

OPTN/UNOS Living Liver and Kidney Donation Update

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Disclosure

- I am on the Board of Directors of UNOS/OPTN
- The data slides come from the OPTN
- Opinions are mine and not that of UNOS or the OPTN





2022 | A year of lifesaving milestones



Exceeded
42,800
transplants*



Surpassed
25,000
kidney transplants
for the first time*



Also set
all-time records
for liver, heart and
lung transplants*

*Based on OPTN data as of Jan. 9, 2023.

Data subject to change based on future data submission or correction

OPTN *Organ Procurement & Transplantation Network*

Regulatory Framework for the Donation and Transplant System

- The Organ Procurement and Transplantation Network (OPTN) is a public-private partnership linking all U.S. donation and transplantation professionals
- Coordinates the allocation of organs and collects clinical data
- Overseen by the Health Resources & Services Administration (HRSA) in the U.S. Department of Health and Human Services (HHS).
- The National Organ Transplant Act (NOTA) established the OPTN in 1984. NOTA requires that the OPTN be run by a private, non-profit organization under federal contract.
- The United Network for Organ Sharing (UNOS) has served as the OPTN since 1986.

Regulatory Framework for the Donation and Transplant System

- HHS established the OPTN's regulatory framework through a federal Final Rule in 2000.
 - The OPTN operates through its Board of Directors and Committees.
 - The OPTN Board of Directors establishes policies (operational rules) and bylaws (membership requirements).
 - The OPTN uses survey instruments, peer reviews and data to review OPTN membership applications and member compliance with OPTN bylaws and policies.

OPTN Role in Living Donation since 2006

- June 2006 -HRSA published a notice in the Federal Register in which the Secretary of HHS directed the OPTN to develop policies regarding living organ donors and organ donor recipients.
- The notice states that the consequence of centers non-compliance with living donor policy matches that of centers non-compliance with deceased donation policy.
- The Federal Register notice states the emphasis of living donor guidelines and policies should be “to promote the safety and efficacy of living donor transplantation for the donor and recipient.”

OPTN and UNOS: Who is Who?

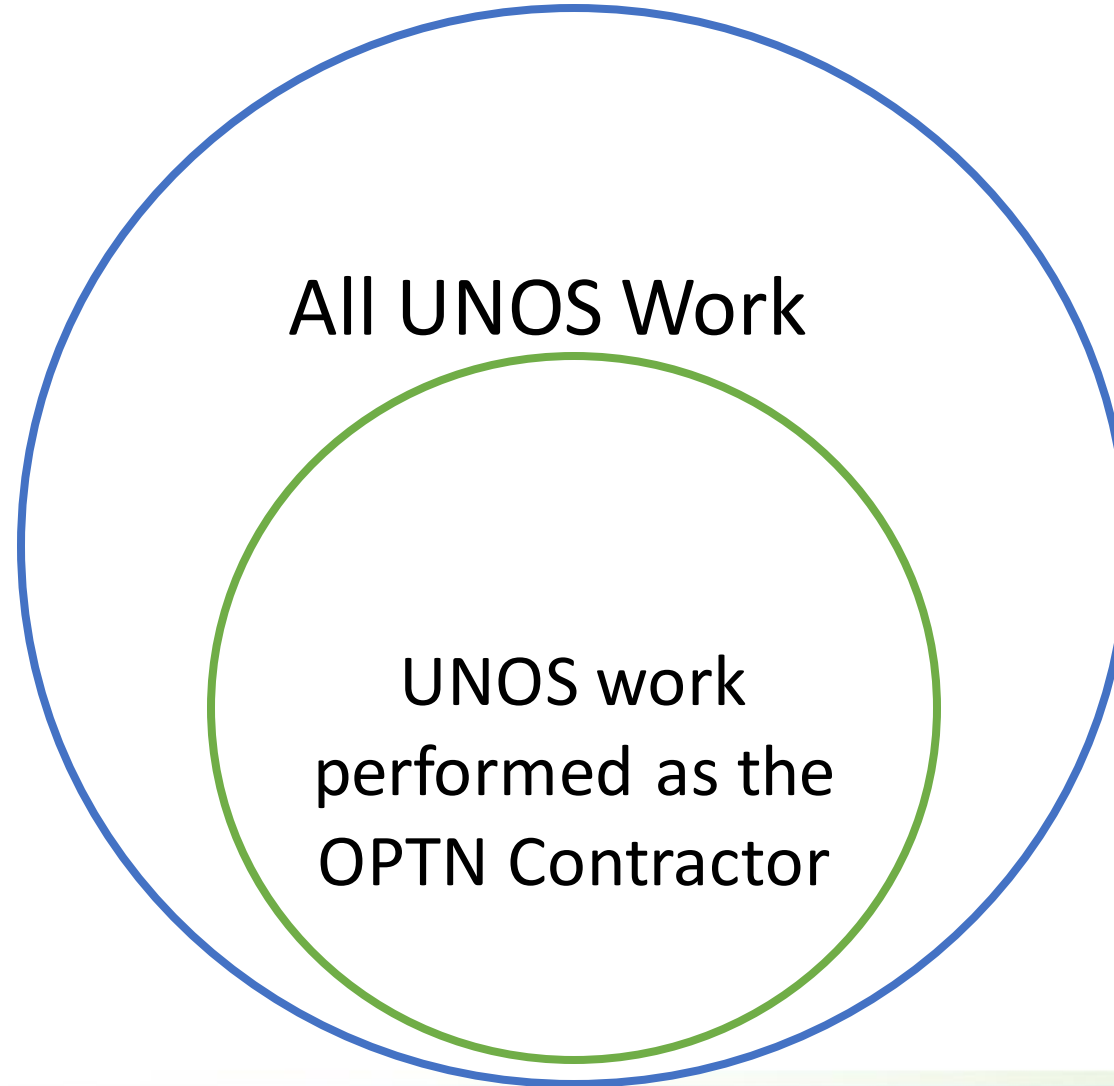
What is the OPTN?

- The OPTN is the entity tasked with managing the national registry for organ matching
- The OPTN is limited in function by statute, regulation, contract, and its own policies and bylaws.

Who is UNOS?

- UNOS is the non-profit contracted to operate the OPTN
- UNOS-private work is limited in function only by its own policies and bylaws

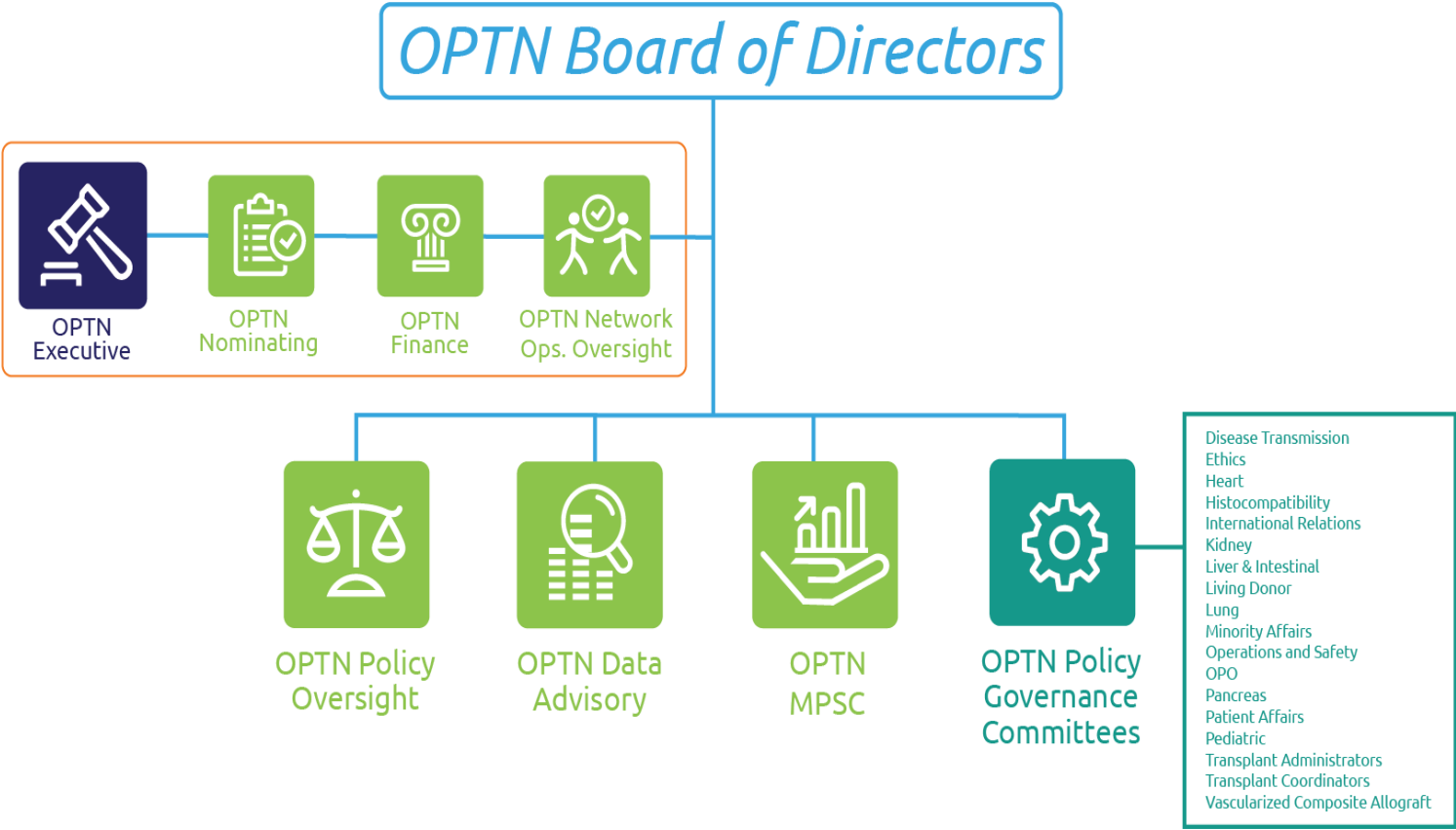
UNOS as the OPTN Contractor



Governing Authorities- OPTN vs. UNOS

| | NOTA | Final Rule | OPTN Contract | OPTN Policies and Bylaws | UNOS Policies and Bylaws |
|------|------|------------|---------------|--------------------------|--------------------------|
| OPTN | ✓ | ✓ | ✓ | ✓ | |
| UNOS | | | | | ✓ |

OPTN Governance Structure



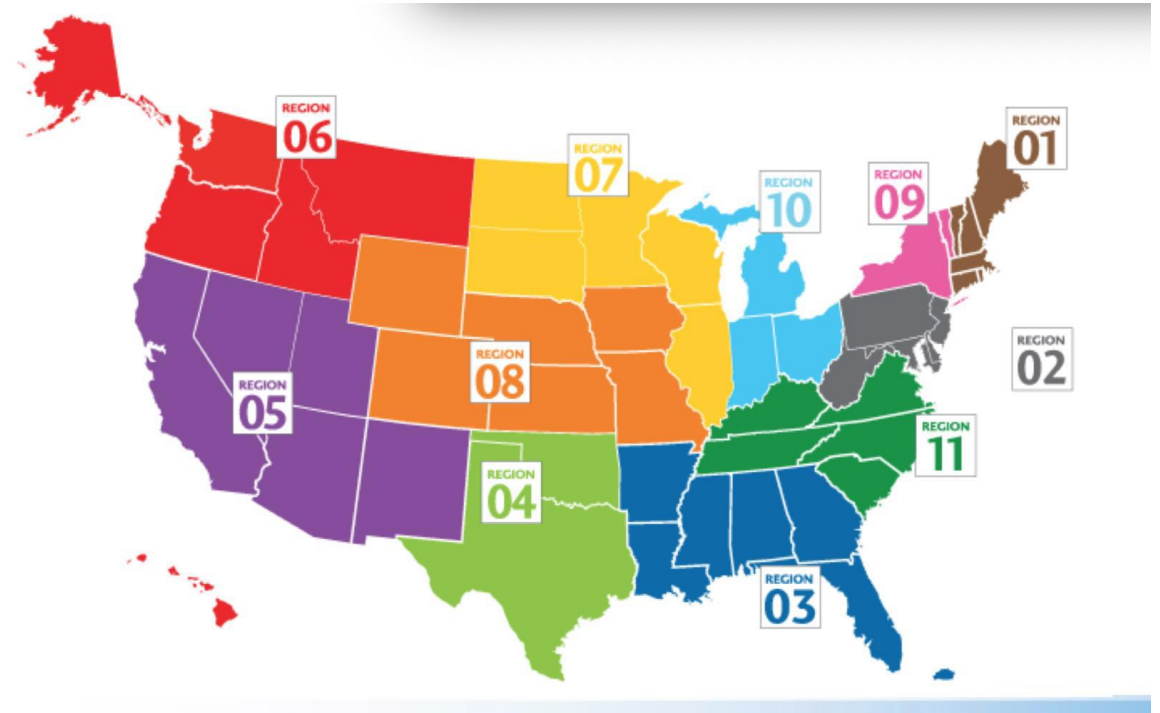
Living Donor Committee

Develops policy and guidance related to the donation and transplantation of organs from living donors to recipients.

The goal of the Committee's work is to continue to improve the informed choice of prospective living donors, and the safety, protection, and follow-up of all living donors.

■ = OPTN Operating Committees □ = OPTN Committees of the Board

Community Driven Policy Development



The Patients Voice in Transplant Policy

- Bylaws: At least 25% of the BOD consists of Patients
 - transplant candidates, transplant recipients, organ donors, and family members representing the diversity of the population of transplant candidates, transplant recipients, organ donors, and family members served by the OPTN, including, to the extent practicable, the minority and gender diversity of this population.
- Each Governance committee has 2 patient members except LD committee (1/3 members)



CONSENSUS STUDY REPORT

Realizing the Promise of Equity in
the Organ Transplantation System



NASEM Report on Donation and Transplantation

- Publicly released February 25, 2022.
- Ordered by Congress (Consolidated Appropriations Act, 2020*)
- Sponsored by the NIH (NIAID)
- Focused on deceased organ donation not living donation
- Analyzed evidence from a systems perspective and guided by the principle of putting the patient at the center of system improvement
- Focused on problems and making improvements

• GOALS:

- **Need to Improve Equity in the system**
- **Need to improve efficiency and system performance**
- **Need to use more donated organs**



Transplantation in the News



Transplant in the Headlines

- **Senate Finance Committee Hearing: A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network**
 - Wednesday, August 3, 2022
- **Organ transplantation is at a crossroads. Major reform is needed**
 - *By Blair L. Sadler and Alfred M. Sadler, Jr. Aug. 18, 2022*
- **New Liver transplant rules yield winners, losers and wasted organs reach record high**
 - Washington Post March 22 2023
- **The government's plan to fix a broken organ transplant system? Break it up.**
 - March 23 2022
- **Troubled U.S. organ transplant system targeted for overhaul**
 - Washington Post March 22, 2023

Current Events

HRSA Announces Organ Procurement and Transplantation Network Modernization Initiative

U.S. Department of Health and Human Services
Health Resources and Services Administration

HRSA NEWS ROOM
[newsroom.hrsa.gov](https://www.hrsa.gov/newsroom)

FOR IMMEDIATE RELEASE
March 22, 2023

Contact: HRSA PRESS OFFICE
Phone: [301-443-3376](tel:3014433376)
Email: Press@hrsa.gov

Initiative includes the release of new organ donor and transplant data; prioritization of modernization of the OPTN IT system; and call for Congress to make specific reforms in the National Organ Transplant Act

OPTN Modernization Aims

The OPTN Modernization Initiative will accelerate progress in five key areas to achieve the following aims:

- **Technology** – The OPTN IT system is reliable, secure, patient-centered, user-friendly, and reflective of modern technology functionality.
- **Data Transparency and Analytics** – OPTN data is accessible, user-friendly, and patient-oriented. Modernization process provides easily accessible, high-quality, and timely data to make informed patient, donor, and clinical decisions
- **Governance** – The OPTN Board of Directors is high-functioning and has greater independence; represents the diversity of communities; and delivers effective policy development.
- **Operations** – The OPTN is effective and accountable in its implementation of organ policy, patient safety and compliance monitoring, organ transport, OPTN member support, and education of patients, families, and the public.
- **Quality Improvement and Innovation** – The OPTN promotes a culture of quality improvement and innovation across the network by leveraging timely data and performance feedback, collaborative learning, and strategic partnerships.

How this affects
living donation
policy and rates is
unknown

OPTN Living Donor Policy

Living Donor OPTN Policy

Policy 14: Living Donation

| | | |
|-------|--|-----|
| 14.1 | Psychosocial Evaluation Requirements for Living Donors | 264 |
| 14.2 | Independent Living Donor Advocate (ILDA) Requirements | 265 |
| 14.3 | Informed Consent Requirements | 266 |
| 14.4 | Medical Evaluation Requirements for Living Donors | 271 |
| 14.5 | Living Donor Blood Type Determination and Reporting | 279 |
| 14.6 | Placement of Living Donor Organs | 280 |
| 14.7 | Living Donor Pre-Recovery Verification | 281 |
| 14.8 | Packaging, Labeling, and Transporting of Living Donor Organs, Extra Vessels, and Tissue Typing Materials | 282 |
| 14.9 | Requirements for Domino Donors and Non-Domino Therapeutic Donors | 283 |
| 14.10 | Living Donor Organ Check-In | 285 |
| 14.11 | Living Donor Pre-Transplant Verification | 285 |
| 14.12 | Reporting Requirements | 285 |

Other OPTN Policy Related to Living Donation

- Prior Living Donor Priority (*Policy 8 for kidney allocation; Policy 10 for lung allocation*)
- Kidney Paired Donation (*Policy 13*)
- Identification and Reporting of Transmissible Diseases (*Policy 15*)
- Packaging and Labeling Requirements for Organs and Extra Vessels (*Policy 16*)
- Data Submission and Reporting Requirements (*Policy 18*)

Recent updates to LD policy

- Modifications to living donor exclusion criteria
 - Implemented July 2022
- Modifications are related to malignancy and diabetes exclusion criteria
 - Intent is to allow transplant programs more autonomy in evaluating potential living donors with low-grade malignancies that have a minimal risk of transmission
 - Type 1 diabetes remain an absolute contraindication to living kidney donation while modifications allowed transplant programs to evaluate select type 2 diabetic individuals for living kidney donation
- Additional modifications align language within OPTN policy

Continuous Distribution Policy Development

new allocation models for all organs



In continuous distribution, every patient will receive a **composite allocation score**

- Each attribute will have a specific weight relative to the entire formula
- Some attributes will have more effect than others on the total score
- No one attribute will decide an organ match
- The total score will determine a candidate's position on the waitlist
- System will be more flexible agile and equitable
- Lung went live March 2023
- **Priority will be given for prior living donors**

UNOS Released a Statement March 2023:

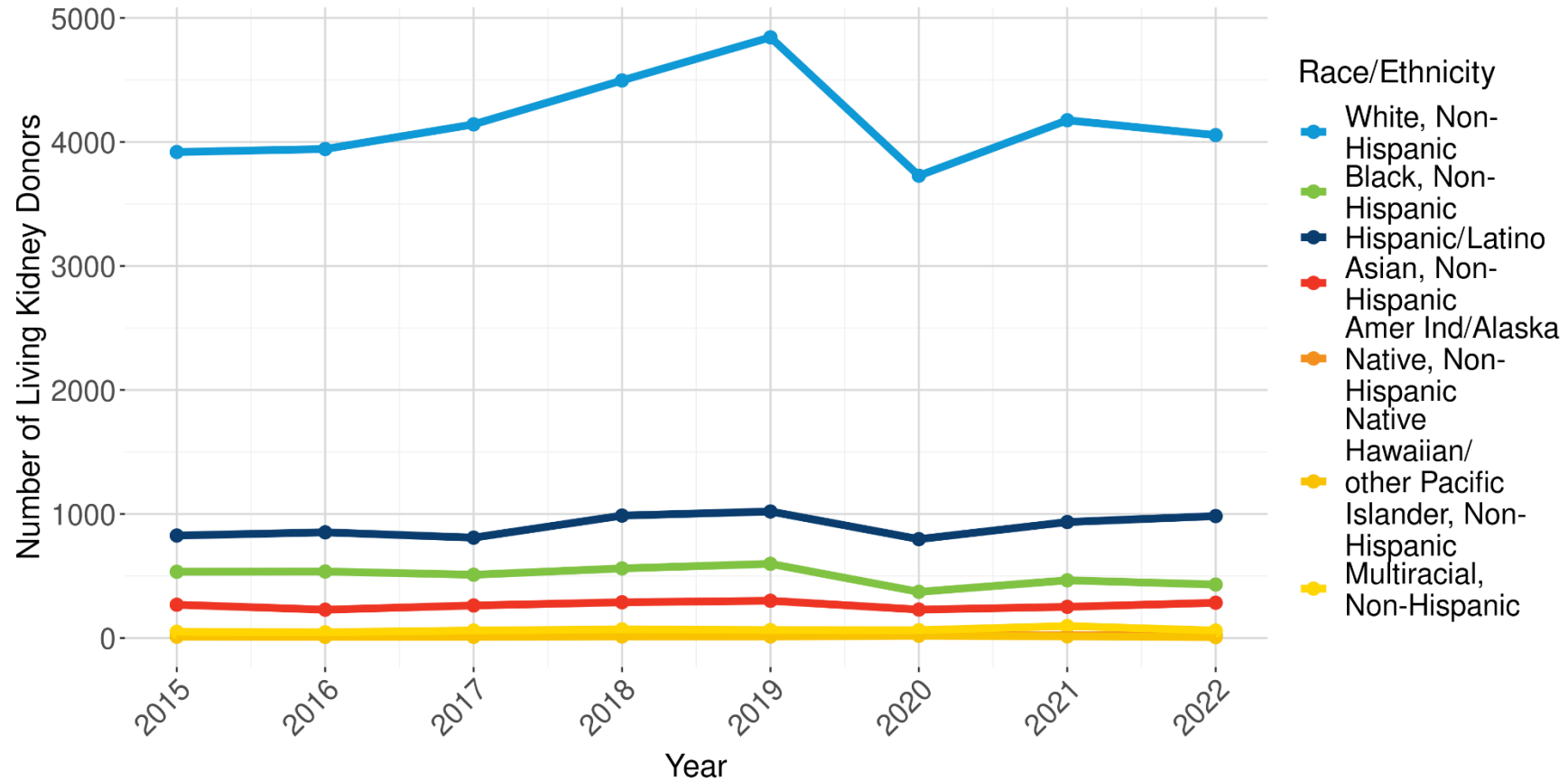
We wish to assure the community that the OPTN Kidney Transplantation Committee intends for both prior and future living donors to receive the same level of priority for a deceased donor organ in the new framework as they receive in the current allocation system.

Living Donor Overview Data



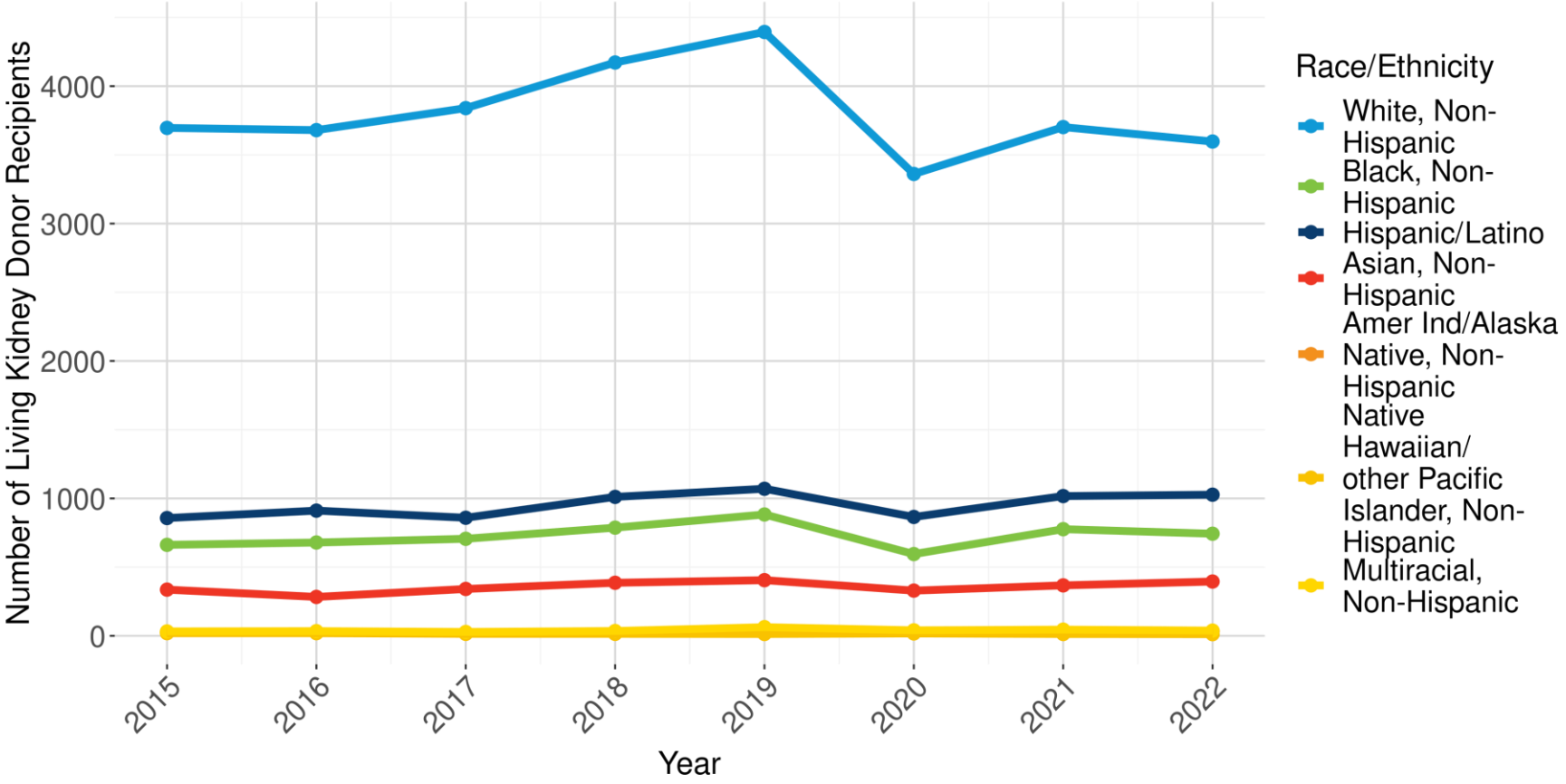
the peak of Mount Kilimanjaro on March 9, 2023.

Living Kidney Donors by Race



This chart excludes any domino or therapeutic donors

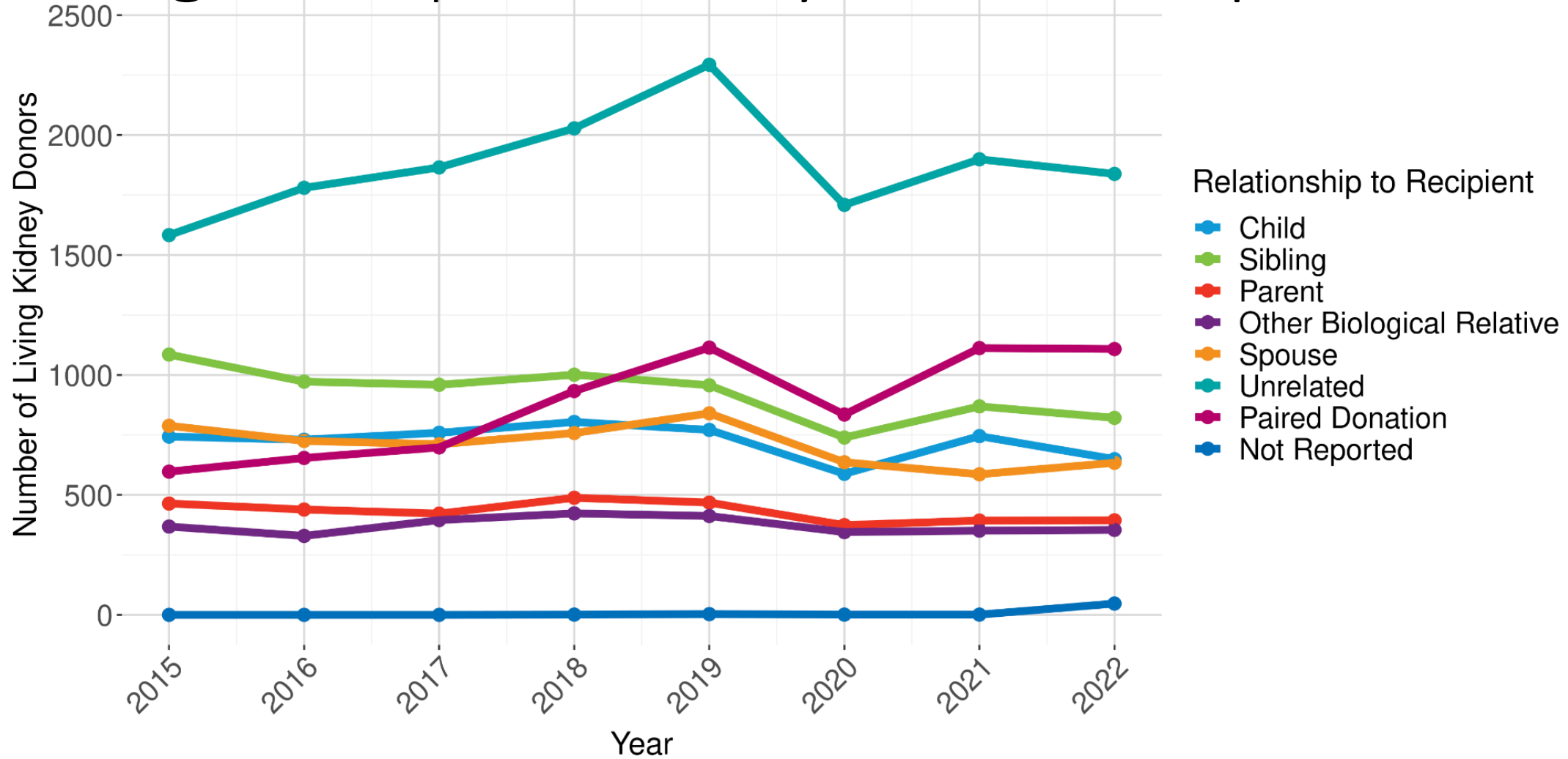
Living Kidney Donor Transplant Recipients by Race



| Kidney Waitlist | |
|---|-------|
| White, Non-Hispanic | 35.8% |
| Black, Non-Hispanic | 30.8% |
| Hispanic/Latino | 22.2% |
| Asian, Non-Hispanic | 9.3% |
| American Indian/Alaska Native, Non-Hispanic | 0.9% |
| Pacific Islander, Non-Hispanic | 0.6% |
| Multiracial, Non-Hispanic | 0.9% |

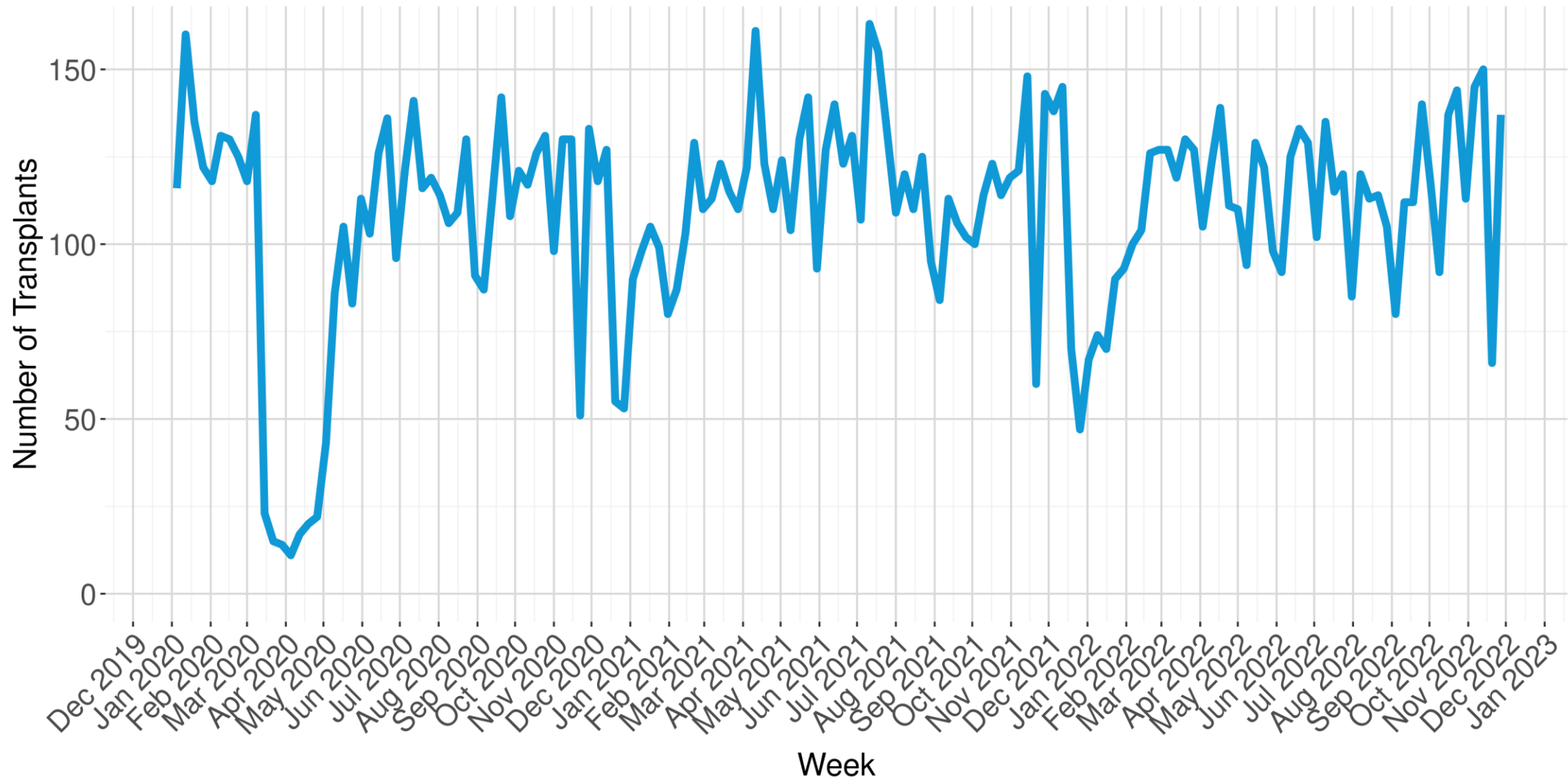
This chart excludes any domino or therapeutic donors

Living Kidney Donors by Relationship



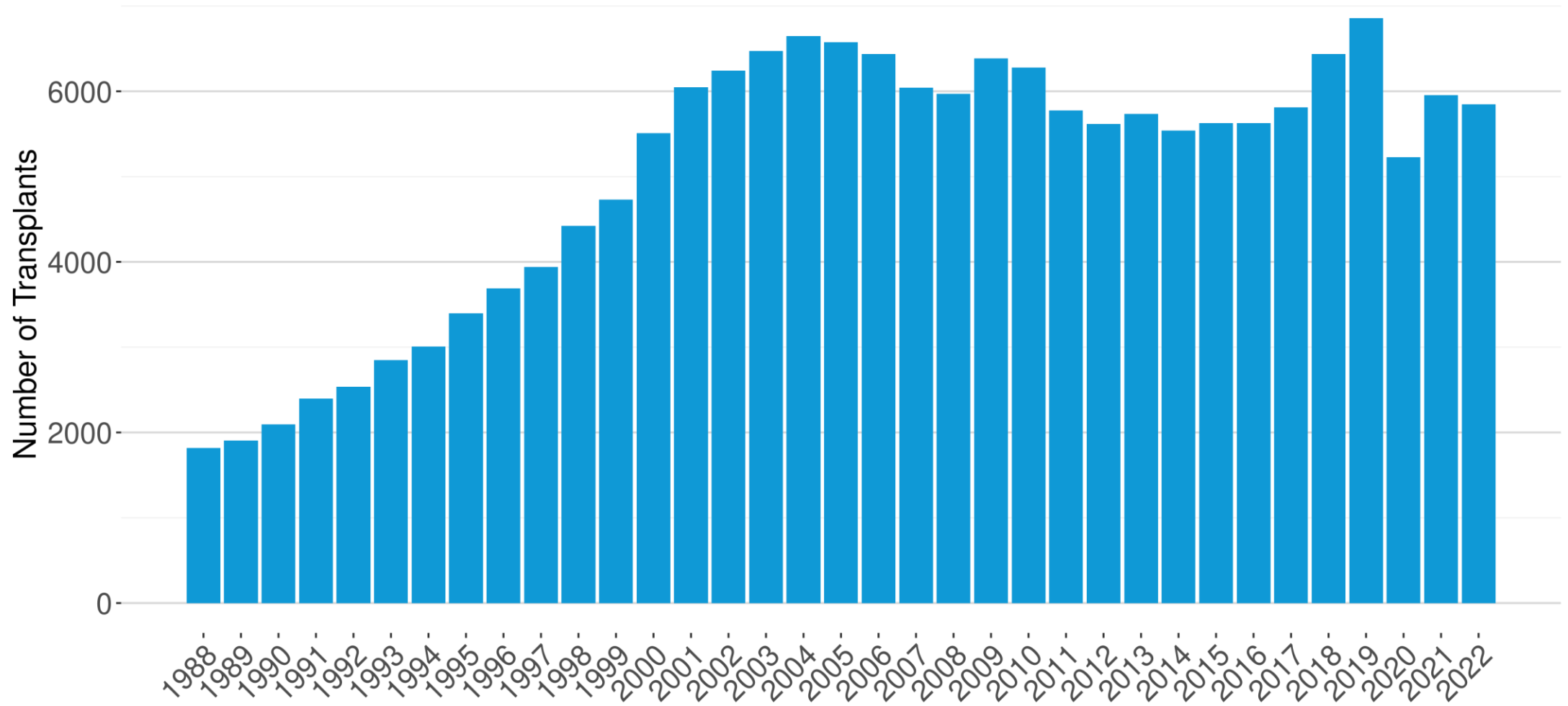
This chart excludes any domino or therapeutic donors

Living Kidney Donor Transplants by Week

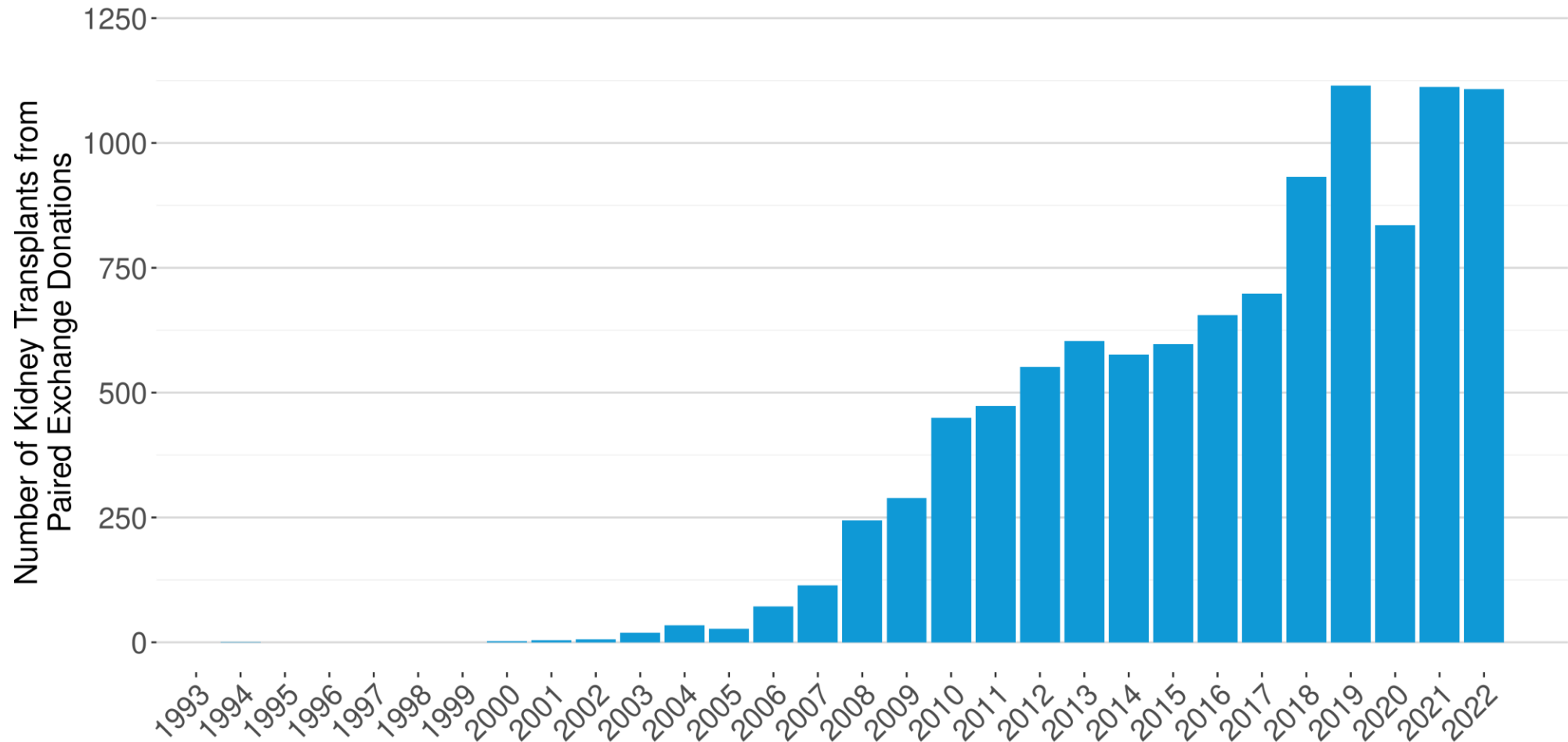


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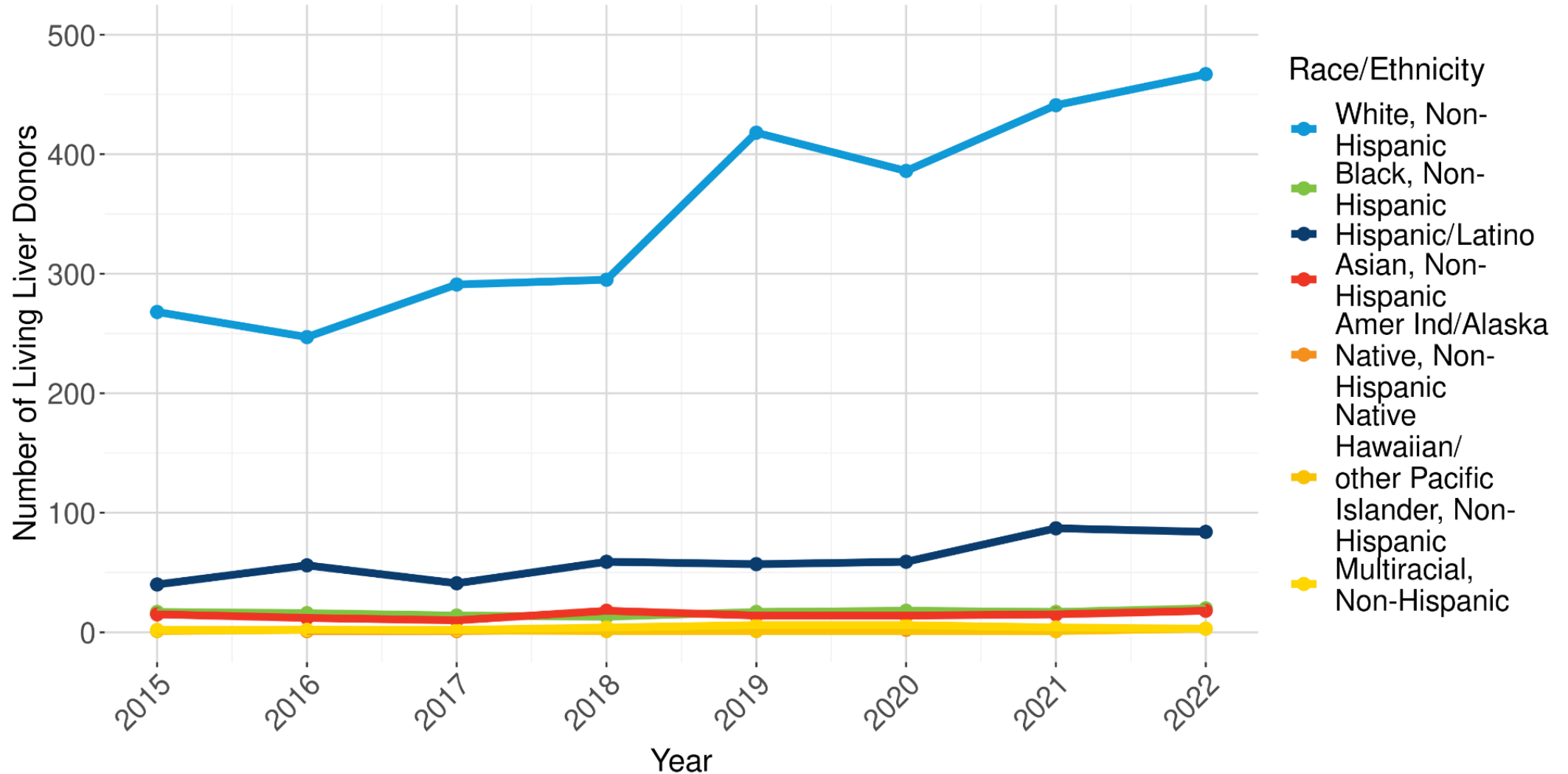
Living Kidney Donor Transplants by Year



Number of Kidney Transplant From Paired Exchange Donations

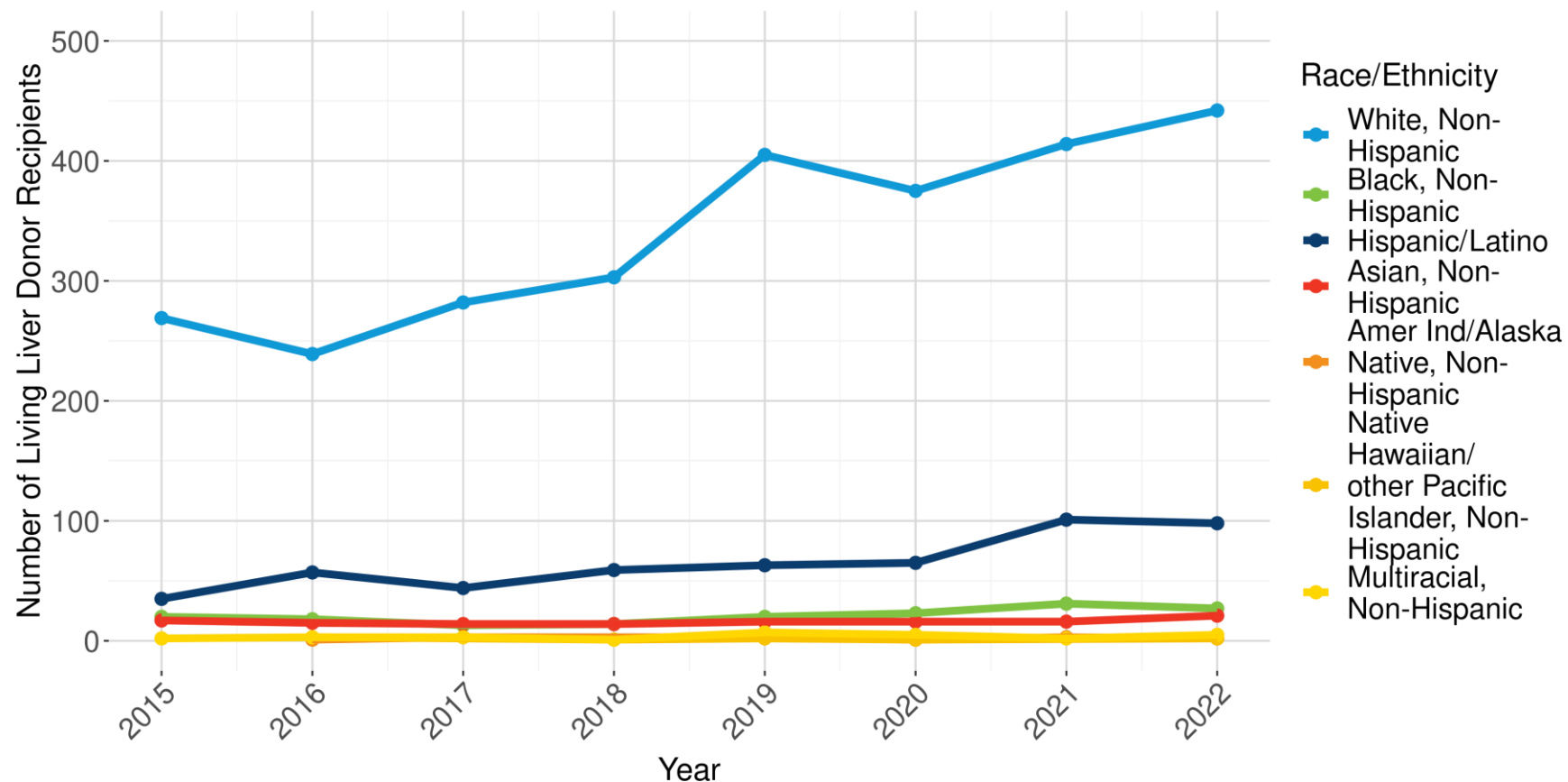


Living Liver Donors by Race



This chart excludes any domino or therapeutic donors

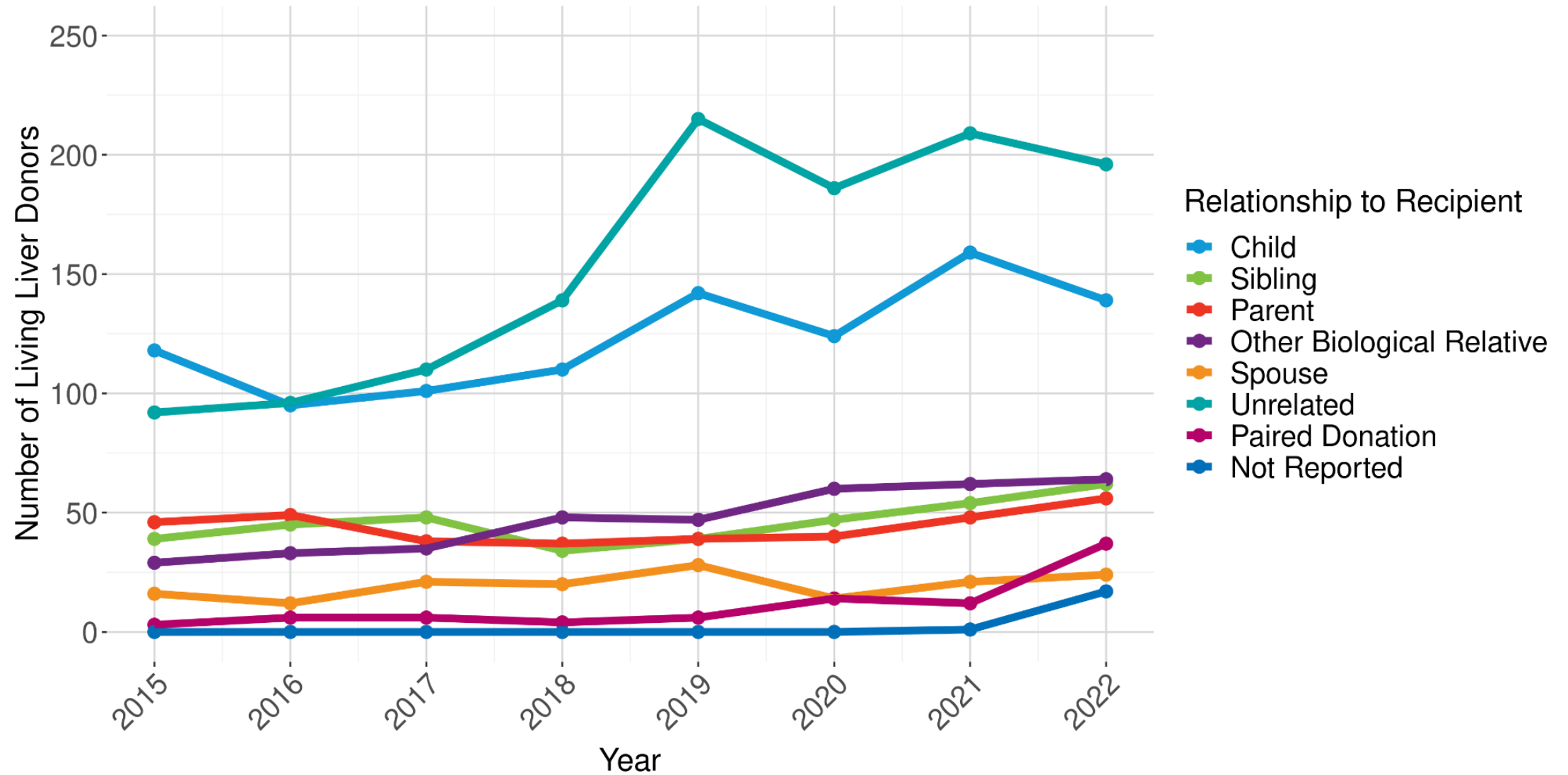
LDLT Recipient by Race



This chart excludes any domino or therapeutic donors

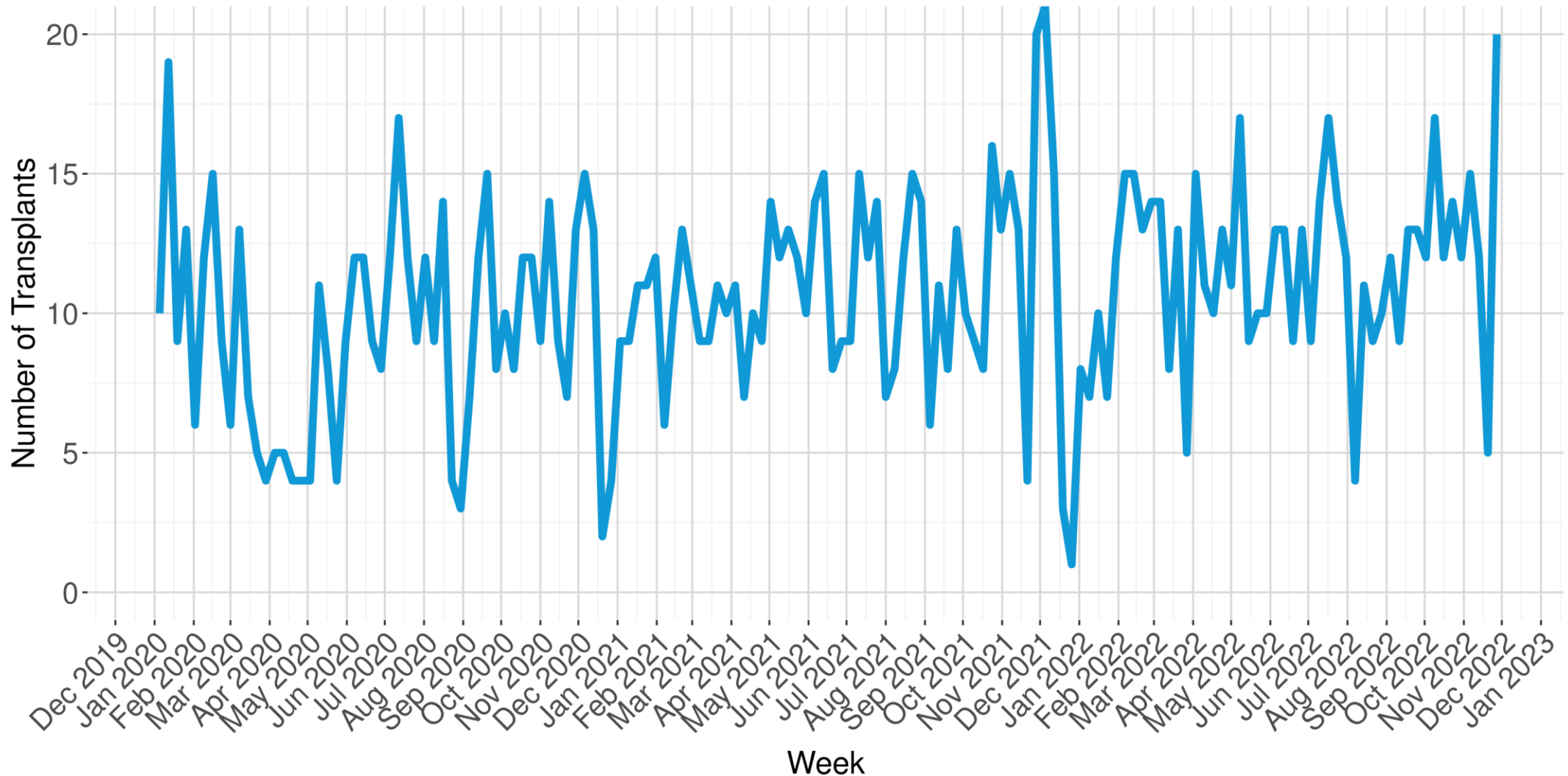
| Liver Waitlist | |
|---|-------|
| White, Non-Hispanic | 66.4% |
| Black, Non-Hispanic | 6.9% |
| Hispanic/Latino | 20.2% |
| Asian, Non-Hispanic | 4.8% |
| American Indian/Alaska Native, Non-Hispanic | 1% |
| Pacific Islander, Non-Hispanic | 0.2% |
| Multiracial, Non-Hispanic | 0.6% |

Living Liver Donors by Relationship

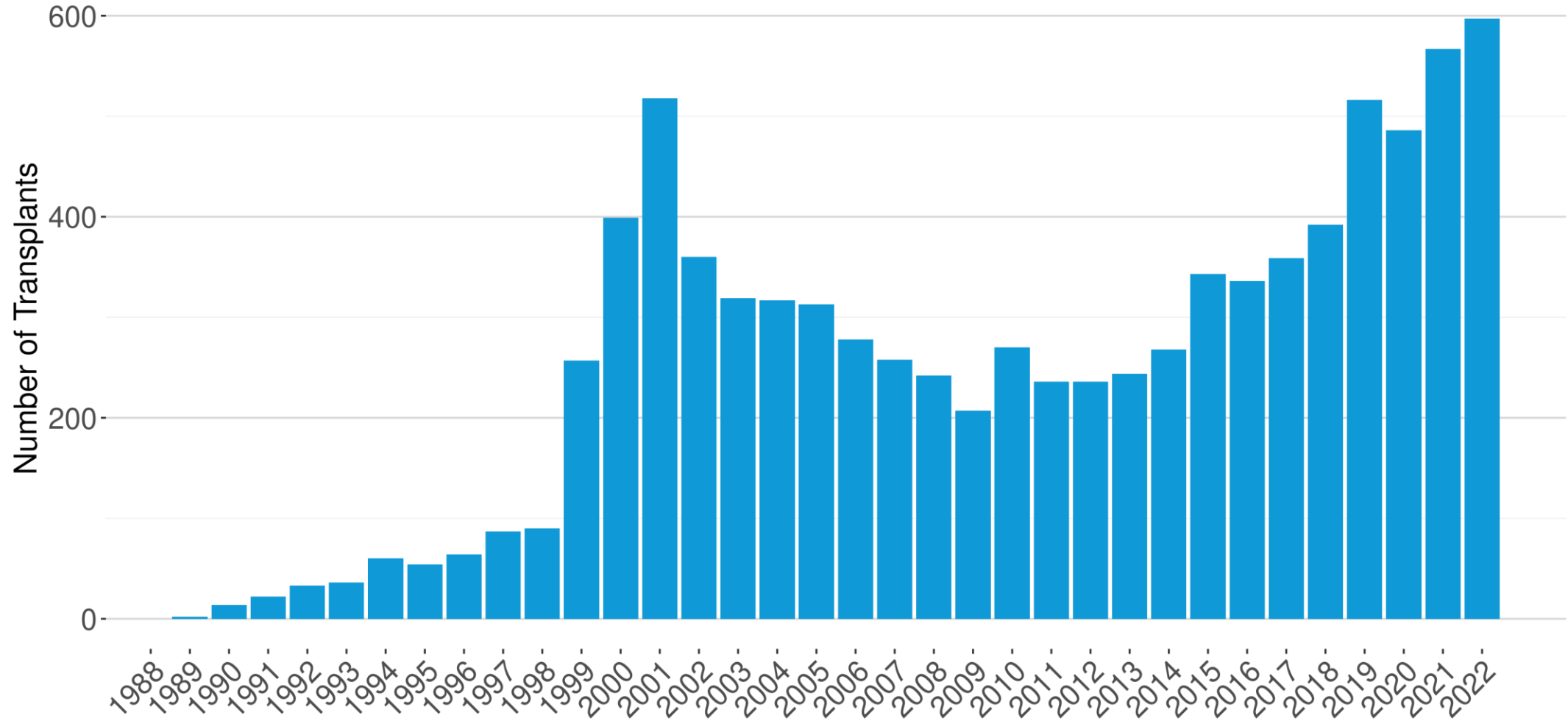


This chart excludes any domino or therapeutic donors

Living Liver Donor Transplants by Week



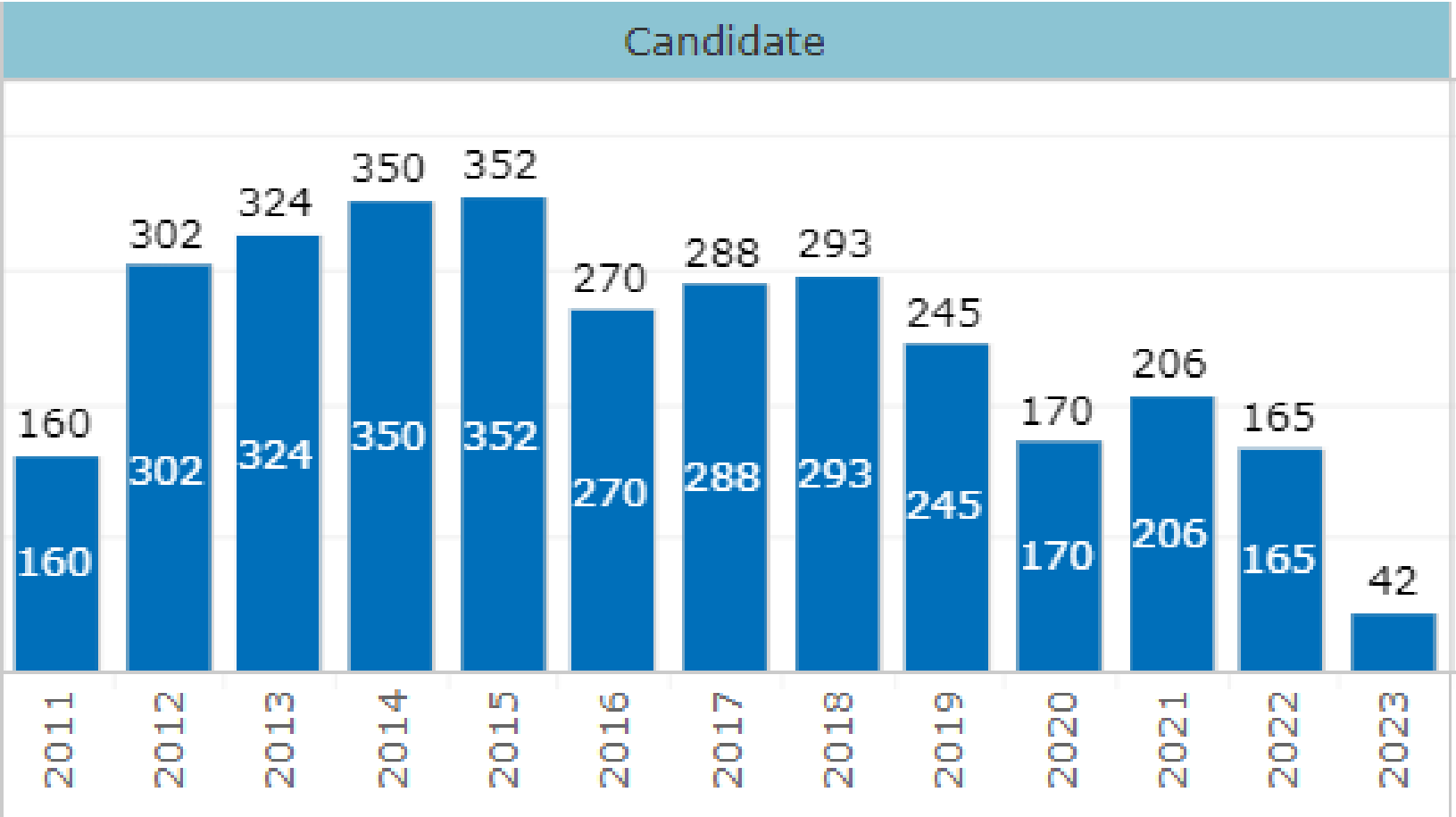
Living Liver Donor Transplants by Year



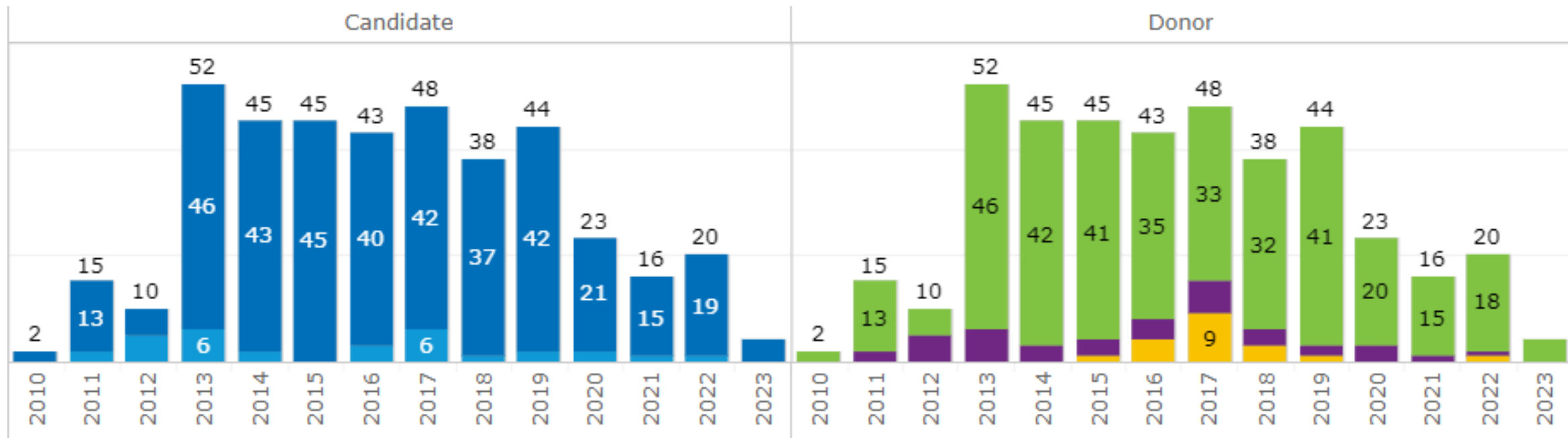
This chart excludes any domino or therapeutic donors

OPTN KPD Data

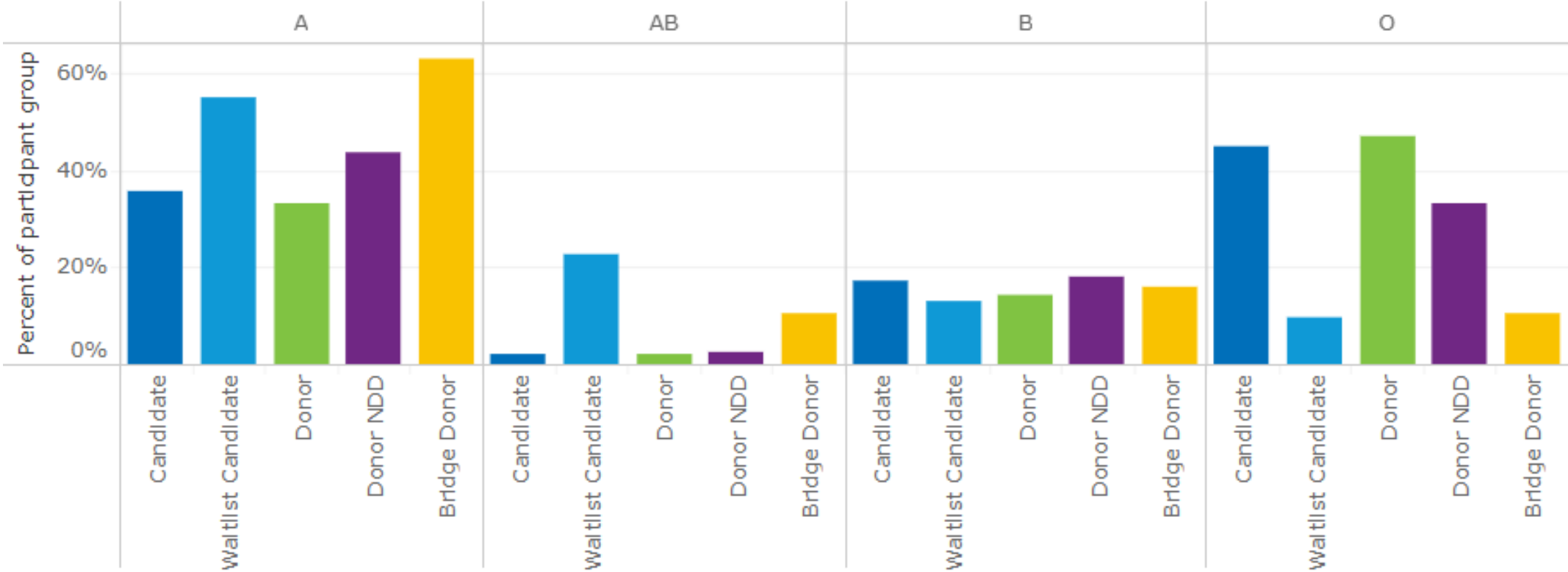
Number of candidates added to KPD by year



Number of candidates transplanted and donors who donated by year

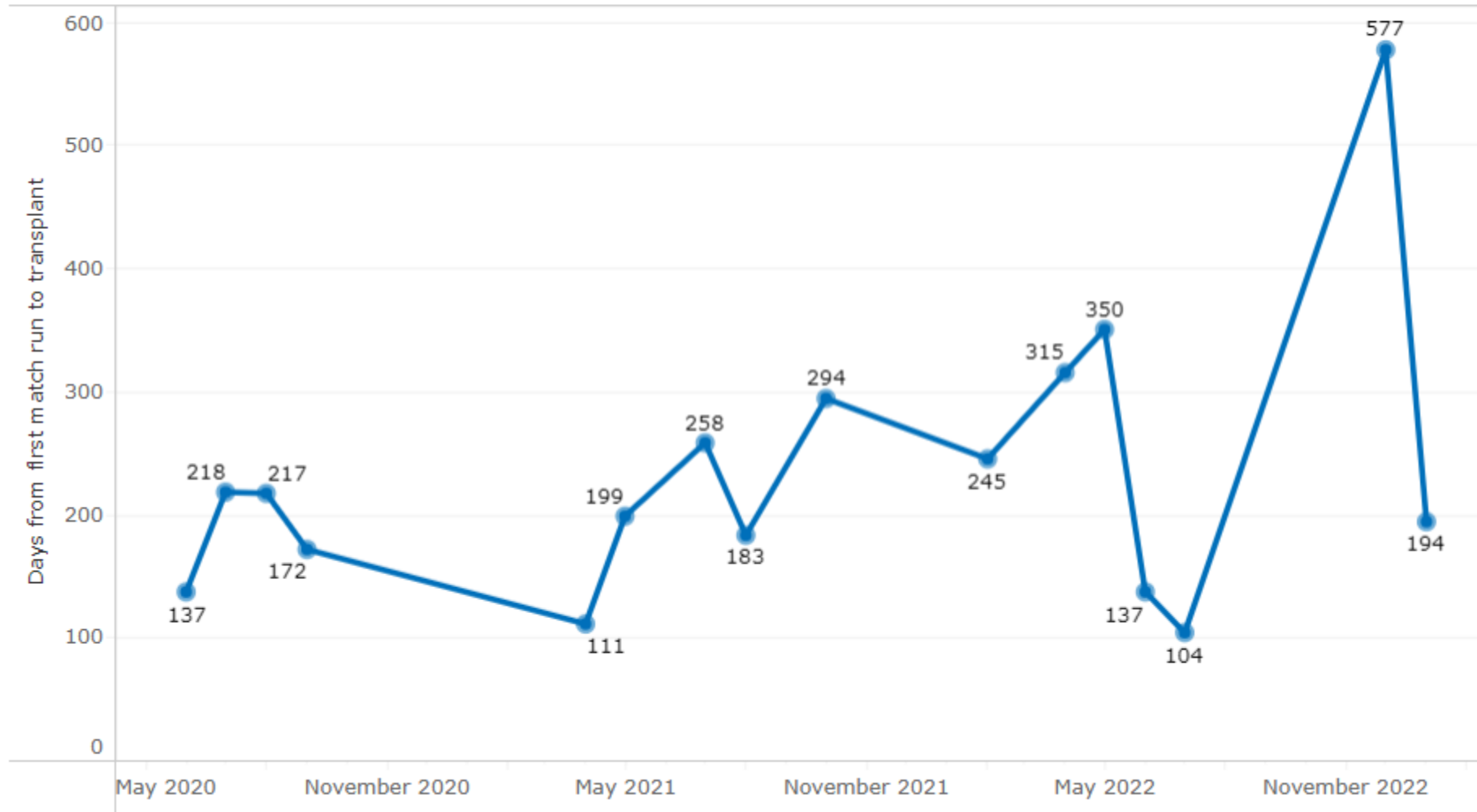


Percentage of KPD transplants by blood type

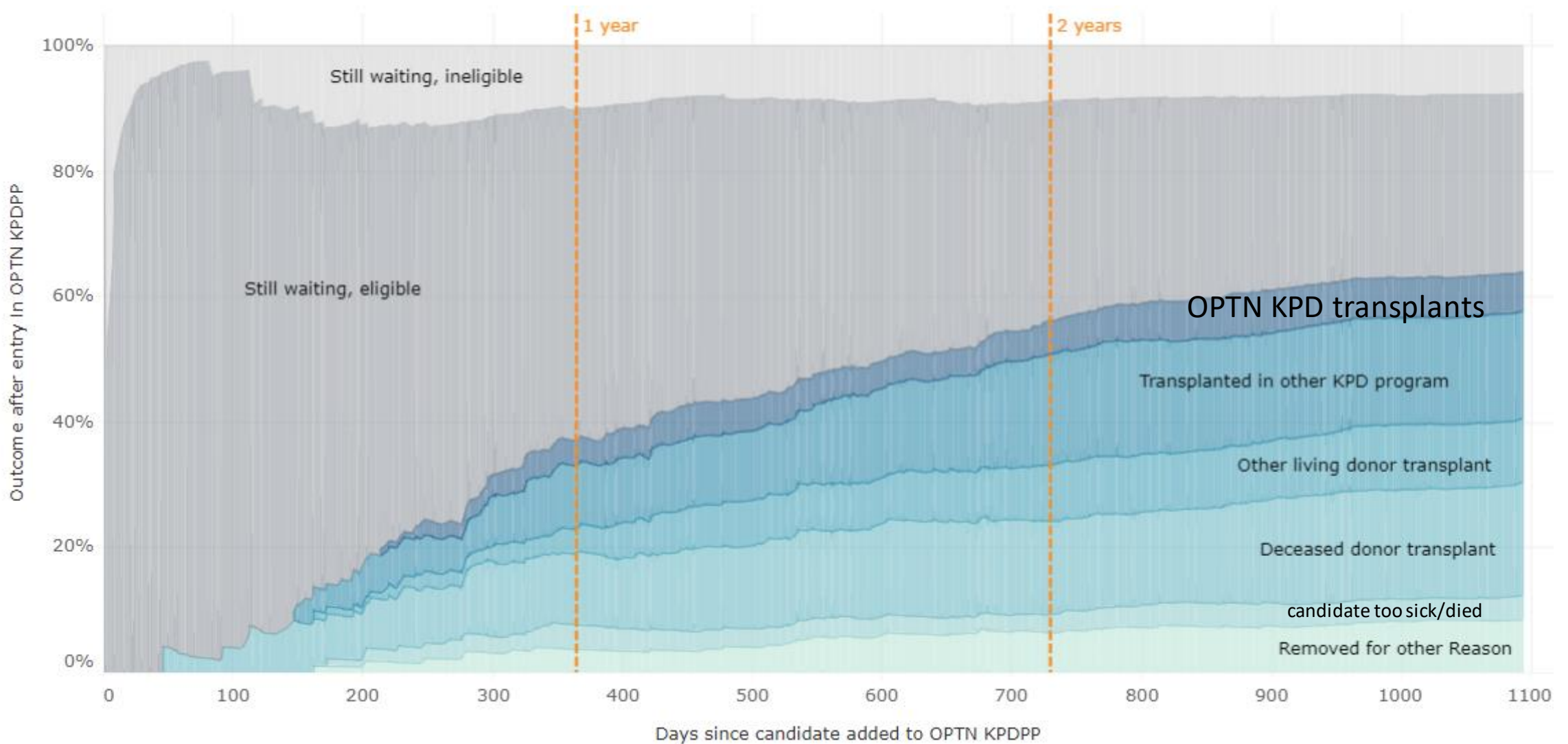


Median days from first match run to transplant

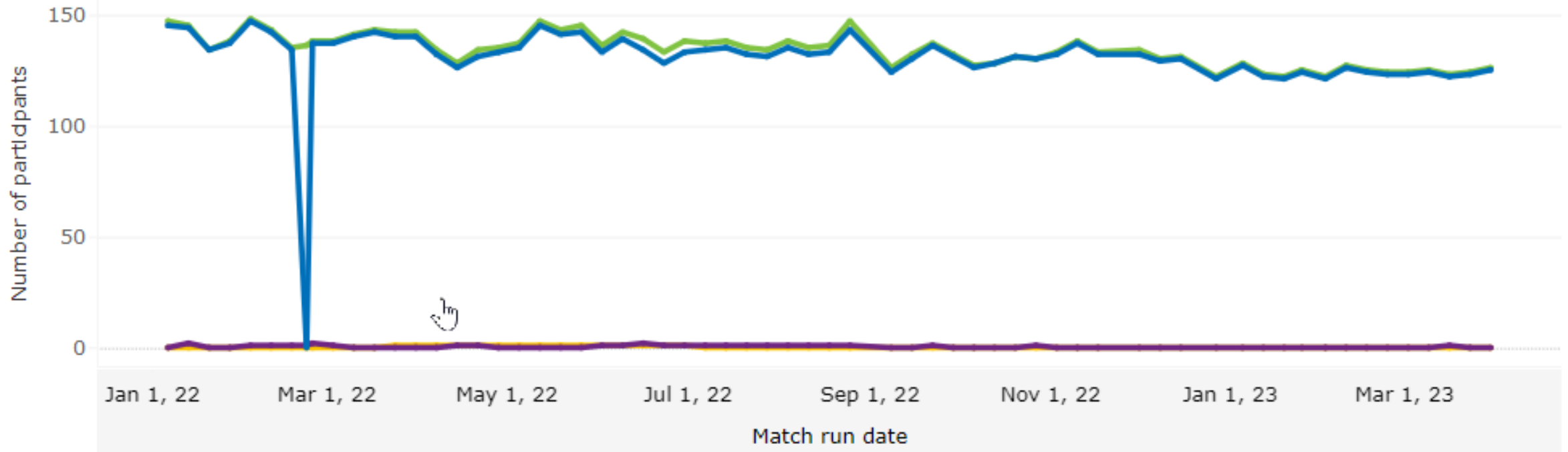
Overall median for the past 3 years: 214.0 days



Outcome after KPD candidate entry in OPTN KPDPP

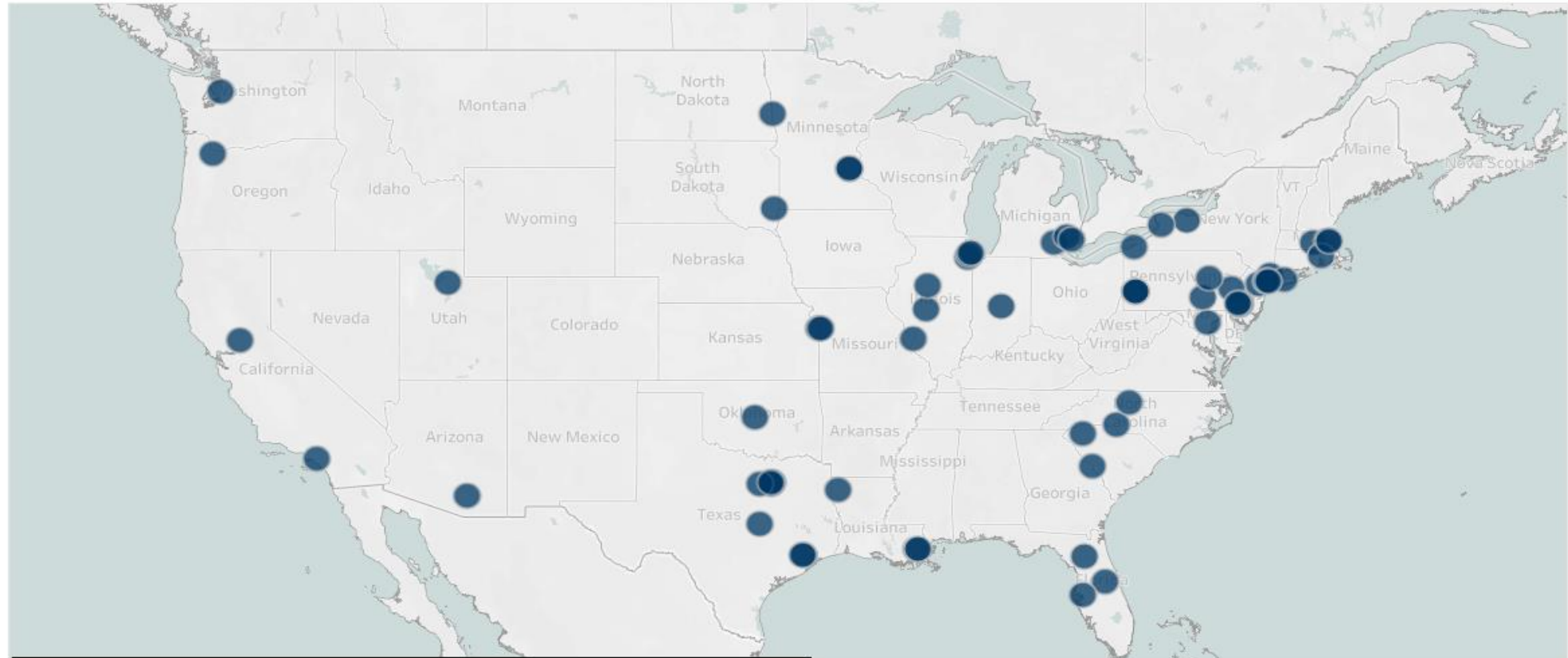


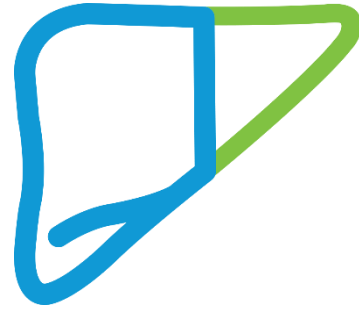
Number of KPD candidates and donors participating on matches for the last year
Click this graph to see information about an individual match run below



Map of Centers Participating in the OPTN KPDPP

| All-time Transplants | | | | | All-time Additions | | | | Currently Waiting | | | |
|----------------------|--------------------|-------|-----------|--------------|--------------------|-------|-----------|--------------|-------------------|-------|-----------|--------------|
| Candidate | Waitlist Candidate | Donor | Donor NDD | Bridge Donor | Candidate | Donor | Donor NDD | Bridge Donor | Candidate | Donor | Donor NDD | Bridge Donor |
| 374 | 31 | 347 | 39 | 19 | 3,167 | 3,263 | 116 | 55 | 138 | 143 | 1 | 0 |





UNOS Liver Paired Donation (LPD) Model Program



Goals

Pilot nation's first multi-hospital liver paired donation (LPD) program

- Increase access to living donor transplant
- Increase candidate access earlier, when in better health
- Determine how to create a nationally available program, how to sustain it, identify challenges
- Keep it algorithmically simple, 2-way only

Part of
UNOS
Labs

Center Requirements

All participating centers must:

- ✓ Have performed ~20 adult LDLTs or more over the last 3 years or a children's hospital affiliated with a donor recovery hospital who meets criteria
- ✓ Have consistent liver transplant program directorship over the last 3 years;
- ✓ Not be under OPTN review for liver transplant or living liver donation-related outcomes

=18

Invited
Programs

Centers must also:

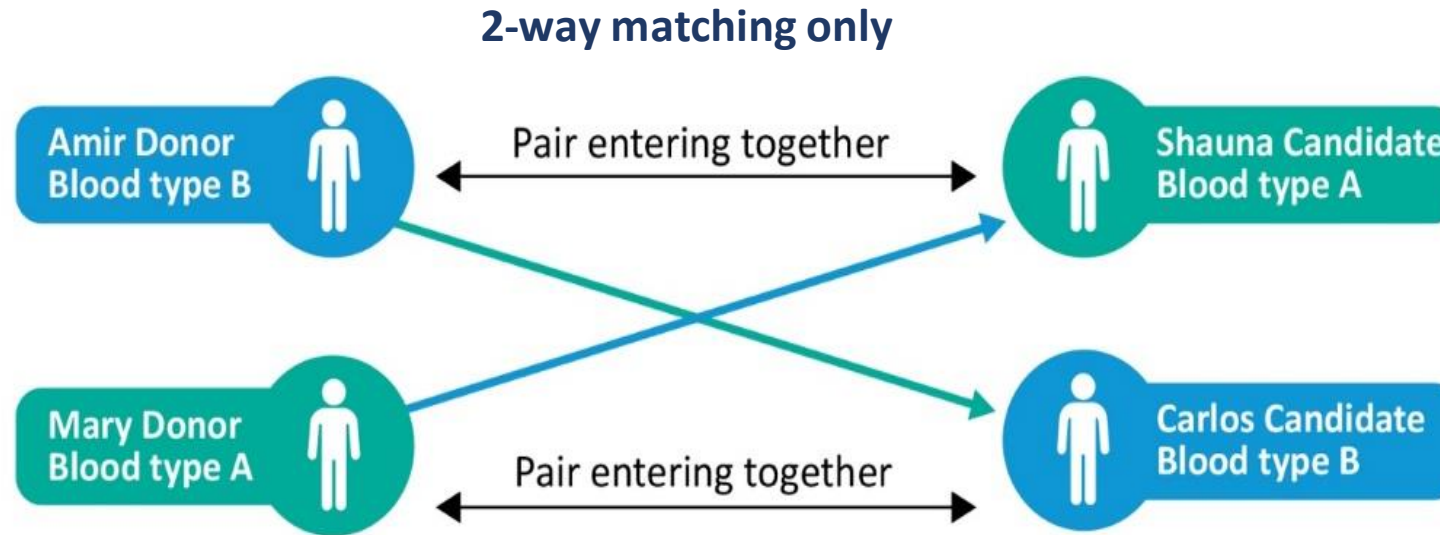
- ✓ Agree to the Participation Agreement;
- ✓ Abide by the Liver Paired Donation Pilot Program Operational Guidelines;
- ✓ Be active OPTN and UNOS members and OPTN-approved to perform liver transplants and living liver recoveries;
- ✓ Abide by all relevant OPTN and UNOS Policies;
- ✓ Agree to share feedback with UNOS to facilitate improvements to the program;

Donor Financial Assistance Options



Available to all donors, regardless of income

Pairs and Matches



Amir and Shauna (and Mary and Carlos) are a Pair

Amir and Carlos are a Match (Matched Donor and Matched Candidate); Mary and Shauna are a Match

The two matches grouped together are an Exchange

- Incompatible
- Compatible
- Non-directed donors can enter with a waitlist candidate to maximize their gift

Current status of program

- Two pairs entered
- Candidate criteria now includes pediatric patients of any age
- Website <https://unos.org/transplant/liver-paired-donation/>

OPTN Living Donor Committee Initiatives

Current OPTN Living Donor Committee Initiatives

- The Committee is performing a granular review of the data elements on the Living Donor Feedback (add donor), Living Donor Registration, and Living Donor Follow-up data instruments
 - LDC will recommend additions, modifications, and removals in an upcoming data collection proposal
 - **Look for future public comment period to weigh in**
- **Committee members are a diverse group with many perspectives**
 - Living donors –1/3 of committee
 - Living donor recipient
 - Transplant surgeons and physicians
 - Social worker
 - Living donor/transplant coordinators
 - OPO representative

Living Donor Follow-up

- OPTN Living Donor Committee has been discussing long-term living donor follow-up and data collection
- LDC presented the following six findings and recommendations to the OPTN Board of Directors in December 2022:
 - Living donors should be followed for their lifetimes.
 - There are barriers and burden associated with transplant programs performing living donor follow-up.
 - A registry may be better situated to perform long-term living donor follow-up.
 - Resource constraints remain a logistical concern for long-term living donor follow-up.
 - There are opportunities for increased efficiencies and integration across organizations that support the transplant community.
 - Broader living donor engagement is necessary.

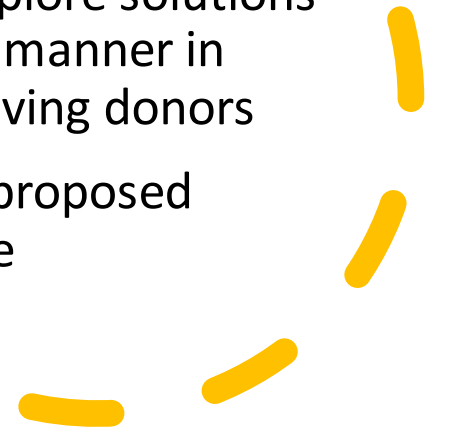



LIVING DONOR COLLECTIVE

An SRTR Initiative

Living Donor Follow-Up

- OPTN Living Donor Committee has been collaborating with the SRTR Living Donor Collective in order to explore solutions that align data collection efforts in an efficient manner in order to support long-term data collection of living donors
- LDC will engage the transplant community on proposed solutions in an upcoming public comment cycle





OPTN Membership & Professional Standards Committee (MPSC) Role in Monitoring Living Donation

Routine Audit Focus

- The OPTN does routine audits once every 3 years
- These audits review a sample of records to verify key elements of the living donor evaluation are properly documented
 - These elements include medical evaluation, psychosocial evaluation, and patient consent
- These audits also examine the pre-recovery verification forms, verify accuracy on the Living Donor Registration and Living Donor Follow-up forms, and ensure compliance with follow up requirements

MPSC Review of Living Donor Events

From February 2022 – February 2023, the MPSC reviewed 50 living donor events under required reporting

| Organ | Aborted Procedures | Death within 2 years of donation | Organ redirected | Non-utilization | Total |
|--------|--------------------|----------------------------------|------------------|-----------------|-------|
| Kidney | 22 | 8 | 5 | 3 | 38 |
| Liver | 10 | 1 | 1 | 0 | 12 |

- Most of the reasons for aborted procedures were recipient cardiac issues, stability, or anaphylaxis; new observations of donor anatomy after incision; and donor heart rate issues during induction or insufflation
- The cases of donor death within 2 years included motor vehicle accidents, suicide, and COVID-19 illness
- Redirection and non-utilization occurred due to recipient instability or unsuitability for transplant, as well as surgical damage to the organ

Improved Dissemination of Safety Events

UNOS has created a [new public page on the OPTN website](#) to increase transparency on MPSC performance improvement and compliance review activities.

The OPTN will issue timely patient safety and improvement communications gleaned from current case reviews to inform the public, help members avoid safety events.



Stay Involved!

Public Comment

- Public comment is an essential part of the policy development process that occurs twice each year.
 - 2023 public comment dates:
 - January 18 – March 18 (closed)
 - July 27 – September 18 (upcoming)



Public Comment

The screenshot shows the OPTN website header with the logo 'OPTN Organ Procurement & Transplantation Network' and 'HRSA Health Resources & Services Administration'. The navigation menu includes 'About', 'Policies & bylaws', 'Patients', 'Professionals', 'Data & calculators', and 'News & events'. The 'Policies & bylaws' menu is highlighted with a red box. Below the menu, there are three columns: 'CURRENT' (Policies, Bylaws, Notices of implemented policies & bylaws, Compliance and evaluation, How we make policies and bylaws), 'IN DEVELOPMENT' (All projects in development, Public comment, Notices of approved policies & bylaws), and 'A CLOSER LOOK' (Race & eGFR, Continuous distribution, Liver allocation and distribution, Multi-organ transplantation, Refusal codes, COVID-19). A blue box with a megaphone icon contains the text 'WINTER 2023 PUBLIC COMMENT' and 'Public comment is now closed.' with a 'View feedback' button.

- Visit the public comment page to review the **full paper** for each item and an **“at a glance” overview** and **educational videos**
- Visit the regional meeting page to find **all presentations** from regional meetings
- **Submit individual public comments** on the OPTN website
- **Participate** in regional meetings

OPTN Board and Committee Interest

- Review roles and vacancies, how to apply, and the selection process, at: <https://optn.transplant.hrsa.gov/about/how-to-get-involved/>

How to volunteer



Roles & vacancies



Application

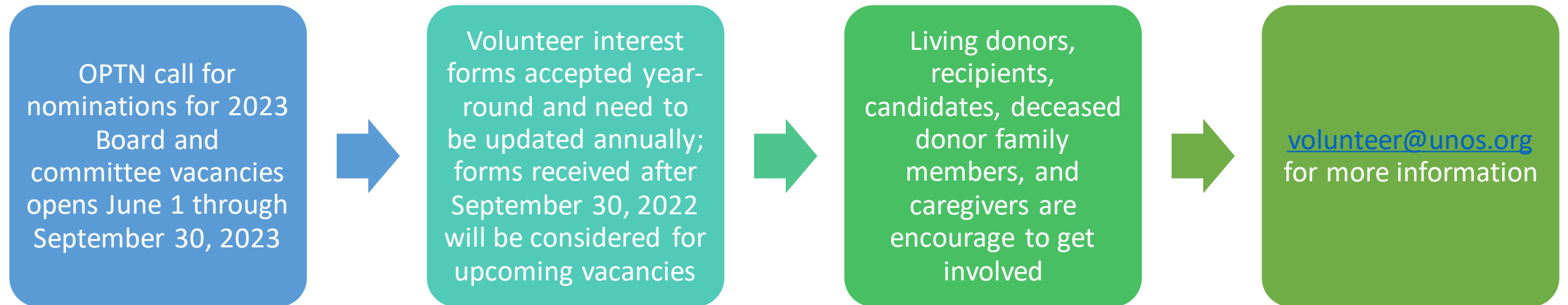


Appointment



Notification

OPTN Committee Interest





UNITED NETWORK FOR ORGAN SHARING

ERNEST
MARION
JAMIE
ANNE
HYLLIS
CURTIS
NANCY DEAN
TAYLOR
MEHRDAD
BONNIE
JOE PONG
BERNARD
ALEXIS
TITIANA
TERESA



NATIONAL DONOR MEMORIAL



Session Survey

Dianne LaPointe Rudow, ANP-BC, DNP, CCTC | April 18th 11:00 AM-11:30 AM

