals of patients are being met. This reflection led to a new cycle of inputs and mediators for the VCA team to consider. These included capturing patient expectations early, assessing alignment of early expectations with procedural realities, and refining tailored educational and rehabilitation efforts to meet those expectations.

“[With VCA]. . . I’m definitely thinking about for a future candidate. . . I think that’s where some peer mentoring from other patients is so important because there are just so few

people who've ever gone through this." (VCA team member, #2)

"They [VCA recipients] don't want to [only] get their hand back so that they can go back to work, they want their hand back so that they can touch the face of their loved one. So that they can hold the hand of their loved one. . . it's holding hands and feeling the skin of their hands. [The hand] kind of is an intimacy organ, you could say. . . they sustain these primary family relationships. So after I started having these new thoughts [of hands as intimacy organs] I started thinking 'now I really haven't thought this through the right way.'" (VCA team member, #8)

Discussion

The growing recognition that complex problems are often best served by cross-disciplinary expertise and intense collaboration has propelled the evolving field of team science. Transplant surgery, including VCA, relies on transdisciplinary teams, collaboration across specialties, and coordination of processes to identify, assess, and list potential transplant candidates, and prepare for the transplant, surgery, recovery, and rehabilitation (Costanzo et al., 2010; De Pasquale et al., 2014; Cajita et al., 2017). It is surprising, therefore, that little research has been conducted to describe the team science of transplant, and how a transplant program's composition, formation, and interactions might influence the effectiveness of patient outcomes and team effectiveness. In that regard, our study is relatively novel and provides an understanding of the components of effective teams and some of the ongoing challenges in VCA.

In our study we found that VCA teams require specialized team members whose scope of practice may not otherwise overlap. Team members need to negotiate about balancing patient safety, psychosocial well-being, and multiple risks throughout the transplant process. The VCA team in our case study required: (1) a significant investment of institutional, medical and financial resources to form; (2) multiple team members with specific expertise and highly advanced skills; (3) careful and precise protocols to reduce the risk for mistakes/errors when multiple external factors are out of the team's control; and (4) significant practice and simulation prior to these relatively rare surgeries in order to improve precision of technique and to build role definition, trust, and a collective mental model of metrics for success. The team's self-reflection on their care processes identified gaps in how patient expectations were assessed, how they defined success, and how their expectations and definitions of success changed throughout the transplant process.

Our findings are consistent with other studies in team science. Institutional culture and values, for example, especially

a culture of cooperation where shared ideas across disciplinary boundaries are communicated and cultivated, is a key indicator to academic innovation (Lee and Jabloner, 2017). As we found in our study, team effectiveness has been shown to hinge on team member familiarity and social cohesiveness, which builds over time and through shared experiences (Stokols et al., 2008). Finally, teams have been shown to perform best when there is cooperation and interdependence of a team's tasks and rewards (Stokols et al., 2008).

Our study does have limitations to consider. First, our examination of team science emerged organically from interview and observation data and was not the original intention of the study. Targeted questions about team science, therefore, were not asked of participants. Future research can build from our findings by developing intentional questions about how teams function and the effect that a team's cohesion has on patient outcomes. Based on our findings we provide potential questions for others to consider when evaluating their own teams in [Supplementary Figure 1](#). Second, the VCA team studied had, to date, only completed one VCA surgery. Data from teams that have a longer record of completed transplants may result in different foci or mediators that affect outcomes. Capturing data from an established team with fewer transplants, however, may provide acute insights into the challenges of early formation of a VCA team or for programs considering expansion into VCA. Third, only two sources of data were used: participant interviews and observations. Additional data sources may have resulted in either a deeper understanding of team dynamics or additional characteristics of the team not found in the available data. Future research may benefit from using sensors to capture data, such as was done by Rosen et al. (2018) or by using other methods, such as video reflexive ethnography (Carroll et al., 2018) where team members review video of their teamwork in order to reflect on opportunities for improvement. These alternative methods may be especially appropriate for specific stages of VCA, such as surgery and recovery and to inform later phases of team development, reflexivity, and sustainability. Finally, understandably, our data had a greater emphasis on the impact of team science on surgery preparation and performance, and less on how team science could directly affect candidate selection and indirectly, recipient outcomes. In order for teams to reflect on process and system improvement, future research could include ethnographic investigations that include different team approaches from candidate identification through final treatment choices. Future research could also focus on how teams build and maintain cohesion and manage attrition during the less intense stages of candidate identification and assessment or when surgery preparation and performance is not imminent.

In spite of these limitations, findings from this study may be especially helpful for other programs considering how to form a team to expand into VCA or improve existing teams, but they may also be of interest to other highly complex, transdisciplinary teams who perform procedures that are not

life-saving, but rather aimed at improving patients' quality of life, such as gender reassignment surgery and bariatric surgery. Based on our findings, these newly forming teams should consider selecting highly experienced, compatible members to participate; an open, methodical, and collaborative approach to leadership; development of team building processes that provides opportunities to practice and build trust; team consensus on definitions of team and patient success; and strategies for self-reflection and evaluation.

Data availability statement

The original contributions presented in this study are included in the article/**Supplementary material**. Further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by the Mayo Clinic Institutional Review Board. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

JG: study conception and design and initial draft of the manuscript. JG and KB: data collection. JG and CK: analysis and interpretation of the data. JG, CK, KB, IH, HA, and SJ-G: critical revisions. All authors reviewed the results, edited early versions of the manuscript, read, and approved the final version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: <https://www.frontiersin.org/articles/10.3389/fpsyg.2022.935507/full#supplementary-material>

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Appendix 6: Presentation Slides



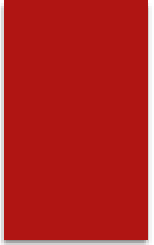
Transforming Shared Decision Making in VCA

SHEILA JOWSEY-GREGOIRE MD

JAN. 12 2023

FY23 RTRP IN PROGRESS REVIEW MEETING

Disclosure



Funding: Dept. of Defense Reconstructive Transplant Research Program (RTRP) Qualitative Research Award of the Congressionally Directed Medical Research Program (CDMRP), Grant Award W81XWH-18-1-0676

Obaid Vascularized Composite Tissue Award

Research Team

- ▶ Transplant Center:

- ▶ Hatem Amer
- ▶ Cassie Kennedy
- ▶ Steven Moran
- ▶ Samir Mardini
- ▶ Adam Miller
- ▶ Katrina Schaefer
- ▶ Audi Chokkalingham

- ▶ PM and R

- ▶ Fantley (Clay) Smither

- ▶ Kern Center for the Science of Health Care Delivery:

- ▶ Joan Griffin
- ▶ Dawn Finnie
- ▶ Karen Schaepe

- ▶ Knowledge and Evaluation Research Unit

- ▶ Ian Hargraves
- ▶ Kasey Boehmer
- ▶ Victor Montori
- ▶ Brianna Sanchez

Outline



Background



Review of our study
findings



Purposeful shared
decision making
(PSDM)



Introduction of the
PSDM prototype



Applications for solid
organ transplantation

VCA

First VCA in modern era, 1998

Currently, apx. 113 hand transplants in 76 patients and 37 face transplants.

Apx. 100 uterine transplants.

Active centers around the world

Mayo: active face and hand transplant program.



Why Vascularized Composite Transplantation?

- ▶ Providing “like with like” for functional, esthetic, occupational, personal identity, social communication and role deficits
- ▶ Positive QOL outcomes for most recipients
- ▶ QOL versus immunosuppressive medications, lengthy rehabilitation, surgery
- ▶ Range of satisfaction with outcomes, rare requests for reamputation or noncompliance leading to amputation.
- ▶ Life enhancing rather than life saving.

Background in PSDM Research

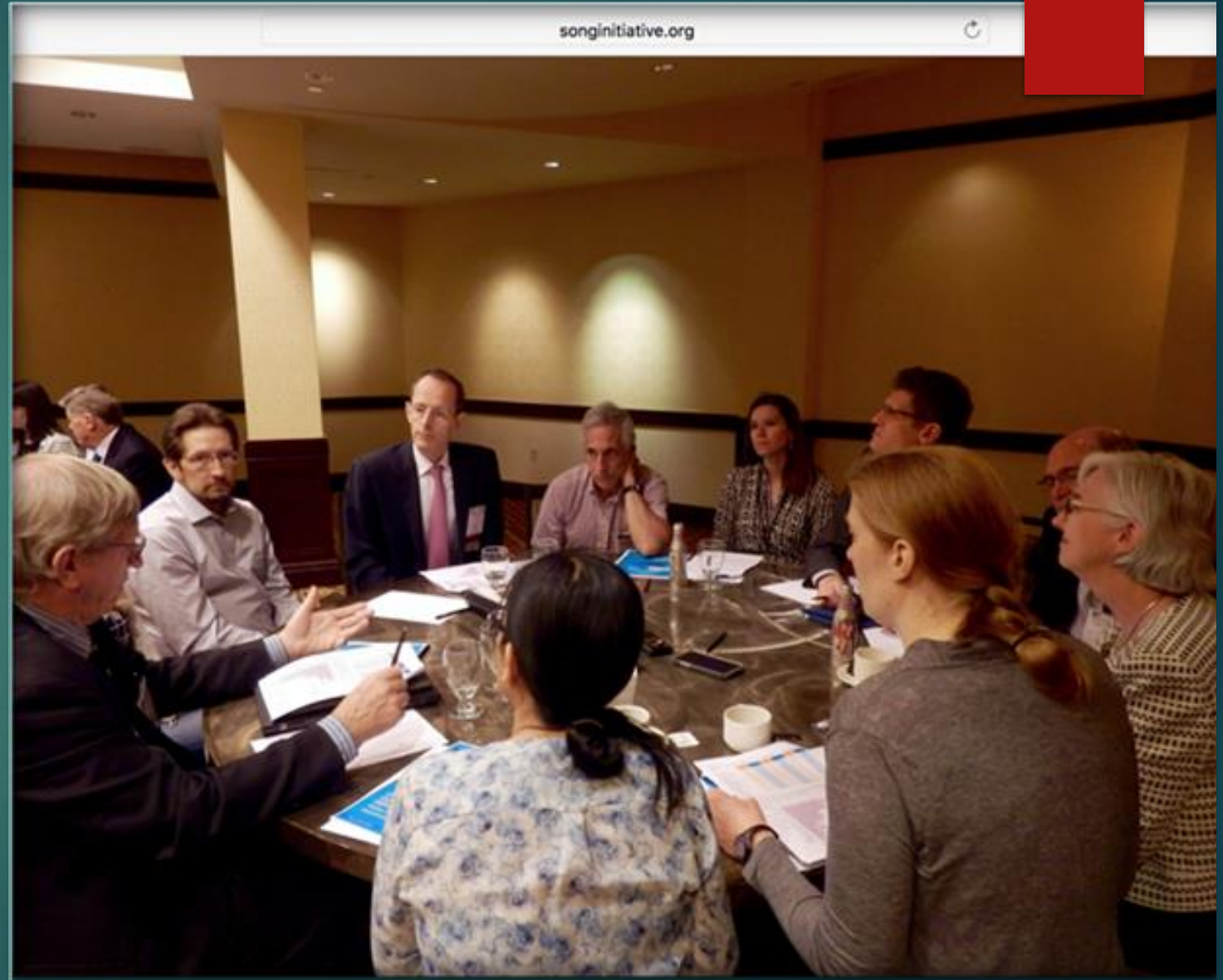
- ▶ 2010 – creation of Vascularized Composite Allograft program in Rochester
- ▶ The Chauvet Workshop background:
 - ▶ Lack of VCA specific QOL tools
 - ▶ Need for qualitative research
 - ▶ Goal to improve selection, meet the expectations of VCA candidates

Kumnig 2022,
Mayo Proceedings



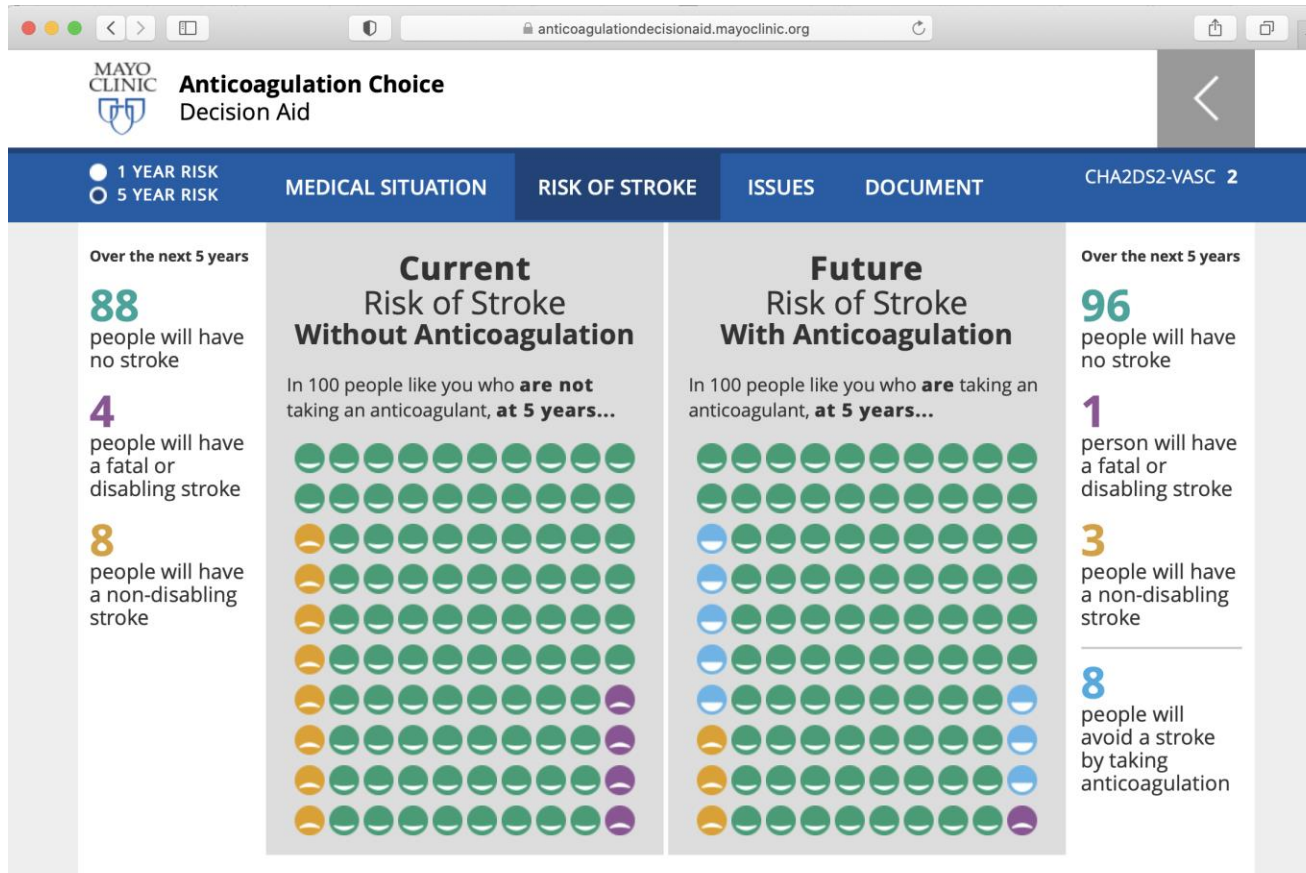
Qualitative Research

- ▶ Refers to the meaning, concepts, definitions, characteristics, metaphors, symbols and description of things from the patient or provider
- ▶ Creation of SONG-TX Life Participation instrument (2022)



SONG-TX Consensus, 2016

Ju et al, Transplantation 2019



Credits & Contacts

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Traditional Shared Decision Making

Aims of PSDM in VCA Study

Aim 1: To determine, through in-depth interviews, the motivations, values, preferences, and expectations of VCA candidates and their caregivers.

Aim 2: To incorporate the psychosocial and situational factors from Aim 1 into a Conversation Aid to support VCA candidates in choosing the most appropriate treatment to address their upper limb amputation and/or facial disfigurement.

Aim 1:

- ▶ Qualitative interviews of limb loss and facially disfigured subjects, caregivers, transplant teams members
- ▶ Improved understanding of the expectations of potential candidates, limb loss subjects and the team's expectations.

c	Screened	Approached	Consented	Enrolled	Interviewed	Withdrew
Transplanted	11	6	5	5	5	
Transplanted Caregiver	2	0	0	0	0	
Candidate	10	9	2	1	1	
Candidate Caregiver	7	4	3	1	1	
Eligible	56	31	13	10	10	1
Eligible Caregiver	9	8	7	6	6	1
Provider	35	23	18	18	18	
Totals	131	84	50	44	44	2

Limb loss subjects:

Many adapted to
limb loss

Concerns about
financial burdens

Adaptation to limb
loss was inversely
associated with
motivation for VCA

Concern about
long-term effects of
overuse and injury
with existing limb.

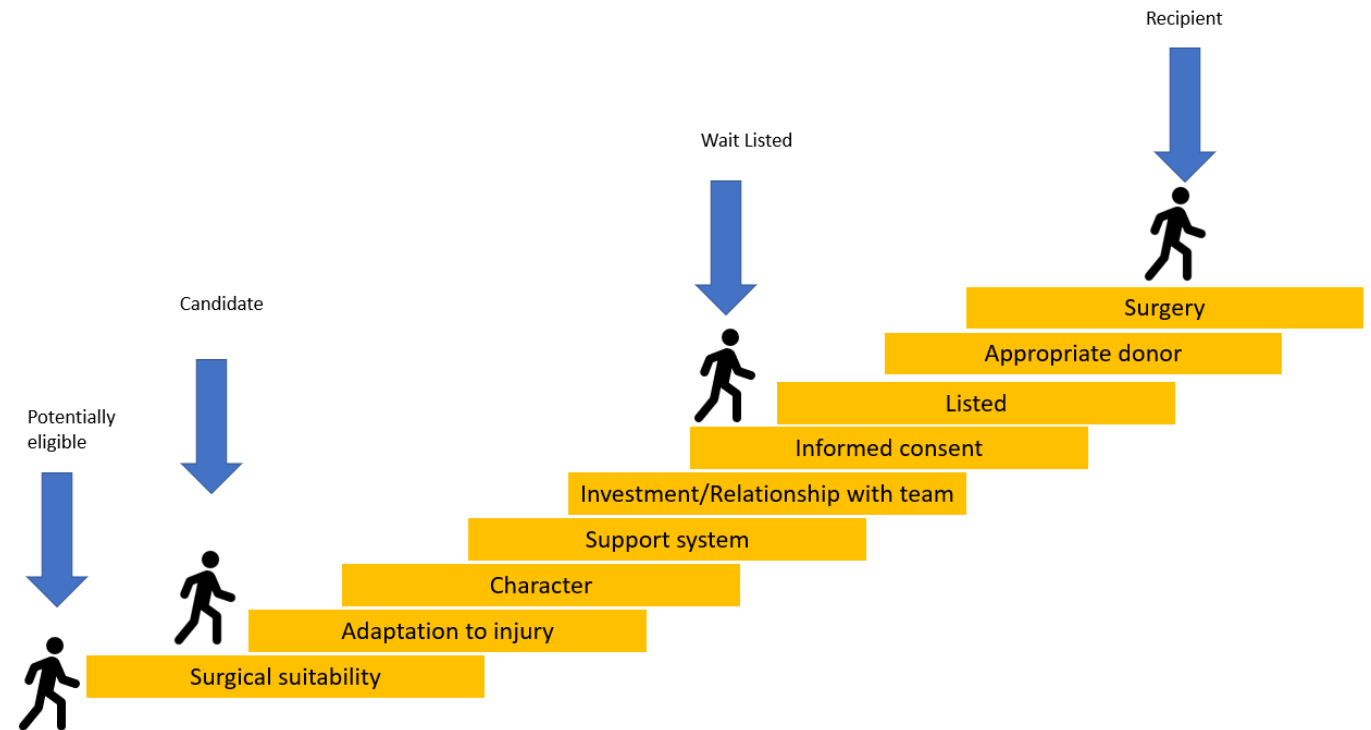
Need for
standardization of
information about
VCA

Candidate Interviews

Table 1: Motivating Factors for Considering VCA (n=9)

	Dissatisfaction with Prosthesis	Chronic Pain	Improved ADLs	Occupational Activities or Opportunities	Dissatisfied with self-image	Burden to others	Concerns about overuse of non-affected limb
Number of Cases (%)	4 (44%)	3 (33%)	9 (100%)	3 (33%)	1 (11%)	2 (22%)	1 (11%)

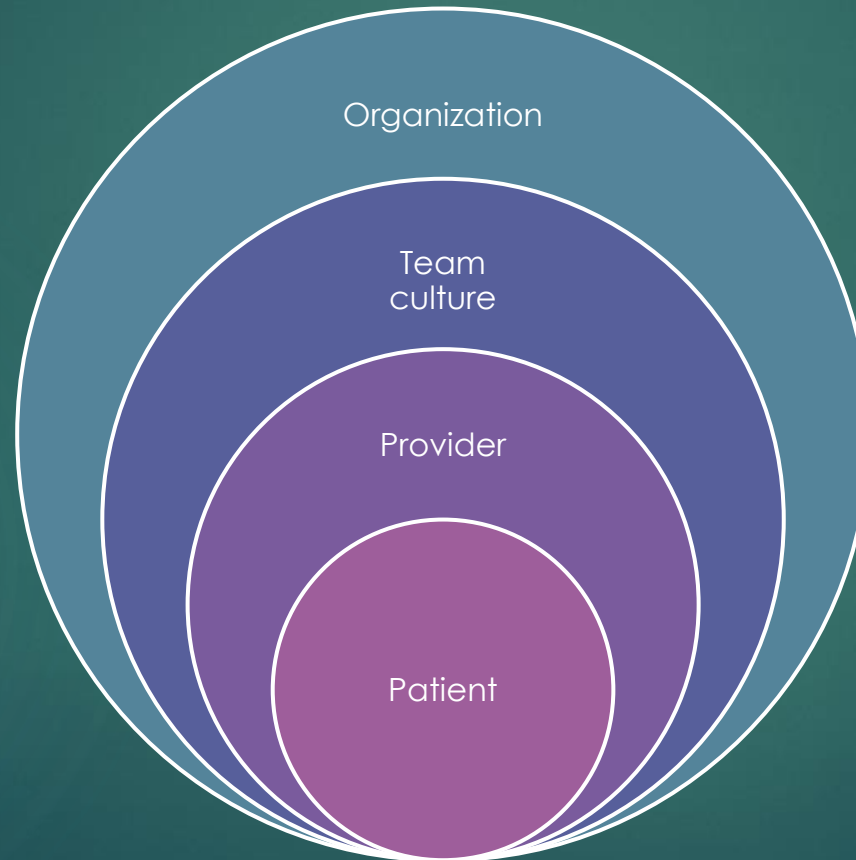
Transplantation Selection Process



Qualitative Interviews of Providers

Indication/ deficit	Surgical appropriateness	Contra- indications	Candidate traits	Candidate's support system	Candidate motivation	Trade offs
Role fulfillment Disability Quality of life Deficits Aesthetics Function	Surgically unsuitable	Cognitive impairment Comorbidities	Risk-taking Self-efficacy Optimism Resilience Flexibility in thinking	Strength of social ties Relationship with clinicians Social network	Expectations Autonomy Hope Hate prosthetic Ambivalence Patient investment	Financial Immunosuppression Long-term health risk

Team Science



Action-oriented:
Communication, leadership

Strategic:
Planning, training

Interpersonal:
Conflict management,
Trust building

Perspectives



A person wearing a grey hoodie and a dark beanie is seen from behind, looking out over a vast, forested landscape at sunset. The sun is low on the horizon, casting a warm, golden glow over the trees and a body of water in the distance. The person's hands are in their pockets.

Considering hand transplant

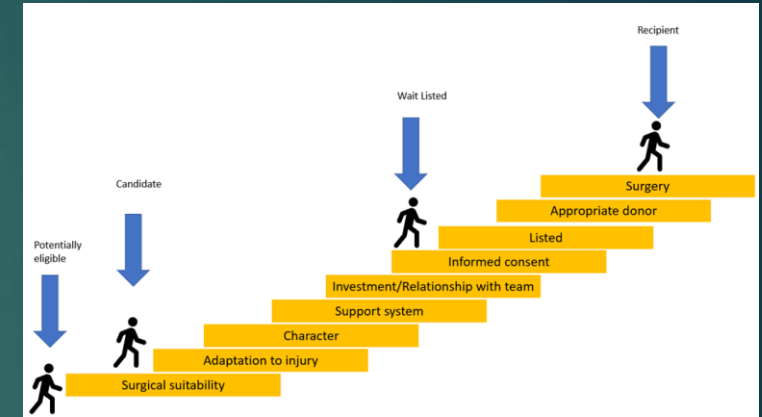
Thinking, talking, and feeling it through

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Please use Google Chrome, Microsoft Edge or another browser

Hargraves, unpublished

Purposeful Shared Decision Making

- ▶ Knowledge: Consider the pros and cons
- ▶ Position of stakeholders and their values
- ▶ What problem needs to be solved?
- ▶ Existential issues – embodiment issues, roles, identity



Hargraves, Montori, Brito, Kunneman et al
Purposeful SDM: A problem-based approach to caring for patients with shared decision making
Patient Education and Counseling, 2019

Hargraves IG, Fournier AK, Montori VM, Bierman AS. Generalized shared decision making approaches and patient problems. Adapting AHRQ's SHARE Approach for Purposeful SDM. Patient Educ Couns. 2020

Hargraves I. Beyond involvement: multiple methods and purposes of shared decision making. J Comp Eff Res. 2019

Decisive issues Mode of Purposeful SDM	Example
1. The upsides and downsides of hand transplant	The risks of lifelong immunosuppression: cancer, infection, etc. The extent and likelihood of recovered function and sensation

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Decisive issues Mode of Purposeful SDM	Example
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2. The conflicting expectations, goals, positions of stakeholders	Spouse not wanting transplant Competing perspectives: alcohol use
3. The problems in the situation • Why act? • How to act?	<i>"My youngest was on the soccer field and scored a goal and I couldn't clap...I had the prosthesis there, but I just couldn't do that..."</i>¹ How to make transplant tolerable, feasible, sustainable • Disruption to caregiver's life, proximity to center, cost, work commitments, where to recover...

¹ <https://www.wdtn.com/news/u-s-world/hand-transplant-recipient-celebrates-20-years/>

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4. Existential significance	Returning to active duty ² Undoing family trauma

¹ <https://www.wdtn.com/news/u-s-world/hand-transplant-recipient-celebrates-20-years/>

² <https://timesofindia.indiatimes.com/city/kochi/hands-on-abdul-rehim-lived-died-a-warrior/articleshow/74369255.cms>

Decisive issues Mode of Purposeful SDM	Requires an SDM method that is capable of...	Example
1. The upsides and downsides of hand transplant	working with knowledge of upsides and downsides and valuing them in relation to one another (weighing)	The risks of lifelong immunosuppression: cancer, infection, etc. The extent and likelihood of recovered function and sensation

Decisive issues Mode of Purposeful SDM	Requires an SDM method that is capable of...	Example
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2. The conflicting expectations, goals, positions of stakeholders	working with positions : voicing, changing, creating, reconceiving, disputing, relating... (negotiation)	Spouse not wanting transplant Competing perspectives: alcohol use

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3. The problems in the situation • Why act? • How to act?	finding the problems that require action, and creating tolerable, feasible, desirable, and sustainable ways of addressing those problems (problem solving)	<i>"My youngest son Jeremy was on the soccer field and he scored a goal and I couldn't clap...I had the prosthesis there, but I just couldn't do that..."</i> How to make transplant tolerable, feasible, sustainable • Disruption to caregiver's life, proximity to center, cost, work commitments, where to recover...

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The kinds of things that we need to talk through



Your situation

Before making a decision we need to be sure that transplant is the right fit for your life and any problems that you are experiencing



People

It is important that you, those who care about you, and your care team are committed to transplant before proceeding



Upsides and Downsides

There are a lot of pros and cons to transplant that need careful weighing before making a decision



Feasibility

For hand transplant to be successful, many things need to be arranged



Meaning



Upsides and downsides of hand transplant

Function and Appearance

Function, Appearance, Sensation,
Durability

Risks

Cancer, Infections, Serious illness,
Rejection, Mental health, Relationships,
Graft failure

Commitment required

Preparation, Recovery, Constant rehab,
Constant medication, Return visits,
Caregiver support, Healthy lifestyle,
Extreme cleanliness

Cancer



Significantly more
common

Infections



More frequent, more
serious

Other Serious Illness



Kidney disease or failure

Rejection



You will experience a
rejection episode at
some point

Mental health



Surgery, recovery, and
maintenance can cause
depression etc.

Relationships



Can place significant
stress on relationships

Graft failure



Would require
amputation of new
hand

Pain



New and old

Add
topic

Risks of infection

You will develop infections more frequently after transplant and they may be more serious or difficult to treat than before you began taking immunosuppressive medicine.

Everyone develops bacterial or viral infections from time to time. With transplant, these will require you to seek medical advice or assistance as soon as symptoms appear. You should expect to be treated frequently for infections. Some of these infections may be life threatening.

Links

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6717012/>



Your situation and problems

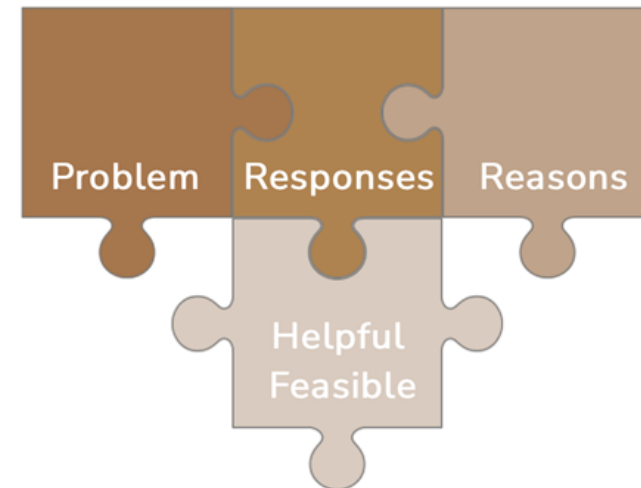


What is the problem that hand transplant could help with?

Hand transplant may or may not be the best approach for you

To figure that out, we need to understand:

- **the problems that you are experiencing**
- **possibilities for responding to these problems in a helpful and feasible way**
- **the reasons why you're considering hand transplant**



It takes time and conversations for patients, families, and care



People involved



People. You, those who care for you, and your care team

There are many people affected by hand transplant—
you, those who care for you, and your care team.

Before making a final decision, it is important that all of these **people's wishes, concerns, and expectations** are talked through, and that everyone is able to commit to making any transplant a success.

You

What are your hopes and expectations?
Do you feel conflicted?
How do your wishes affect others?

Those Who Care For You

What are the hopes, expectations, and
concerns of the people supporting you?
How will you meet their needs?

Your Care Team

What is your care team's perspective,
concerns, and goals?
Do they align with yours?





Meaning



Meaning. Making sense of it all.

Limb loss changed your life and the life of those around you. How have you made sense of what happened?

You've told the story of what happened when you lost your limb many times, and to many people. What do you focus on when you tell that story? What things do you add or leave out? How has the story changed?

A lot has happened since then, some good, some bad, some routine. What are the stories, images, or events that stand out? Why do they stand out?

1

When you talk about it, how has the story of your limb loss changed over time?

Other Populations of Interest:

- ▶ LVAD versus heart transplantation
- ▶ IgA nephropathy
- ▶ Retransplantation
- ▶ Elderly candidates
- ▶ Living donors
- ▶ COPD management options

