NATIONAL ACADEMIES Sciences Engineering Medicine

PRINCIPLES AND FRAMEWORK TO GUIDE THE DEVELOPMENT OF PROTOCOLS AND STANDARD OPERATING PROCEDURES FOR FACE AND HAND TRANSPLANTS: WEBINAR #2 (APRIL 17, 2024)

Public Understanding and the Policy Environment of VCAs

Richard Hasz,
President & CEO, Gift of Life Donor Program

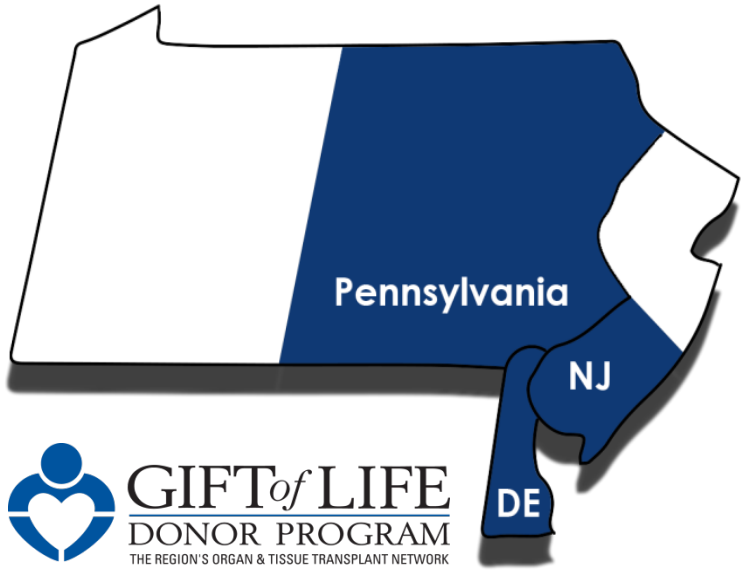
GIFT of LIFE DONOR PROGRAM
A Legacy of **HEROES.** A Future of **HOPE.**

Disclosures

- I have nothing to disclose

Gift of Life Donor Program

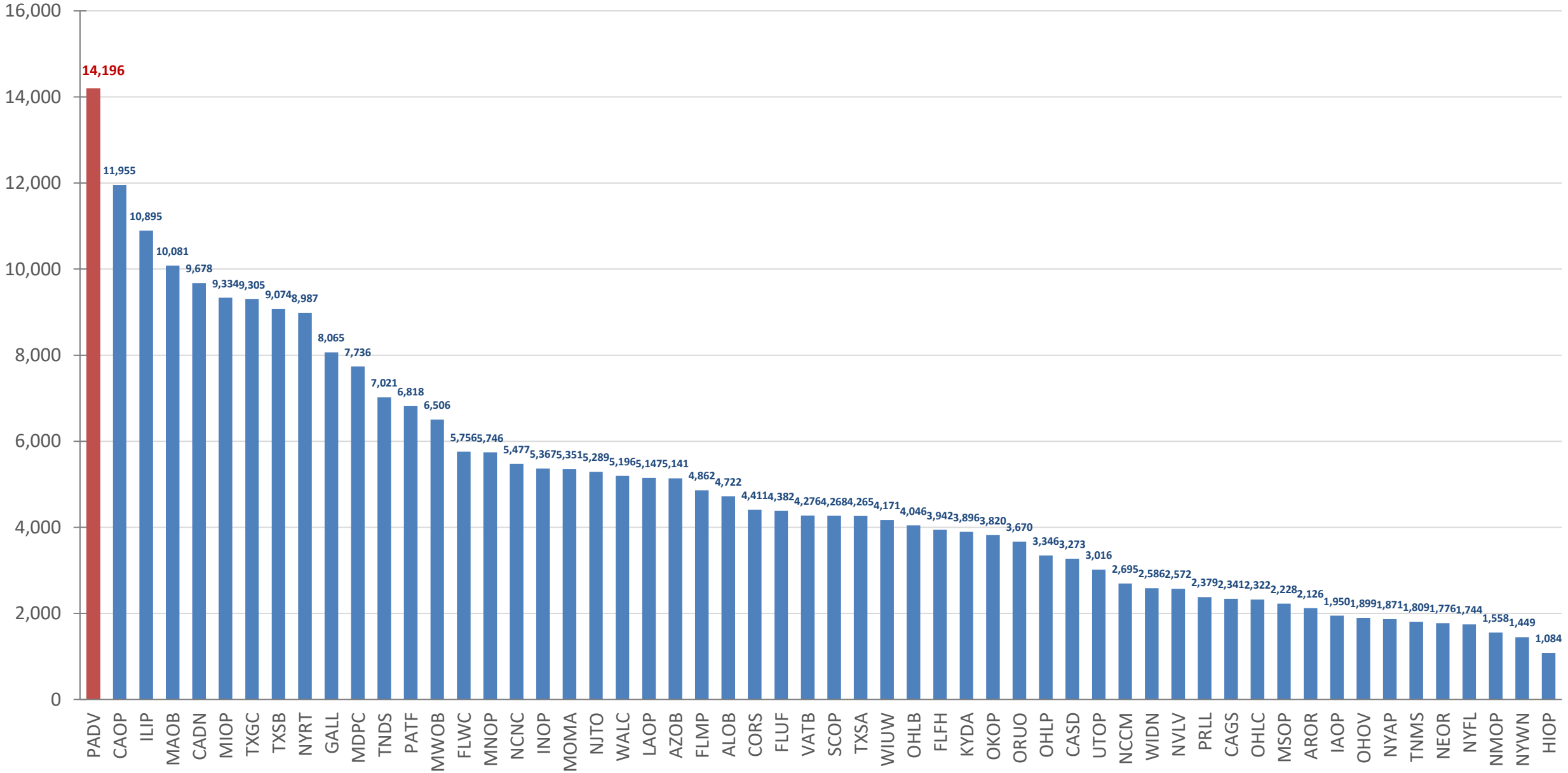
Philadelphia, Pennsylvania USA



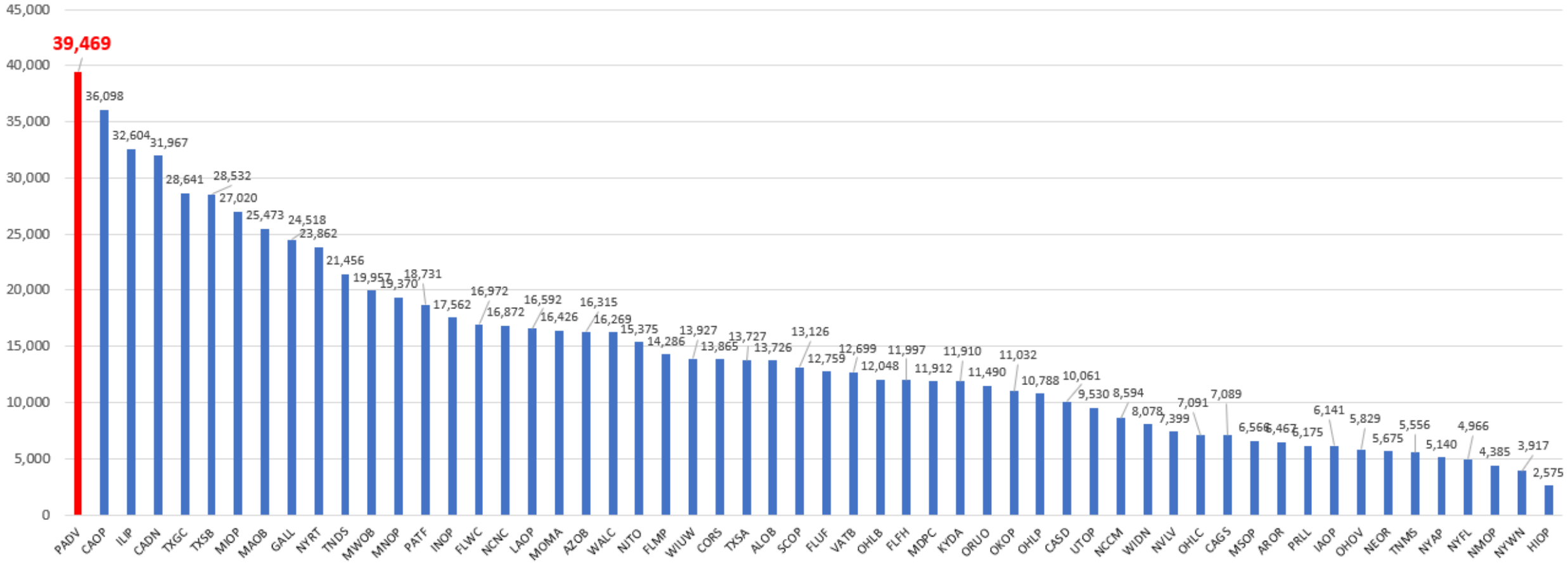
GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

- Non-Profit OPO/Tissue Recovery/Eye Bank
- Established in 1974
- Federally designated OPO (Medicare) for eastern PA, Southern NJ & Delaware
  - 126 Acute Care Hospitals
  - 12 Transplant Centers, 35 Programs
  - 11.3 Million Population
- **693 organ donors in 2023**, **resulting in 1,734 organ transplants** (61 donors/MM and 153 transplants/MM); 2,665 tissue donors, including 1,433 musculoskeletal donors and 2,278 cornea donors
- **More than 61,000 organs coordinated for transplantation** and over 2,000,000 tissue allografts

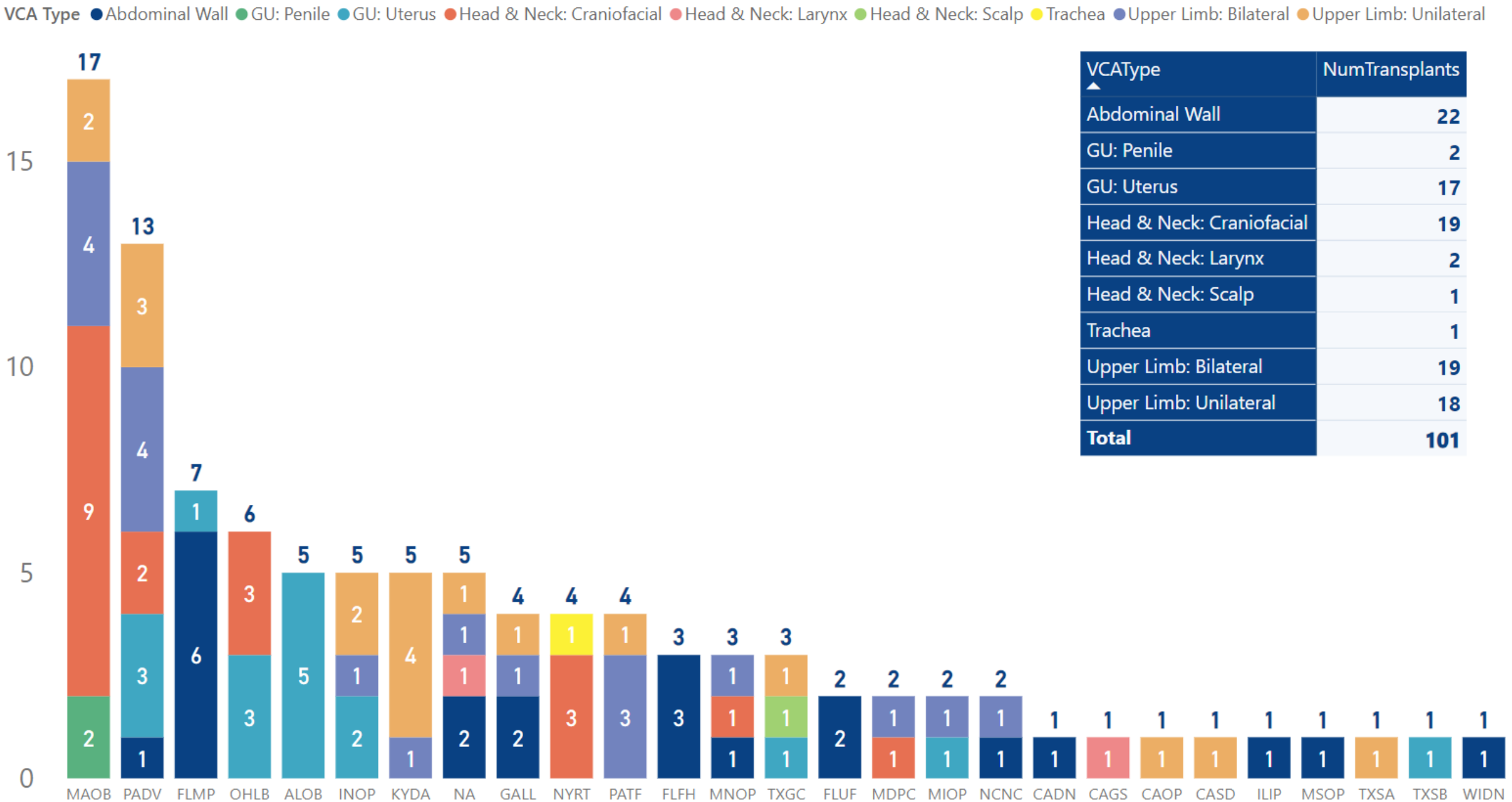
Total Deceased Organ Donors by 56 U.S. OPOs for Years 1988 to 2023 – UNOS data



Total Organs Transplanted by 56 U.S. OPOs for Years 1988 to 2023 – UNOS data

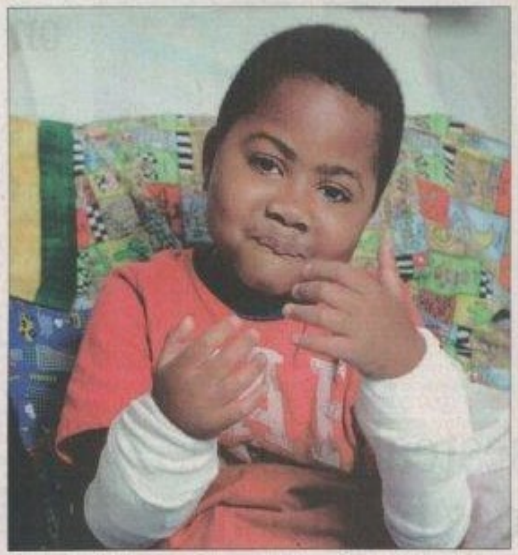


Vascular Composite Allografts (VCA) Recovered from Deceased Donors by OPO January 1, 1998 - March 31, 2024



VCAType	NumTransplants
Abdominal Wall	22
GU: Penile	2
GU: Uterus	17
Head & Neck: Craniofacial	19
Head & Neck: Larynx	2
Head & Neck: Scalp	1
Trachea	1
Upper Limb: Bilateral	19
Upper Limb: Unilateral	18
Total	**101**

The Philadelphia Inquirer



Zion Harvey, 8, of Baltimore, shows off his new hands at Children's Hospital of Philadelphia. Zion lost his hands and feet to a bloodstream infection when he was 2.

Reaching Out To a Milestone

Double hand transplant here is world's first for a child.

By Marie McCullough

Sitting on his bed at Children's Hospital of Philadelphia, the first child in the world to receive a double hand transplant talked about his big plans.

Zion Harvey, 8, of Baltimore, wants to climb the monkey bars. Throw a football. Play the guitar. Maybe even become a doctor.

"But I'll be the kind that doesn't give shots," he said with an impish grin Monday.

On Tuesday afternoon, a team from Children's and the University of Pennsylvania announced its early-July surgi-

World's first pediatric double-hand transplant performed at The Children's Hospital of Philadelphia
July 2015

abc NEWS

Quadruple Amputee Gets Two New Hands on Life

Lindsay Ess, 29, lost her limbs to an infection five years ago.

By ABC News
January 3, 2013, 4:34 PM

Jan. 4, 2013 -- It's the simplest thing, the grasp of one hand in another. But Lindsay Ess will never see it that way, because her hands once belonged to someone else.

Growing up in Texas and Virginia, Lindsay, 29, was always one of the pretty girls. She went to college, did some modeling and started building a career in fashion, with an eye on producing fashion shows.

Then she lost her hands and feet.

When she was 24 years old, Lindsay had just graduated from Virginia Commonwealth University's well-regarded fashion program when she developed a blockage in her small intestine from Crohn's Disease. After having surgery to correct the problem, an infection took over and shut down her entire body. To save her life, doctors put her in a medically-induced coma. When she came out of the coma a month later, still in a haze, Lindsay said she knew something was wrong with her hands and feet.

Lindsay Ess' Story: From Quadruple Amputee to Hand Transplant Recipient to CrossFit Competitor

Lindsay Ess, 32, went from losing all four limbs to being a CrossFit competitor.

By ABC News
April 20, 2016, 5:30 PM

Lindsay Ess, the first bilateral hand transplant patient at Penn Med, has become a regular at the gym.

Penn Medicine Announces Baby Successfully Born To Woman Who Received Uterus Transplant From Deceased Donor

CBS NEWS PHILADELPHIA

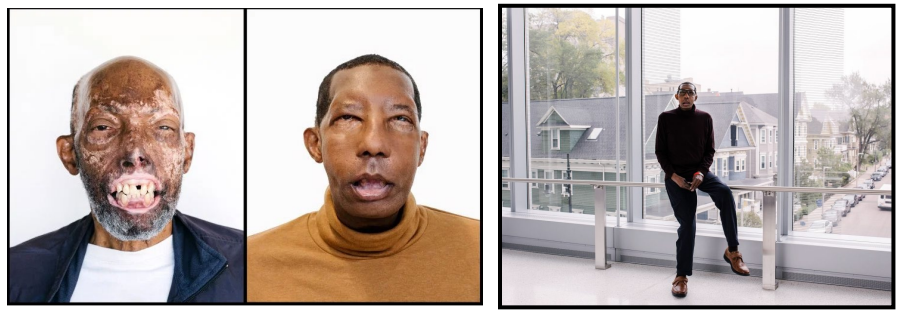
January 9, 2020 / 6:41 PM EST / CBS Philadelphia

TIME

HEALTH • HEALTHCARE

He's the First African American to Receive a Face Transplant. His Story Could Change Health Care

July 2019 - Robert Chelsea received his transplant from a GLDP donor



NYU Langone Health NewsHub

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COMPLEX CASES, INNOVATION, PRESS RELEASES | FEBRUARY 3, 2021

NYU Langone Health Performs World's First Successful Face & Double Hand Transplant

After receiving a face and double hand transplant—the first successful case of its kind in the world—Joe DiMeo is working hard to get back to the activities of everyday life he enjoyed before his accident.

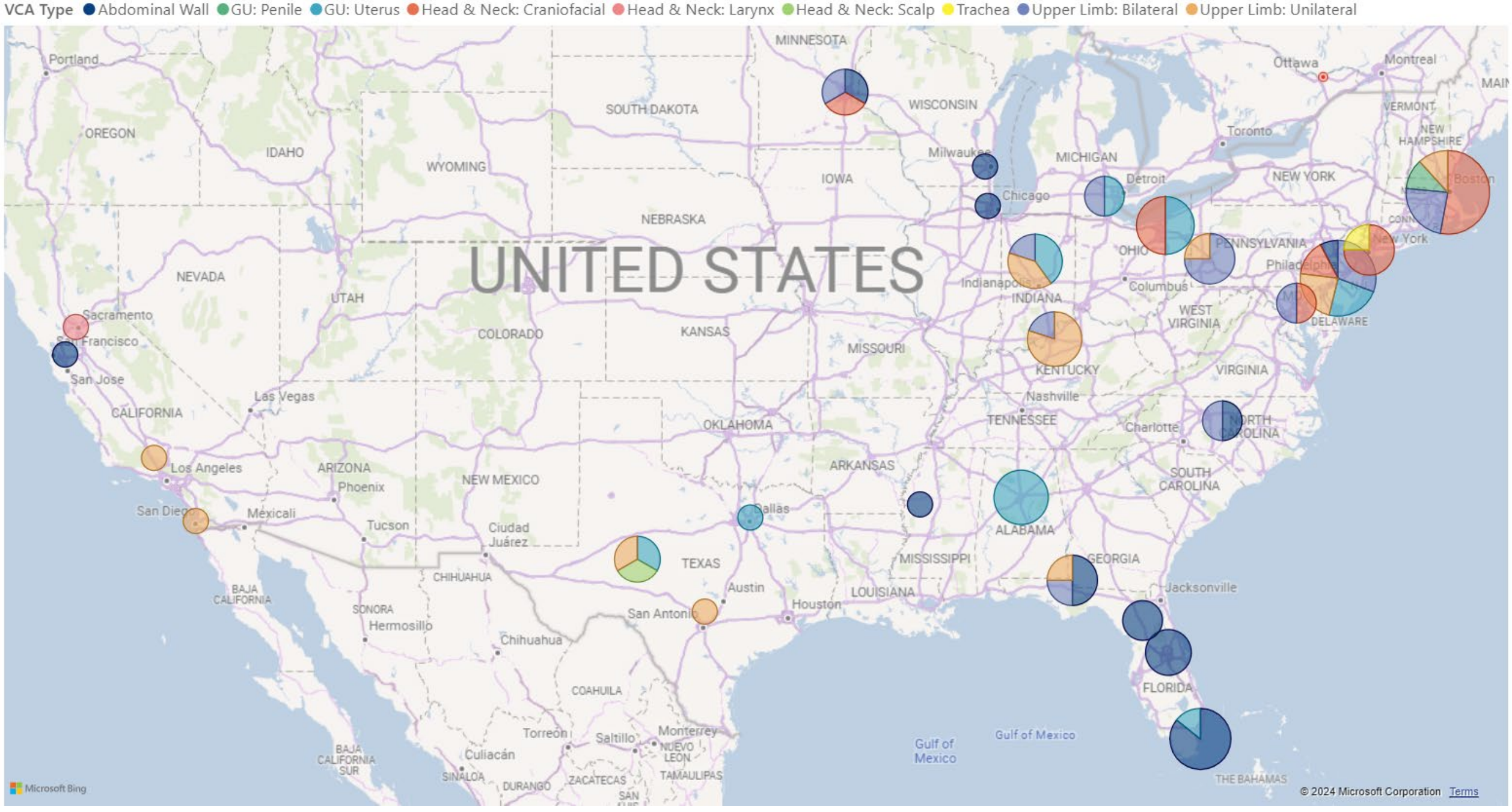
CNN

World's first face and hands transplant gives New Jersey man a second chance at life

By Evan Simko-Bednarski, CNN

4 minute read · Updated 6:42 PM EST, Wed February 3, 2021

Vascular Composite Allografts (VCA) Recovered from Deceased Donors by OPO January 1, 1998 - March 31, 2024



Tracking the Wait List: Early Days vs. Now

Candidates Waiting for a Vascularized Composite Allograft (VCA) Transplant as of 11/7/2018 12:29:45 PM

Selected OPO	PADV-OP1 Gift of Life Donor Program
Selected OPO Region	2
UNOS Donor ID	AFKI345
VCA Organ Offered	Other VCA
Other VCA Organ Offered	Uterus

Region	UNOS VCA Candidate ID	Transplant Hospital	VCA Organ(s)	If Applicable, Specify Other VCA Organ(s)	Offer Accepted	Refusal Reason / Bypass Reas
2		PAUP-TX1	Other VCA	UTERUS	Yes	
10		OHCC-TX1	Other VCA	UTERUS		
4		TXTX-TX1	Other VCA	UTERUS		
10		OHCC-TX1	Other VCA	UTERUS		
10		OHCC-TX1	Other VCA	UTERUS		
10		OHCC-TX1	Other VCA	UTERUS		
10		OHCC-TX1	Other VCA	UTERUS		
10		OHCC-TX1	Other VCA	UTERUS		

MS Excel Spreadsheets

OPTN Organ Procurement & Transplantation Network

U.S. Department of Health & Human Services — HRSA Health Resources & Services Administration

Format Count

Portrait | Candidates | Go

Add Field to Report :

Go

count flip cols rows both export print

	All Organs	Kidney	Liver	Pancreas	Kidney / Pancreas	Heart	Lung	Heart / Lung	Intestine	Abdominal Wall	VCA - head and neck	VCA - upper limb	VCA - uterus
All Donation Service Areas	103,968	89,361	9,847	834	2,074	3,402	950	42	202	2	3	3	7
ALOB-OP1 Legacy of Hope	1,172	994	151	0	20	26	9	3	0	0	0	0	3
AROR-OP1 Arkansas Regional Organ Recovery Agency	212	160	24	0	5	25	0	0	0	0	0	0	0
AZOB-OP1 Donor Network of Arizona	1,677	1,428	179	3	38	59	15	0	0	0	0	0	0
CADN-OP1 Donor Network West	8,065	7,190	722	38	120	69	33	3	7	0	0	0	0
CAGS-OP1 Sierra Donor Services	1,989	1,975	12	0	1	2	0	0	0	0	0	0	0
CAOP-OP1 OneLegacy	8,898	7,717	926	42	160	173	39	0	36	0	0	0	0
CASD-IO1 Lifesharing - A Donate Life Organization	1,731	1,566	114	8	25	48	8	2	0	0	0	0	0
CORS-OP1 Donor Alliance	1,248	1,062	155	20	17	25	10	0	0	0	0	0	0
FLFH-IO1 OurLegacy	686	624	37	1	4	18	3	0	0	0	0	0	0
FLMP-OP1 Life Alliance Organ Recovery Agency	1,748	1,541	143	13	24	61	6	0	17	1	0	0	0
FLUF-IO1 LifeQuest Organ Recovery Services	1,675	1,359	143	20	46	114	30	1	0	0	0	0	0
FLWC-OP1 LifeLink of Florida	1,360	1,161	142	1	12	35	23	0	0	0	0	0	0
GALL-OP1 LifeLink of Georgia	2,875	2,513	259	3	27	125	7	0	0	0	0	0	0
HIOP-OP1 Legacy of Life Hawaii	314	287	27	0	0	0	0	0	0	0	0	0	0
IAOP-OP1 Iowa Donor Network	603	538	20	6	24	13	9	0	0	0	0	0	0
ILIP-OP1 Gift of Hope Organ & Tissue Donor Network	3,998	3,423	264	73	110	207	41	0	7	0	0	0	0

Electronic Database

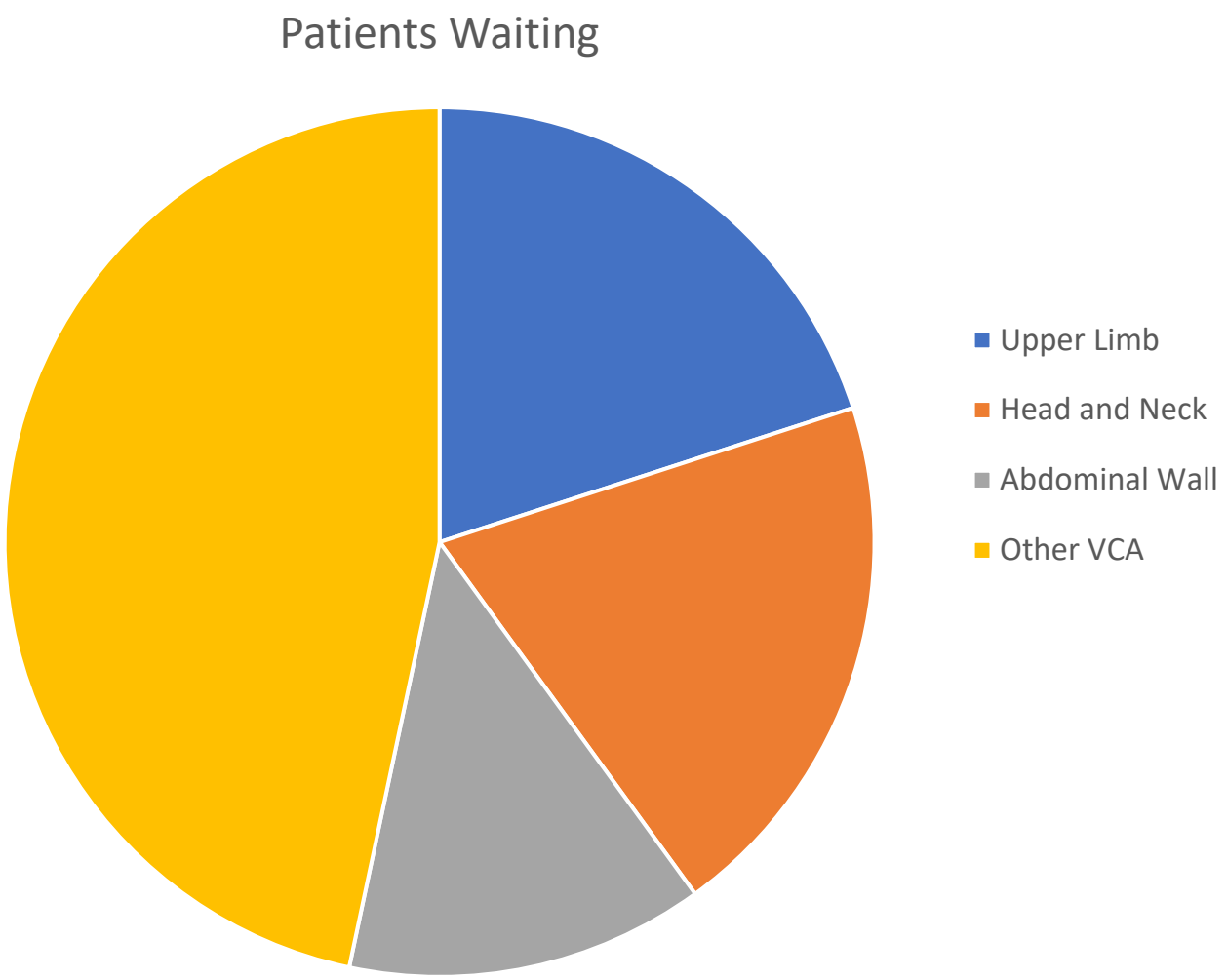
UNOS National List (as of 4/12/2024)

Upper Limb (3)

Head and Neck (3)

Abdominal Wall (2)

Uterus (7)



transplantology

MDPI

Article

Availability of Deceased Donors for Uterus Transplantation in the United States: Perception vs. Reality

Kathleen O'Neill [1,*], Elliott G. Richards [2,*], Jessica Walter [3], Sharon West [4], Richard Hasz [4], Giuliano Testa [5], Shreya Kalra [1], Tommaso Falcone [2], Rebecca Flyckt [6], Nawar Latif [1], Andreas Tzakis [7] and Liza Johannesson [5,8]

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* Correspondence: kone@upenn.edu (K.O.); richare@ccf.org (E.G.R.)

Abstract: Uterus transplantation (UTx) is a rapidly evolving treatment for uterine factor infertility. New centers offering this treatment must decide whether to utilize living donors, deceased donors, or both. Although limiting UTx to deceased donors eliminates the surgical risks for living donors, an adequate supply of suitable deceased uterus donors in the United States is an emerging concern. Previous studies describing the paucity of deceased uterus donors failed to consider key donor characteristics, potentially overestimating the available organ pool. To estimate the United States' supply of deceased donor uteri; we extrapolated detailed clinical and demographic information from the regional donor datasets available from three organ procurement organizations to the national Organ Procurement and Transplantation Network donor pool. We estimate there are approximately 3700 possible and 400 optimal uterus donors annually in the United States. Given these projections and the number of women with uterine factor infertility in the U.S. who pursue parenthood through alternative strategies, we conclude that, as uterus transplant transitions from research to established clinical care, demand could quickly exceed the deceased donor supply. The liberalization of deceased donor selection criteria may be insufficient to address this imbalance; therefore, fulfilling the anticipated increased demand for uterus transplantation may require and justify greater use of living donors.

Keywords: uterus transplant; deceased donor; living donor; donor availability

check for updates

Citation: O'Neill, K.; Richards, E.G.; Walter, J.; West, S.; Hasz, R.; Testa, G.; Kalra, S.; Falcone, T.; Flyckt, R.; Latif, N.; et al. Availability of Deceased Donors for Uterus Transplantation in the United States: Perception vs. Reality. *Transplantology* **2024**, *5*, 27–36. https://doi.org/10.3390/transplantology5010003

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1. Introduction

Uterus transplantation (UTx) is a rapidly evolving treatment option for individuals with uterine factor infertility (UFI). The first successful surgical transplantation of a deceased uterus to a recipient was performed in Turkey in 2011, although the first live birth from a UTx occurred in 2014 from a living donor in Sweden and in 2017 from a deceased donor in Brazil [1–4]. Following early feasibility studies, there have been over 37 uterus transplants and 25 live births since 2016 in the United States (US) alone [5–7]. There have also been 45 additional uterus transplants performed, with 19 associated live births, recorded in the first report of the Registry of the International Society of Uterus

transplantology

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GLDP Experience

CHALLENGES

Creating policies and procedures to keep up with the expanding VCA opportunities

Keeping all staff educated on VCA donation

Staff competency with VCA authorization

Lack of consistency in screening = missed opportunities
VCA List not specific to donor

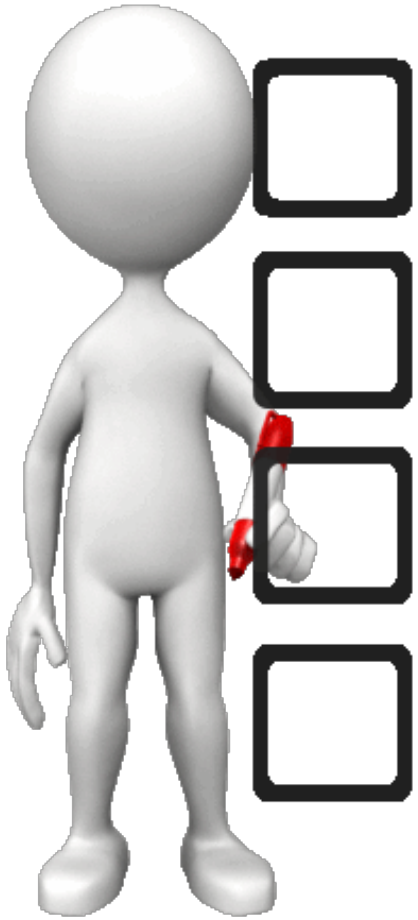
Transplant centers unfamiliarity with VCA recovery

GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

The Role of OPOs

- Identification of Potential VCA Donors
- Donor Family Communication and Support
- Authorization for VCA Donation
- Communication with VCA Transplant Programs
- Medical Examiner and Funeral Home Communication
- Care Team and OR Staff Communication
- Recovery Coordination
- Follow-up Letters through Family Services

Every Donor, Every Time



Quality control checks in place to ensure that every donor is screened for VCA

Documentation of the review of the VCA list as well as any offers made and outcomes of the offers

Electronic record will not pass pre-OR QC check without this documentation

Weekly Organ Utilization Review

- Staff follow-up provided with any missed opportunities

GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

Policy & Checklists

GIFT OF LIFE DONOR PROGRAM

TITLE: Vascularized Composite Transplant Coordination and Recovery

Document:	Revision
CS-02-040	1 Effective 1

1. **Scope**

1.1. Gift of Life Donor Program will establish and
Vascularized Composite Allograft (VCA) dor
grafts, which is consistent with accepted solid
Transplantation Network (OPTN) requiremen

1.2. The purpose of this procedure is to outline re
procurement and roles and responsibilities for
recovering VCA Transplant Program.

2. **Definitions**

2.1. UNOS – United Network for Organ Sharing

2.2. VCA – Vascularized Composite Allograft

3. **Responsibility**

3.1. VCA Transplant Program and Procurement T
Coordinators (TC), Organ Administrator on C
Transplant Information Center (TIC), GLDP

4. **Related documents, Materials, or Equipment**

4.1. CR-05-001, "Packaging of Recovered Organs

4.2. CR-06-001, "Labeling Process for Organ Dor

4.3. CS-02-002.1, "Medical History and Behavior

4.4. CS-02-002.1, Addendum 3, Uterine Transpla
Assessment Questionnaire"

4.5. CS-02-012, "Packaging, Labeling and Transp
Transplantation"

4.6. CS-02-030.1, "Operating Room Organ and Ti

4.7. CS-02-031, "Authorization and Disclosure fo

4.8. CS-02-040.1, "VCA Intraoperative Documen

4.9. CS-02-040 Attachment 1, "Supplemental Aut

4.7 TC-JOB-002, "VCA Transplant Checklist"

4.8 TIC-JOB-008, "TIC VCA Checklist"

5. **Donor Selection Criteria:**

5.1. The VCA Transplant Program will maintain t
candidates, which include:

5.1.1. Deceased donors based on neurologic

5.1.2. Height and weight compatibility with

GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

TC-JOB-002 Rev 1 Eff 11/10/2017

401 North 3rd Street
Philadelphia, PA 19123
215.557.8090

VCA TRANSPLANT CHECKLIST

Pre-Operative

Donor: _____ **UNOS ID:** _____ **GRAFT:** ☐ **Facial** ☐ **Hand/Arm**
Completing TC: _____ **Date:** _____ ☐ **Uterus** ☐ **Penis**

- ☐ **Identify Potential VCA Donor;** Brain Dead Donor Who Meets Preliminary Tissue Screening Criteria
- ☐ **Review VCA Candidate List **Filtered for PADV**** on the UNet Secure Enterprise Under Data Reports
- ☐ Review Donor Acceptance and Exclusionary Criteria for ABO Compatible Patients on List
- ☐ Identify Potential Match(es), Review Donor with VCA Transplant Surgeon to Determine Interest for Their Recipient
  - ☐ VCA Authorization Addendum ☐ ME/Coroner Clearance for VCA Graft ☐ Funeral Home Updated
- ☐ Meets Tissue Donor Criteria. Screened With_____(Tissue AOC)
- ☐ Complete Donor Evaluation With VCA Surgeon
  - Name/Transplant Center and Contact Info_____
  - ☐ Review of All Available Donor Information Including Medical/Social History and Current Admission Course
    - ☐ Review ABO _____ ☐ Review Serology Results ☐ Physical Assessment Findings
    - ☐ Images or XR of Grafts as Requested ☐ Review Required Vasculature Needs
  - ☐ Send 4 Yellow Top Tubes and 2 Red Top Tubes to Transplant Center HLA Lab for Cross-Match
- ☐ TC/IHC to Save UNOS VCA List to P:TIC/VCA, Update All Codes (Bypass/Refusal) for Patients p/t Accepting Center
- ☐ Meet With Hospital Operating Room Staff To Prepare for VCA Recovery
- ☐ Review Equipment Needs With Recovery Team and Update OR
- ☐ Other Recovery Teams Notified Of Intended VCA Recovery/Conference Call Organized by GLDP w All Surgeons
- ☐ Transportation Arrangements Completed - # of Team Members coming to OR _____
- ☐ Prepare Donor For Recovery – ☐ Move Hospital ID to Ankle ☐ Move Aline from Radial to Femoral
- ☐ One (1) Red Top And Two (2) Yellow Top Blood Tubes Required At The Time Of Recovery

Intra-Operative

Completing TC: _____ **Date:**_____

- ☐ VCA Recovery Team to Review Donor Info and Graft Site and Confirm Acceptance of Graft
- ☐ Complete VCA Intraoperative Documentation/Allograft Data
- ☐ Confirm Presence Of Prosthetic If Applicable
- ☐ Review And Confirm Label Information
- ☐ **Facial Recovery** To Occur Prior To Solid Organ Recovery, **BEFORE** Administration of Heparin
  - Facial Recovery Team Will Recover Forearm Graft and Dress Site
  - VCA Team to Sew on Prosthetic and Secure ETT After Facial Graft Recovery
- ☐ **Hand/Arm Recovery** To Occur After Solid Organ Dissection, Prior to X-Clamp, **AFTER** Administration of Heparin
  - Position Hand/Arm Donor With Arm(s) At 90 Degrees And Abducted
  - Test Pneumatic Cuff/Tourniquet System When Prepping Hand/Arm
  - With Femoral A-line Abdominal Recovery Teams Will Not Place Cannulas Until After Hand Recovery
- ☐ **Uterus Recovery** Dissection to Occur After Solid Organ, p/t X-Clamp, Recovery to Occur After Solid Organ
  - Pelvic Exam to be Completed p/t Start of Recovery
- ☐ **Penis Recovery** To Occur Prior To Solid Organ Recovery. **BEFORE** Administration of Heparin
  - VCA Team Responsible for Closing/Covering Wound And Providing Bulk Prosthetic
  - If Requested, VCA Team Responsible for Recovery of Saphenous Veins After Solid Organ Recovery
- ☐ Post Recovery Tissue Pack To Include Nodes (If Available) and Spleen (If Possible, If Not Extra Nodes)
- ☐ Place Recovery Operative Note in The Donor Hospital Chart (PAUP and MDJH Notes Available on Infozone)
- ☐ MDJH Recipients - Vertebral Bodies Recovery to Occur After Organ Recovery, Spine Stabilization Provided
  When Vertebral Bodies are Recovered, Musculoskeletal Donation Will Be Prohibited

Vascularized Composite Allograft Intraoperative Documentation

Donor: _____ **UNOS ID:** _____

ABO, Labeling and Documentation- Verification

We verify that the donor ABO : _____ is identical to and/or compatible with the recipient ABO_____

_____ GLDP staff initials _____Transplant Center/Outside OPO staff initials

We verify the accuracy of the UNOS ID# on the labels and packaging and we verify the integrity and contents of the container prior to transport of the Vascularized Composite Allografts.

_____ GLDP staff initials _____ Transplant Center/Outside OPO staff initials

We verify the accuracy of the internal and external UNOS organ labels, as well as the VCA graft destination as entered into Transnet.

_____ GLDP staff initials _____ Transplant Center/Outside OPO staff initials

Vascularized Composite Allograft Data

☐**Heparin Administration Time :_____ (N/A for Face and Penis Recovery)**

Graft Type: ☐ Facial Graft ☐ Forearm Graft (L or R) (Circle One) ☐ Left Arm ☐ Right Arm ☐ Penis ☐ Uterus

Incision Date/Time	Recovered Date/Time	Back table Flush Date/Time	Preservation Solution	Flush Volume (mls)	Storage Volume (mls)

Solution Manufacturer:	Lot#:	Exp Date:
Graft Description (size, area, anatomy):		
Anatomical abnormality ☐ Yes ☐ No	Surgical damage ☐ Yes ☐ No	
Recovery Surgeon:	Transplant Program:	

Graft Type: ☐ Facial Graft ☐ Forearm Graft (L or R) (Circle One) ☐ Left Arm ☐ Right Arm ☐ Penis ☐ Uterus

Incision Date/Time	Recovered Date/Time	Back table Flush Date/Time	Preservation Solution	Flush Volume (mls)	Storage Volume (mls)

Solution Manufacturer:	Lot#:	Exp Date:
Graft Description (size, area, anatomy):		
Anatomical abnormality ☐ Yes ☐ No	Surgical damage ☐ Yes ☐ No	
Recovery Surgeon:	Transplant Program:	

Additional Comments:

GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

UNOS Policy – Authorization for VCA

2.14.E Deceased Donor Authorization Requirement

The host OPO may only recover organs that it has received authorization to recover. An authorized organ should be recovered if it is transplantable, or a potential transplant recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery.

Extra vessels may only be recovered with at least one organ. To recover and use extra vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the extra vessels will be used for transplant.

Recovery of covered VCAs for transplant must be specifically authorized from individuals authorizing donation, whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for covered VCAs must be documented by the host OPO.

VCA Authorization

List reviewed and VCA offers made **PRIOR to** family approach

Donor family is approached only **AFTER** VCA team has expressed intent to accept graft

Approaches made to families who have already expressed support of donation

Authorization Form

SUPPLEMENTAL AUTHORIZATION FOR VASCULARIZED COMPOSITE ALLOGRAFT DONATION

The following authorization is made in conjunction with the attached Authorization or Disclosure for Organ and/or Tissue Donation form and incorporates all authorizations and disclosures made therein.

I _____, being the _____ and authorized Next of Kin of _____, authorize the
(Printed name of Next of Kin) (Relationship) (Printed Name of Donor)

donation of the following Vascularized Composite Allograft(s) (VCA) to Gift of Life Donor Program (GLDP) for the purposes of transplantation.

Right Hand and Arm Yes □ No □ N/A □ **Left Hand and Arm** Yes □ No □ N/A □

Facial and Forearm Yes □ No □ N/A □ **Uterus** Yes □ No □ N/A □ **Penis** Yes □ No □ N/A □

I understand that the recovery of the facial graft will involve the removal of the face which may include skin/mucosa, underlying muscles, nerves and bone, blood vessels and fat tissue of the nose, lips and surrounding cheek. The facial graft may be small or may be a significant portion of the donor's facial tissue depending on the need of the individual recipient.

I understand that the forearm graft will include skin, the radial artery and vein and some fat tissue located under the skin. This graft will be recovered from the palm side of the forearm just above the crease of the wrist. This will be used as a biopsy site to test for rejection of the facial graft.

I understand that the recovery of the hand and arm grafts will involve the removal of the hand and arm above or below the elbow and below the shoulder and include skin, underlying muscles and nerves, blood vessels and bone. The length of the graft will vary depending on the need of the individual recipient.

I understand that the recovery of the uterus graft will include the recovery of associated blood vessels as well as the cervix and portion of the vagina. The ovaries may be recovered for the purposes of included vasculature to support the transplantation but will not be transplanted into the recipient with the uterus graft.

I understand that the penis graft will include the penis shaft, blood vessels, nerves and surrounding skin and muscle tissue from the pelvic area surrounding the penis. Skin from the scrotum may also be recovered. The reproductive tissue, ie. the testes and sperm, will not be removed.

I understand that this
the use of surroundin
minimizing changes t
donor's appearance.

I understand that this donation will alter the appearance of the affected area on the donor and that reconstruction will occur with the use of surrounding skin tissue for wound closure. When applicable, prosthetics will be attached for the purposes of minimizing changes to the outward appearance of the donor's body. I understand that despite this, there will be changes to the donor's appearance.

I understand that this
for research, training,

I understand GLDP and/or other involved agencies may record and use images (e.g. pictures and/or video) of the gifts and the recovery process which do not disclose the donor's identity. I consent to the use of such images by GLDP and/or other involved agencies to

I understand that GL
consent. However, I
may receive significa
and/or recipient may

I understand that GLDP will not make public any information concerning the identity of the donor or donor family without my consent. However, I understand that due to the unique nature of vascular composite allograft transplantation, the recipient may receive significant media attention and that despite the best efforts of GLDP, the identities of the donor, donor family and/or recipient may become known.

I acknowledge that I
have answered any questions and that I fully understand this document.

I consent to the donation as described above.

Signature of the Next of Kin: _____ Initials: _____

Completed by: _____ Signature: _____
(Printed name of GLDP representative)

Witnessed by: _____ Signature: _____
(Printed name & title of hospital representative)

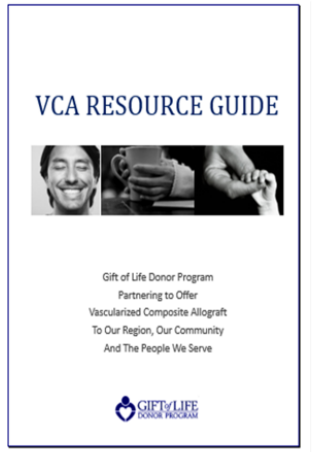
Date & Time of Authorization: _____ ❑Check Box if telephonic authorization completed and recording of authorization obtained; Print name(s) of Next-of-Kin

GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

401 North 3rd Street, Philadelphia, PA 19123, 800- DONORS-1 CS-02-040 Att 1 Eff 11-1-17

GLDP Family Communication & Authorization Practices

Supplemental Authorization



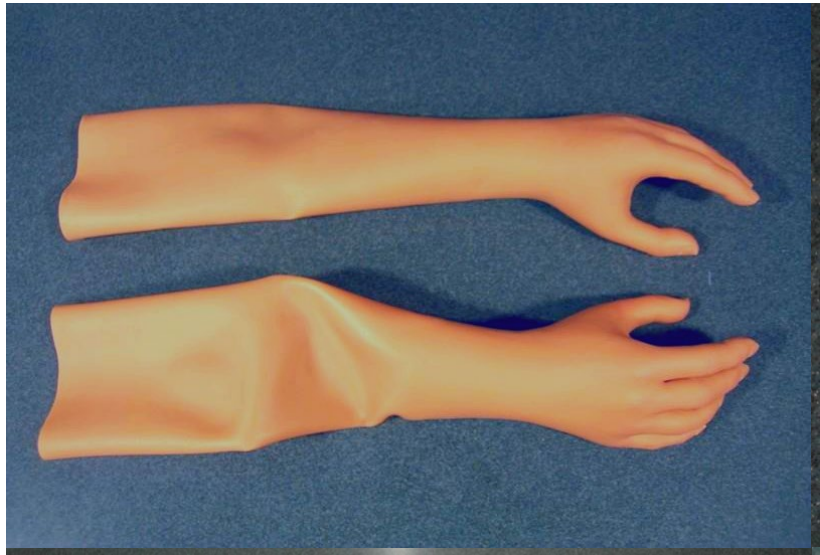
- Supplemental Authorization for VCA Donation obtained **AFTER** initial acceptance of donor from VCA team
- Family made aware that further testing is still pending and may affect the ability for donation to move forward
- Authorization includes awareness of unique nature of VCA transplantation and potential for recipient media attention

See *VCA Resource Guide* for descriptive sentences that can help with family communication located on the *Clinical Infozone > Inter-Departmental Tools and Resources > Clinical Tools*

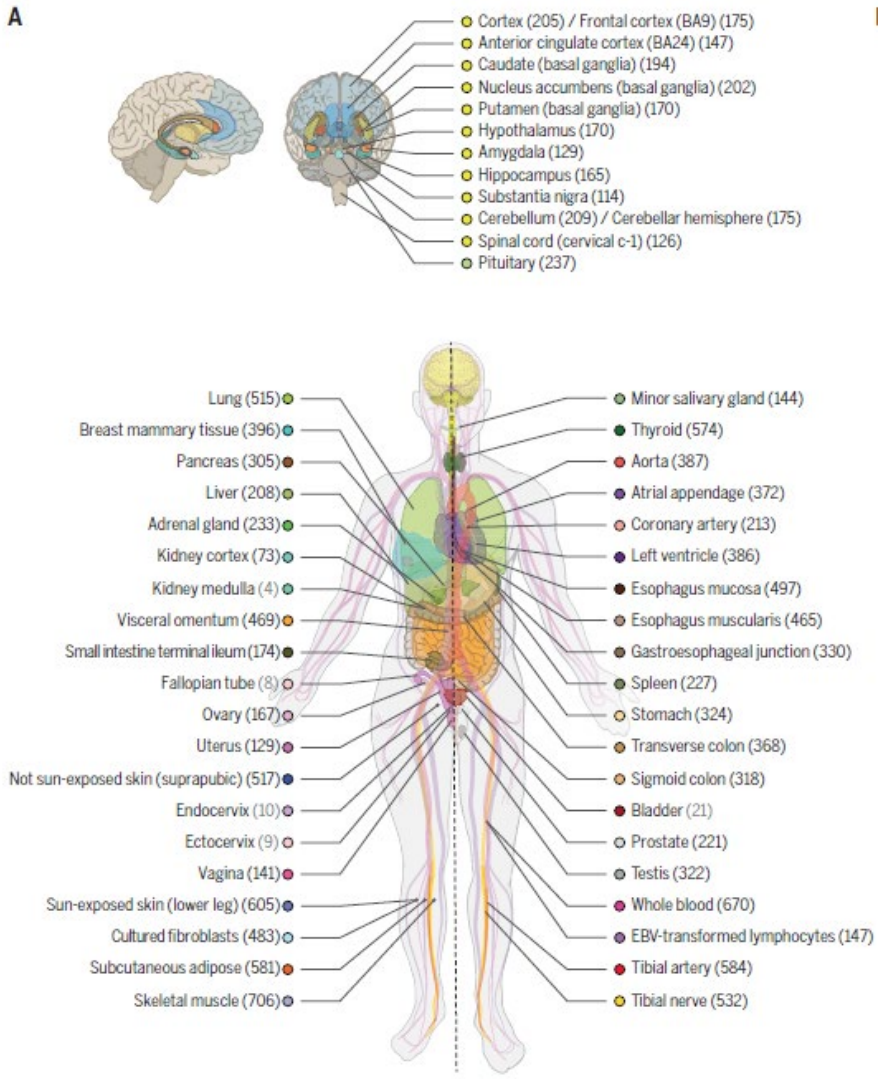
Clinical Infozone

"Thank you so much for your generous gifts. I want to share with you that Sam and your family may also have the *extraordinary and powerful* opportunity to impact the life of someone through the gift of a hand transplant. Most of us cannot imagine what it might be like to suffer an injury that would claim one or both of our hands. Often, amputees share that their prosthetics can cause discomfort because of poor fit—often feeling bulky and awkward. The gift of a hand transplant is the hope of independence to care for themselves or hold a loved one, and so much more."

Donor Prosthetics



GTEx Tissue Collection



GTEx collection approach yielded an extensive data set of RNA to evaluate how gene expression is regulated in different tissue and cell types

Project Gains:

- Development of standardized tissue collection methods for DNA and RNA analyses
- Biospecimen processing advances for RNA analysis
- Tools for the research community to analyze gene activity
  - PrediXcan – statistical method
  - GTEx Portal – access to the reference data set

Data from *GTEx Consortium. The GTEx Consortium atlas of genetic regulatory effects across human tissues. Science 2020 September: 369:1318-1330.*

dGTEx Authorization

For telephonic authorization, please have the authorizing person verbalize the following:

I,_____, being the_____ of _____,
(print name of authorizing person) *(relationship)* *(print name of donor)*

authorize Gift of Life Donor Program and NDRI for the donation of the tissue types and associated connective tissue indicated below. Please state yes or no to each:

Stomach and digestive tract	□Yes	□No	Whole brain	□Yes	□No
Muscles	□Yes	□No	Whole heart with associated vessels	□Yes	□No
Neurological tissue	□Yes	□No	Whole lungs with airways	□Yes	□No
Adipose (fat)	□Yes	□No	Pancreas	□Yes	□No
Skin	□Yes	□No	Reproductive tissue	□Yes	□No
Blood	□Yes	□No	Spleen and lymph nodes	□Yes	□No
Liver	□Yes	□No	Aorta	□Yes	□No
Kidney	□Yes	□No	Endocrine glands	□Yes	□No

Tissue list

Testing and release of medical records for suitability

I authorize the performance of all necessary tests and procedures. This may include testing for HIV and viral hepatitis to determine medical suitability of the tissues for research purposes. I authorize the release and copy of any medical information, including medical and social history, and hospital records to NDRI to determine tissue suitability for medical research. I understand that some tissue may be found unsuitable for use in the project, and that in such an event the tissue samples would be disposed of.

Recovery Plans

Upper Extremity

- Immediately prior to X-Clamp, after solid organ dissection complete

Facial Recovery

- Completed prior to solid organ recovery
  - *Solid organ teams required to be present to preserve donation opportunity

Uterus Recovery

- Additional dissection in the warm. Uterus flushed via femoral or iliac cannulation. Recovered after solid organs, prior to vessels.

Penis Recovery

- Completed prior to solid organ recovery
  - *Solid organ teams required to be present to preserve donation opportunity

VCA Recovery

Recovery plan must be reviewed and approved prior to the OR

CONFERENCE CALL held with ALL Recovery Teams

In the event of instability, the **solid organ recovery** will **ALWAYS** take precedence over the VCA recovery

Multi-OPO & Transplant Center Collaboration

GLDP case involving travel across multiple states, 2 OPOs involved

GIFT of LIFE DONOR PROGRAM
A Legacy of HEROES. A Future of HOPE.

Bilateral Hand/Face Transplant

nj.com True Jersey.

Union

Three-quarters of this 20-year-old's body burned in a car wreck. His recovery has just begun.

Updated Jan 24, 2019; Posted Jan 24, 2019

Joseph DiMeo, 20, was at Saint Barnabas Medical Center in Livingston after he suffered third degree burns on over 75 percent of his body. (Courtesy DiMeo family)

Didactics for new staff: process and family communication

Ongoing education for existing staff

Email updates about VCA needs

Review of donor cases in real time to facilitate VCA screen

Stress importance of being proactive with VCA screen and allocation, happening as soon as a case begins to avoid delays

Resources

VCA RESOURCE GUIDE

Gift of Life Donor Program
Partnering to Offer
Vascularized Composite Allograft
To Our Region, Our Community
And the People We Serve

GIFT of LIFE DONOR PROGRAM

Clinical Infozone

Hand/Upper Extremity Recovery Quick Reference Guide

Pre-OR

- Utilize VCA Transplant Checklist (TC-JOB-002) and VCA Intraoperativ (CS-02-040.1)
- Always review recovery plan and any additional equipment needs w team prior to the OR.
- Prior to the OR, remove all nail polish or jewelry from the hand/arm
- Remove any IV lines from the arm(s) to be recovered.
- Ensure A-line has been moved to the opposite arm or placed femora recovery.

OR

- Patient is prepped and draped for arm recovery at same time as sol
- Position patient with arm(s) to be recovered at 90-degrees abductio
- Place pneumatic cuffs on arm(s) and test the tourniquet system, bu remain inflated at this time.
- Allow for solid organ teams to perform all dissection necessary to p clamp, up to the preparation and/or placement of cannulas.
- If both hands/arms are being recovered, and patient has a femoral cannulas until after the upper extremity recovery, so we don't lose monitoring.
- Administer HEPARIN and allow to circulate for 5mins p/t inflation o
- Recovery team will perform the recovery of the hand/arm(s) – reco but typically takes ~15-45mins. Once the hands/arms are recovered will move to cross-clamp.
- If recovery time is extended review with AOC for potential need to
- Pneumatic cuffs will remain inflated until the organ recovery is com

Post Recovery

- If discussed and requested by family, update funeral home on wha prosthetics placed, and dressings to be expected

**** In the event of instability, VCA recovery will be aborted to preserve so**

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Uterus Recovery Quick Reference Guide

Utilize VCA Transplant Checklist (TC-JOB-002) and VCA Intraoperative Docu

Always review recovery plan and any additional equipment needs with the VC

In the OR

1. **Uterus recovery team:**
   a. Will perform a vaginal exam in the OR prior to the start of recovery.
   b. May request patient be positioned on a lithotomy table fo may just utilize available staff to manually position patient
   c. Will extend the midline abdominal incision to also include abdominal incision for access to the uterus.
   d. Will scrub in with the solid organ teams, but then will nee ~2hrs of dissection time prior to X-clamp.
2. **Uterus and Organ Flushing**
   a. The uterus and solid organ flushes will occur simultaneous use bilateral femoral cannulas that will also provide the aor isolated flush via the iliacs.
   b. When using femoral cannulas, a *back-up, aortic cannula* m and ready, in the event the femoral flushes are not creatin to the abdominal organs.
3. **Recovery Order**
   a. The uterus will be recovered after all of the solid organs h removed from the body, AND BEFORE vessels, nodes and recovered.

**** In the event of instability, VCA recovery will be aborted to preserve**

Face Recovery Quick Reference Guide

F A C E

Pre OR

1. Utilize VCA Transplant Checklist (TC-JOB-002) and VCA Intraoperative Documentation (CS-02-040.1).
2. Always review recovery plan and additional equipment needs with VCA recovery team prior to OR.
3. Give the standard doses of Ancef and Solumedrol in the ICU 1hr prior to OR.
4. ALL organ recovery teams must arrive on site prior to moving patient to OR.
   a. Any deviation from that plan must be discussed with the AOC.
   b. You may need to find somewhere in the OR for the teams to rest depending on time of day and length of facial graft recovery.

OR

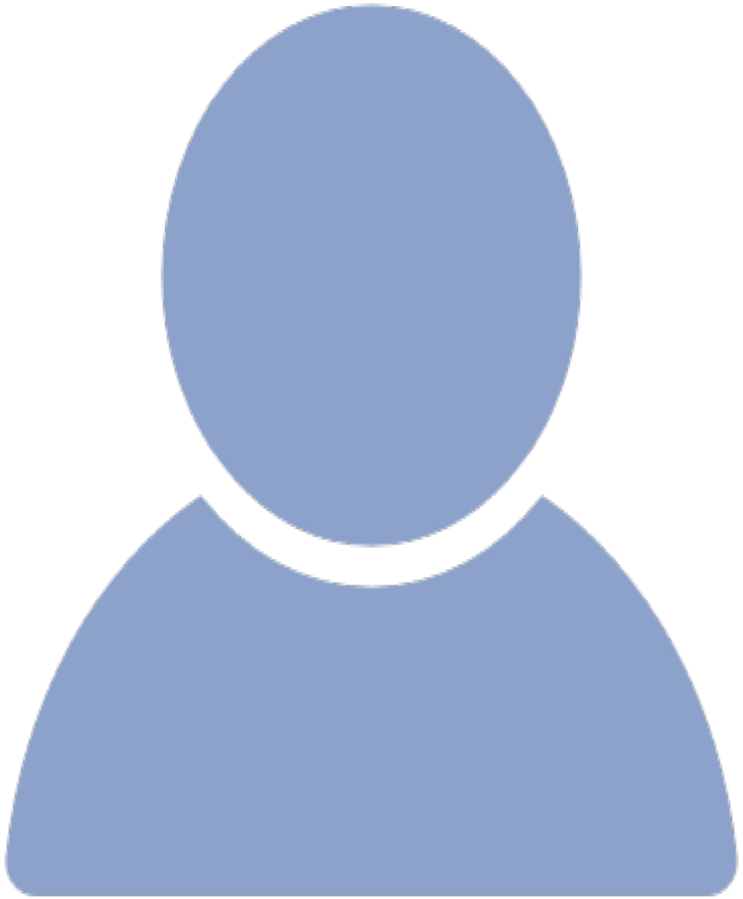
1. Face recovery occurs **BEFORE** solid organ recovery begins.
   a. Recovery time ~4-8 hours (depending on extent of graft)
2. Reverse OR table to position patient with feet at anesthesia.
   a. Patient will be turned and re-prepped for the solid organ recovery.
3. Meds
   a. **No** HEPARIN administration before face recovery.
   b. **No** neuro muscular blockade.
   c. If Vasopressin is running, it can be continued until 1hr p/t start of solid organ recovery.
   d. Mannitol/Lasix will **Not** be administered until solid organ recovery begins.
   e. Administer Ancef q8hrs and Solumedrol q8hrs after pre-op doses.
4. For extended recoveries continue to monitor ABGs and labs as needed.
5. Facial recovery team is responsible for securing the ETT for during and after facial graft recovery.

Post Recovery

1. Recovery team will cover the graft site with silicone mask and secure dressing.
2. If requested, the facial recovery team may recover a 3cm x 6cm patch from the donor's forearm and are responsible for dressing the site.

**** In the event of instability, VCA recovery will be aborted to preserve solid organ recovery****

VCA "Champion" Coordinator



- Tasked with overseeing the VCA program

Involved in the creation of policies and procedures as well as checklists to streamline the VCA process

Provides VCA-related training

Acts as a VCA resource and supports the team as needed (via phone and on site) through screening, allocation, authorization, and OR

Collaborates with local VCA transplant centers

GIFT of LIFE DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

There is nothing more powerful than the human spirit and our individual ability to help… to heal… to provide hope.

Zion Harvey at the 2016 Annual AOPO Meeting

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THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

THANK YOU

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