SUMMER 2023

UNOS Region 5
Educational Collaborative

Wyndham San Diego Bayside • August 23, 2023

Everyone learns. Everyone teaches.

Brittany Stark

Normothermic Regional Perfusion
Ethics, Best Practices, and Lung Utilization

UNOS Region 5 Educational Collaborative

August 23, 2023

Setting The Stage & Case Studies

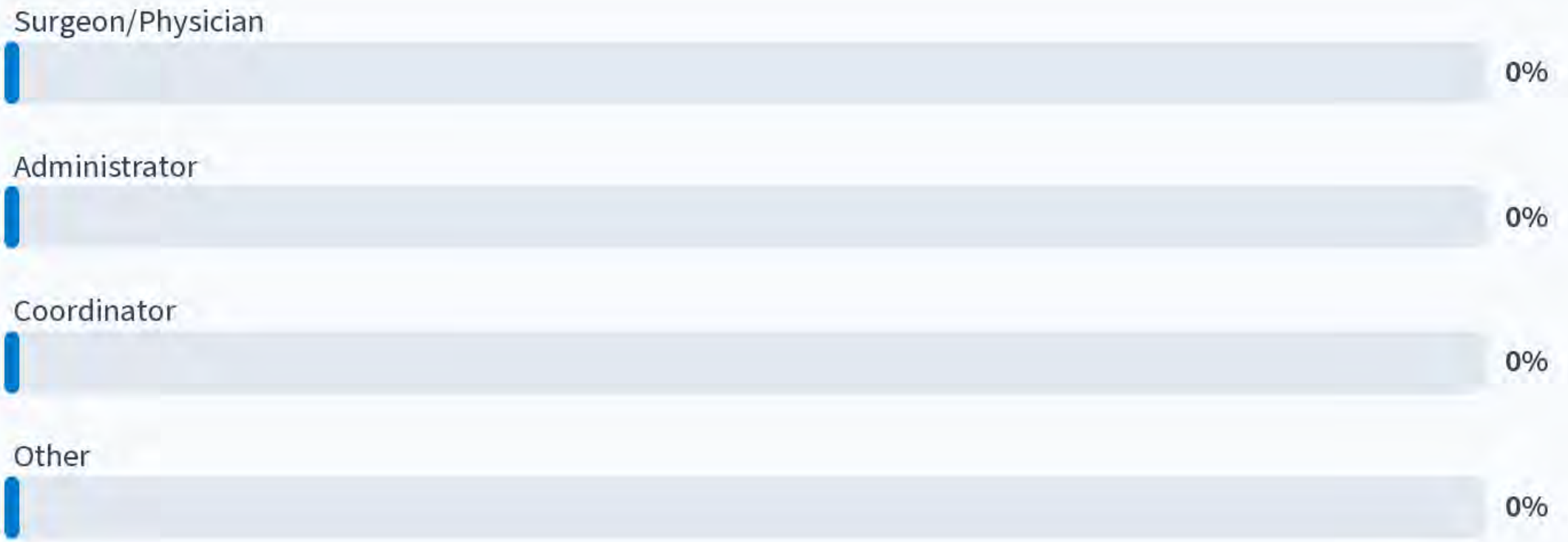
Elizabeth Shipman, MBA

Senior Director of Organ Services

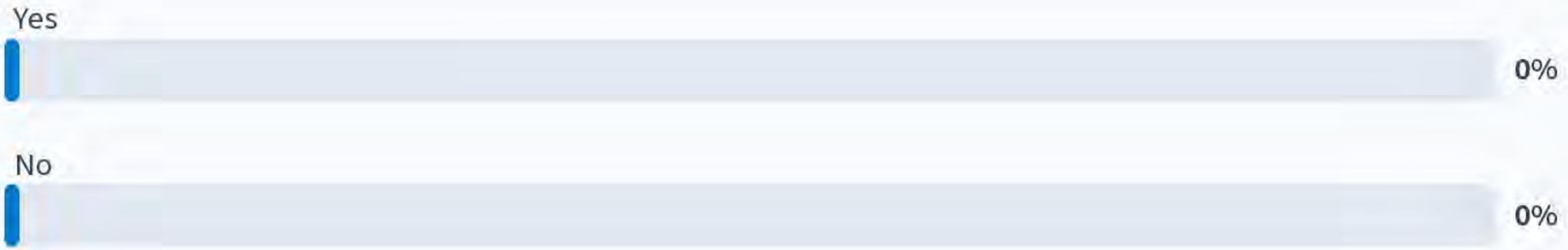
Nevada Donor Network

I am here on behalf of a/an

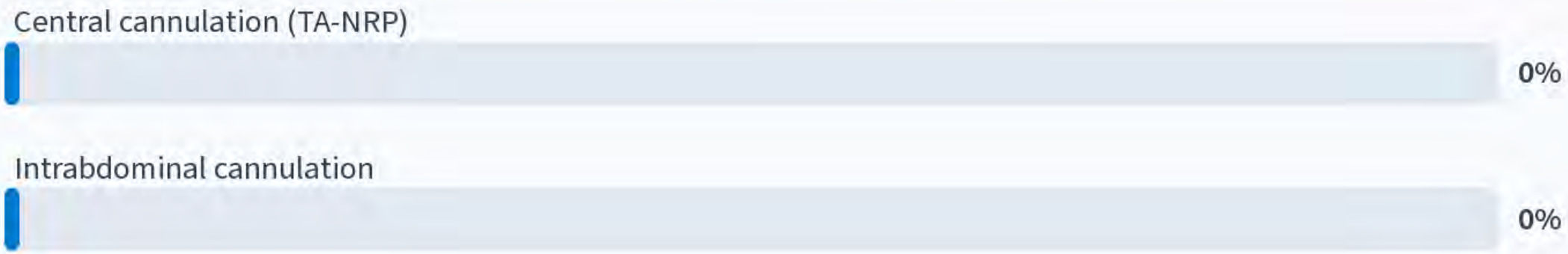
I am a/an



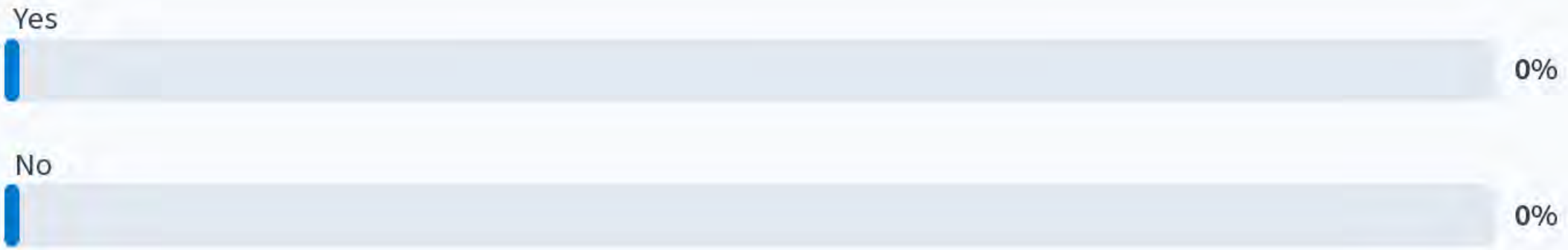
Does your organization participate in NRP?



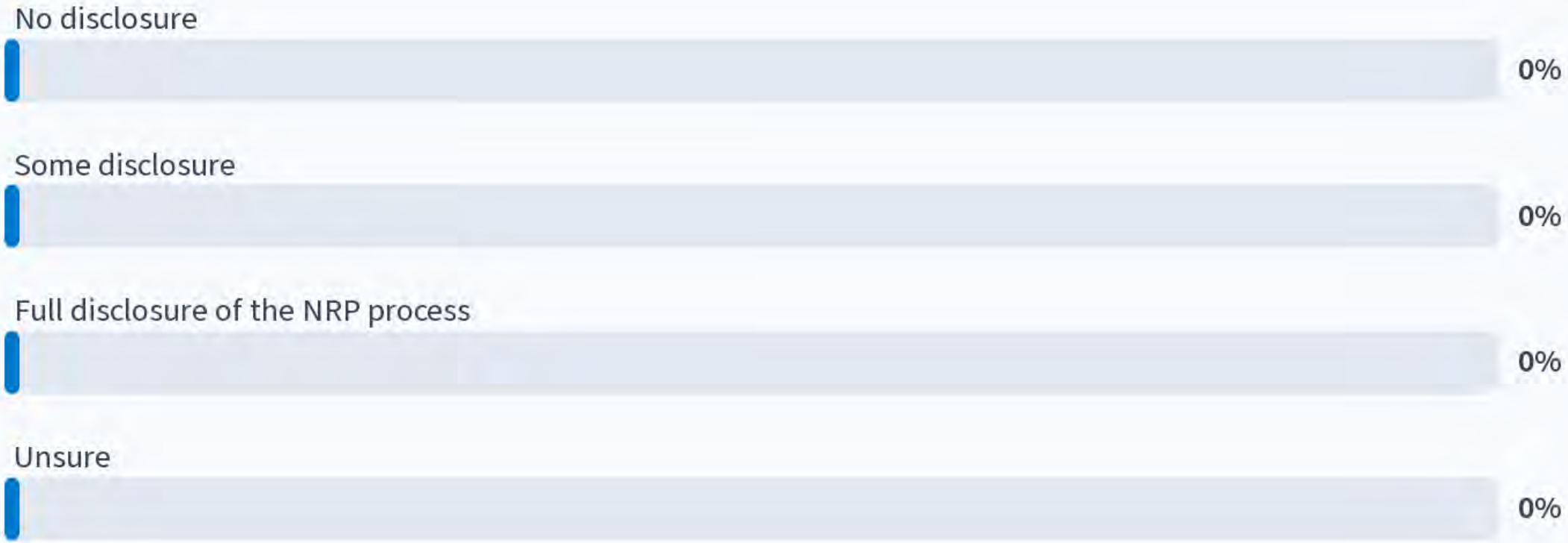
If your organization does participate in NRP, which method do you primarily utilize?



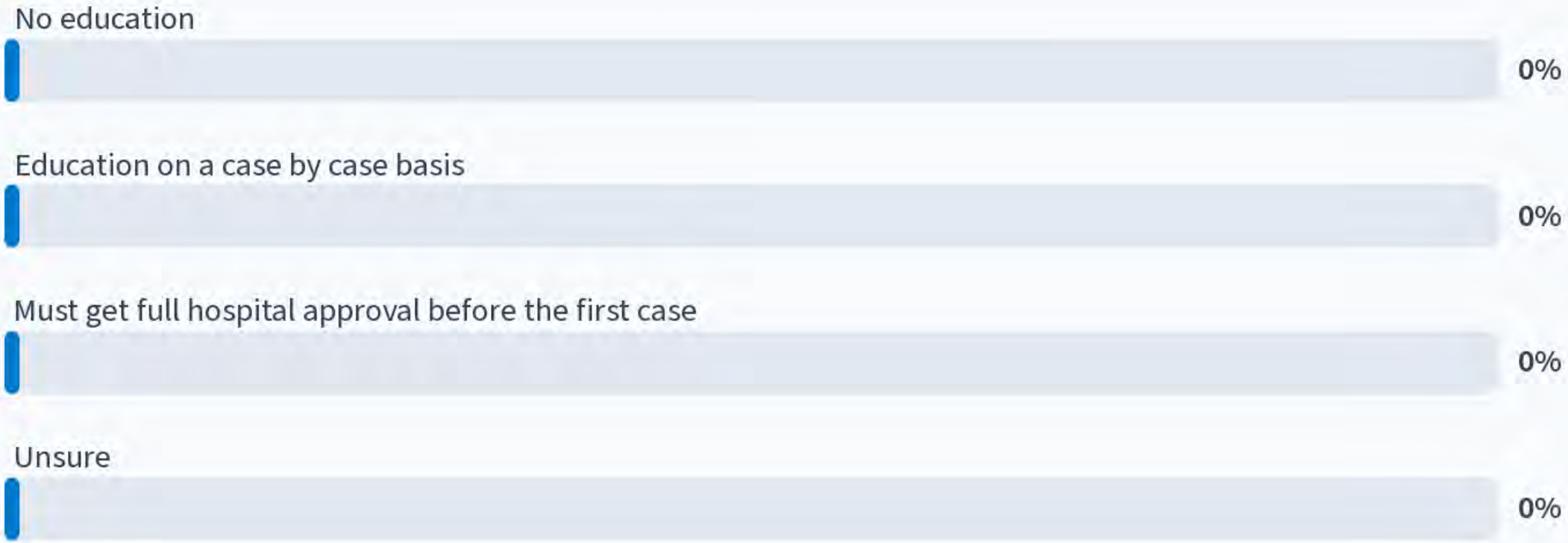
Ethically, Do you believe there is a difference between TA-NRP and intrabdominal NRP?



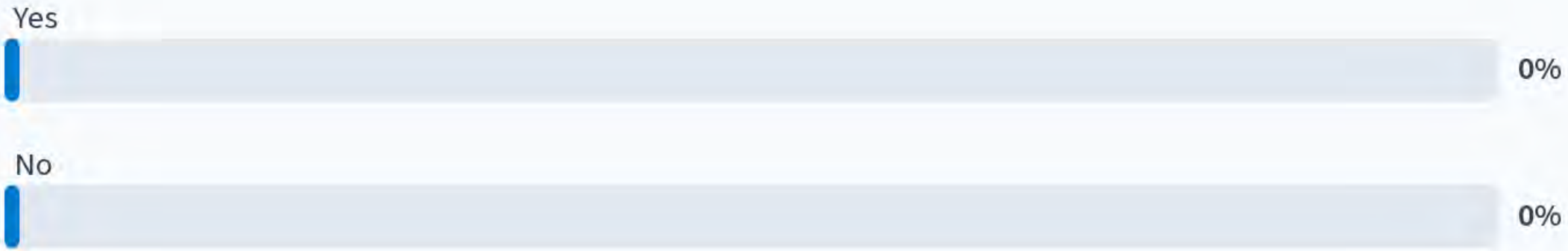
How much disclosure should be given to a family regarding NRP?



How much education should be provided to the hospital?



If the lung team is against NRP, will you bypass them? If you are a transplant center, do you think the lung team should be bypassed?



Case #1 – 26Y/M

- GCS 3 – on sedation, when off sedation postures, no other reflexes
- Unable to go to CT due to high vent settings
- Heart accepted for NRP seq 2 @ 09:43, OR set for 17:00
- Huddle initiated with: **transplant team** (accepting MD, nurse manager, administrator, first assist) and **OPO team** (medical director, director of organ, manager of organ, surgical team, PTC)
- Heart team required extubation to happen in the OR
- Reapproached family. Request not granted.

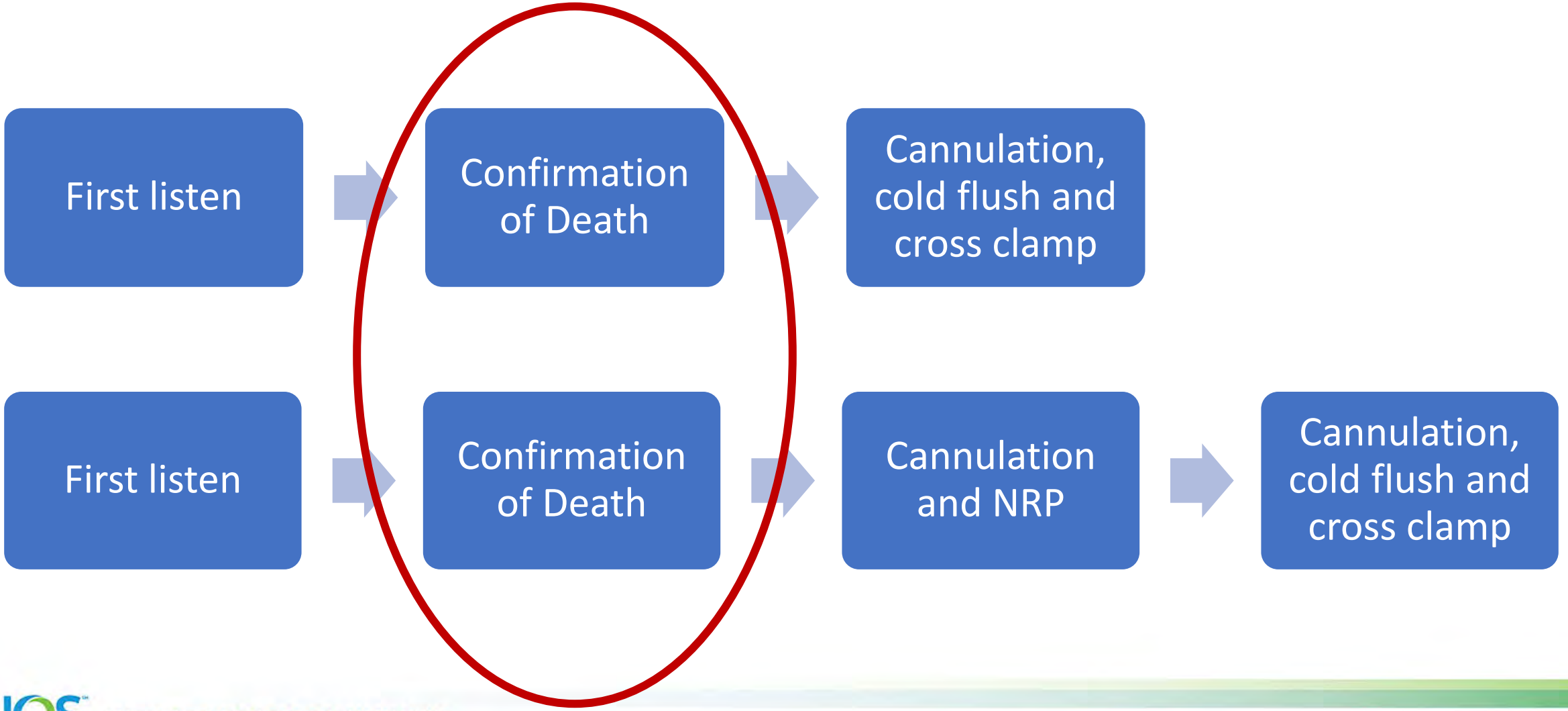
Outcome: right and left kidneys transplanted

Case #2 – 35Y/M

- GCS 3 – spontaneous respiratory effort, no other reflexes
- Same hospital, same extubation area
  - WDL to incision 19min

Outcome: heart, liver, and right kidney transplanted

NVLV NRP Practice



Donor Hospital & Family Considerations

Heather Osipowicz, BA, MSBS, CTBS

Director of Hospital Services

Nevada Donor Network

Normothermic Regional Perfusion (NRP) – Previous Focus

- Basics
- Technical procedure
- Equipment and personnel needs
- Preparing partners
- Benefits of NRP

REVIEWS

Abdominal Normothermic Regional Perfusion in Donation After Circulatory Death: A Systematic Review and Critical Appraisal

van de Leemkolk, Fenna E.M. MD[1,2]; Schurink, Ivo J. BSc[3]; Dekkers, Olaf M. MD, PhD[4]; Oniscu, Gabriel C. MD, PhD[5]; Alwayn, Ian P.J. MD, PhD[1,2]; Ploeg, Rutger J. MD, PhD[2,6]; de Jonge, Jeroen MD, PhD[3]; Huurman, Volkert A.L. MD, PhD[1,2]

Author Information

Transplantation 104(9):p 1776-1791, September 2020. | **DOI:** 10.1097/TP.0000000000003345

Received: 24 September 2019 | Revised: 27 November 2019 | Accepted: 29 December 2019

DOI: 10.1111/ajt.15735

PERSONAL VIEWPOINT

AJT

Maintaining the permanence principle for death during in situ normothermic regional perfusion for donation after circulatory death organ recovery: A United Kingdom and Canadian proposal

Alex Manara[1] | Sam D. Shemie[2,3] | Stephen Large[4] | Andrew Healey[5,6] | Andrew Baker[7] | Mitesh Badiwala[8,9] | Marius Berman[4] | Andrew J. Butler[10,11] | Prosanto Chaudhury[2,12] | John Dark[13] | John Forsythe[14] | Darren H. Freed[15] | Dale Gardiner[16,17] | Dan Harvey[16,17] | Laura Hornby[18,3] | Janet MacLean[5] | Simon Messer[4] | Gabriel C. Oniscu[19,20] | Christy Simpson[21] | Jeanne Teitelbaum[22] | Sylvia Torrance[3] | Lindsay C. Wilson[3] | Christopher J. E. Watson[10,11]

JOURNAL OF HEPATOLOGY

uper-rapid
circulatory

Received: 4 October 2021 | Revised: 27 December 2021 | Accepted: 28 December 2021

DOI: 10.1111/ajt.16947

VIEWPOINT

Respons
ethics of
ment on the
erfusion

Brendan Pare
ntgomery[2]

ELSEVIER

The Journal of Heart and Lung Transplantation

Volume 40, Issue 11, November 2021, Pages 1408-1418

Original clinical science

Early US experience with cardiac donation after circulatory death (DCD) using normothermic regional perfusion

Jordan R.H. Hoffman MD, MPH[a 1], William G. McMaster MD[a 1], Aniket S. Rali MD[b], Zakiur Rahaman MD[a], Keki Balsara MD[a], Tarek Absi MD[a], Melissa Levack MD[a], Marshall Brinkley MD[b], Jonathan Menachem MD[b], Lynn Punnoose MD[b], Suzanne Sacks MD[b], Mark Wigger MD[b], Sandip Zalawadiya MD[b], Lynne Stevenson MD[b], Kelly Schlendorf MD[b], JoAnn Lindenfeld MD[b], Ashish S. Shah MD[a]

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doi: 10.1111/ajt.14214

ORGAN PRESERVATION AND PROCUREMENT: EDITED BY GABRIEL C. ONISCU

Extending normothermic regional perfusion to the thorax in donors after circulatory death

Tsui, Steven S.L.[a]; Oniscu, Gabriel C.[b]

Author Information

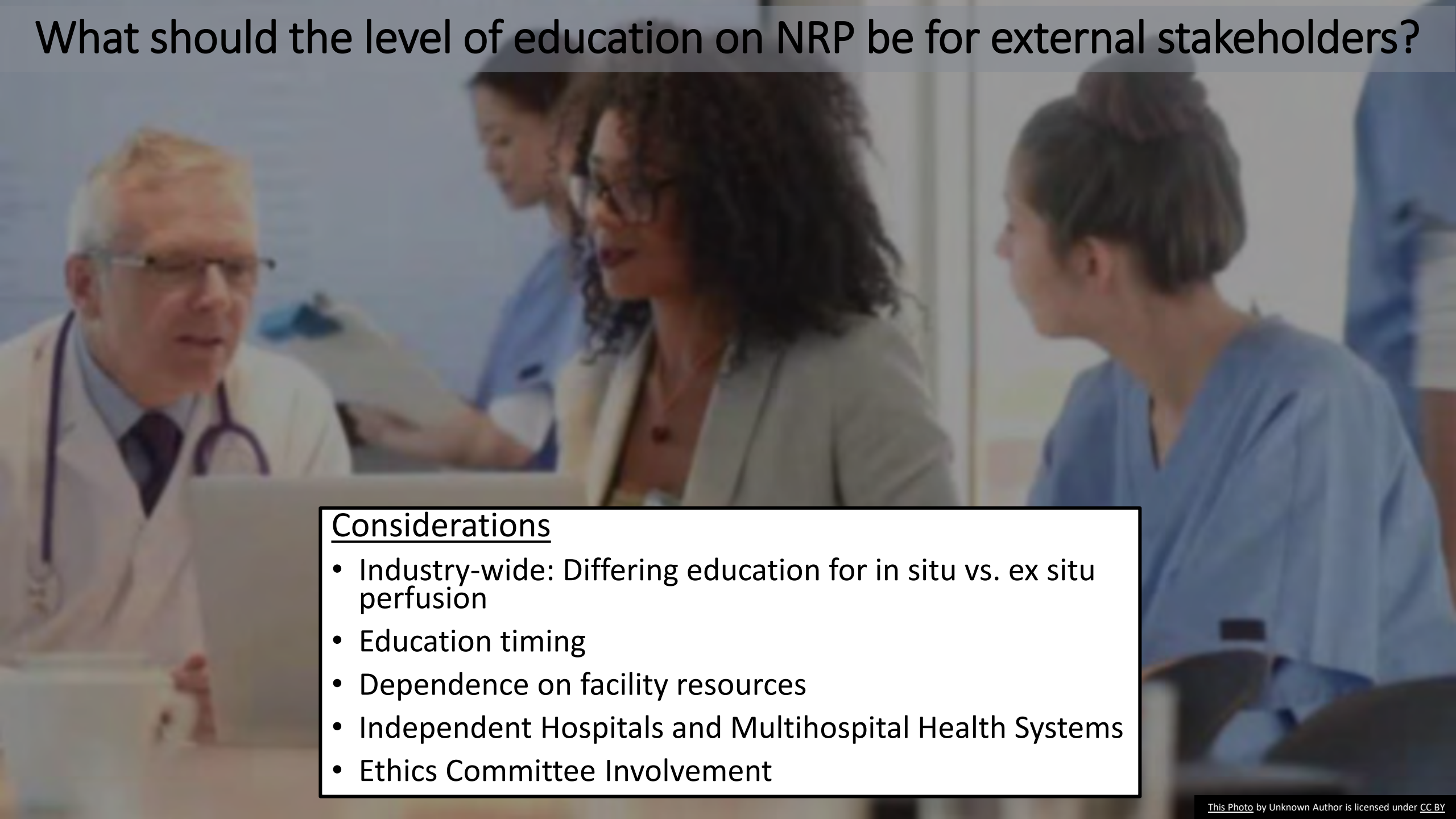
Current Opinion in Organ Transplantation 22(3):p 245-250, June 2017. | **DOI:**

UNOS UNITED NETWORK FOR ORGAN SHARING

External Stakeholders – Everyone has an opinion

- Physicians
- Administrators
- Nursing Staff
- Donor Family
- Surgical Staff
- Medical Directors
- Transplant Team
- Potential Recipients
- Public

What should the level of education on NRP be for external stakeholders?



Considerations

- Industry-wide: Differing education for in situ vs. ex situ perfusion
- Education timing
- Dependence on facility resources
- Independent Hospitals and Multihospital Health Systems
- Ethics Committee Involvement

Authorization Process and Anatomical Gift Form Language Inclusion

How much information should be included in the family conversation about NRP?

How much detail should be included in the Anatomical Gift Form?

☑ NDN is authorized to perform and administer any testing, procedures, and therapeutic interventions necessary to evaluate and maintain the viability of donated gifts. This may include, but is not limited to surgical and medical intervention, transmissible disease testing, diagnostic imaging, and blood testing. During recovery, removal of specimens which may include, but is not limited to, blood or tissue for biopsy or testing will be obtained for the purposes of determining compatibility and eligibility of donor and recipient. State law requires that NDN report any confirmed positive test results that may pose a health risk. Samples may be archived for future testing.

Surgical Considerations and Organ Utilization

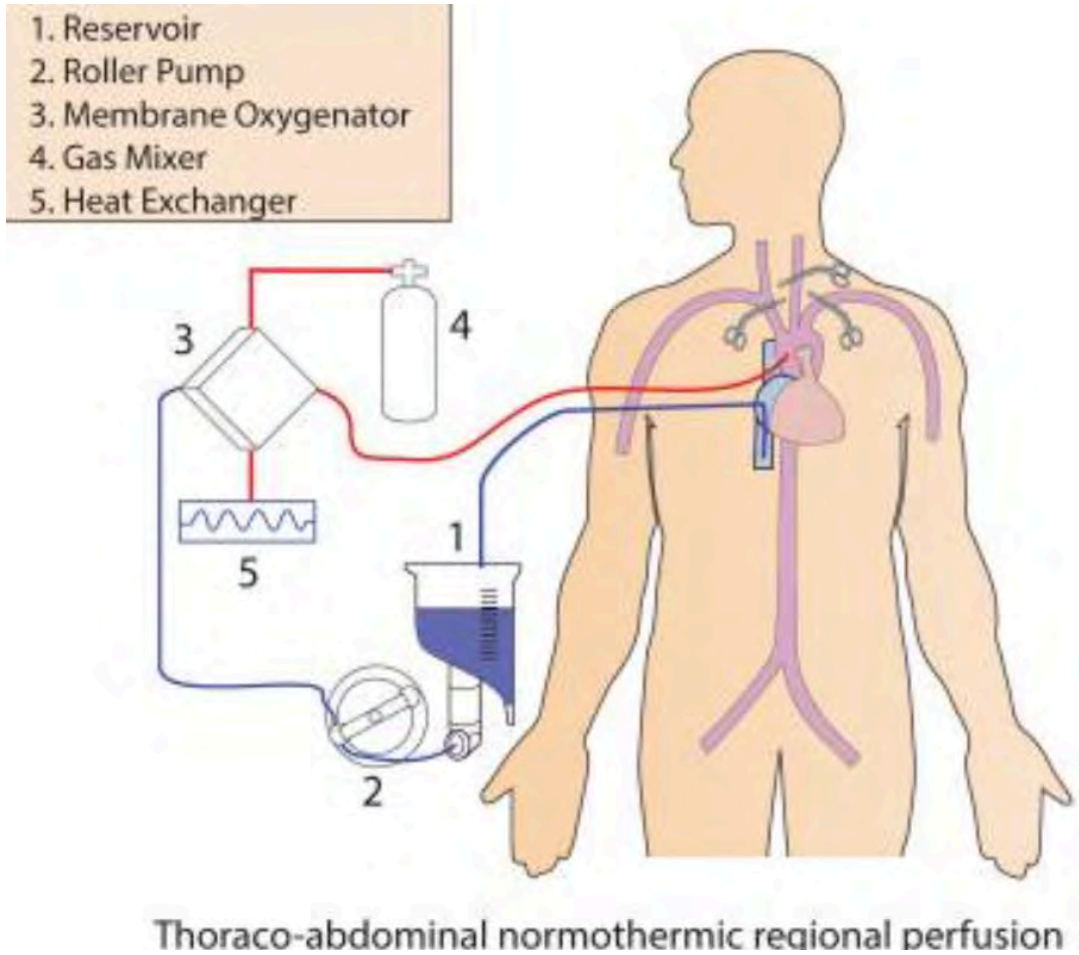
Lara Schaheen, MD

Cardiothoracic Surgery and Lung Transplantation
Assistant Professor of Surgery
Norton Thoracic Institute
St. Joseph's Hospital and Medical Center
Creighton University School of Medicine

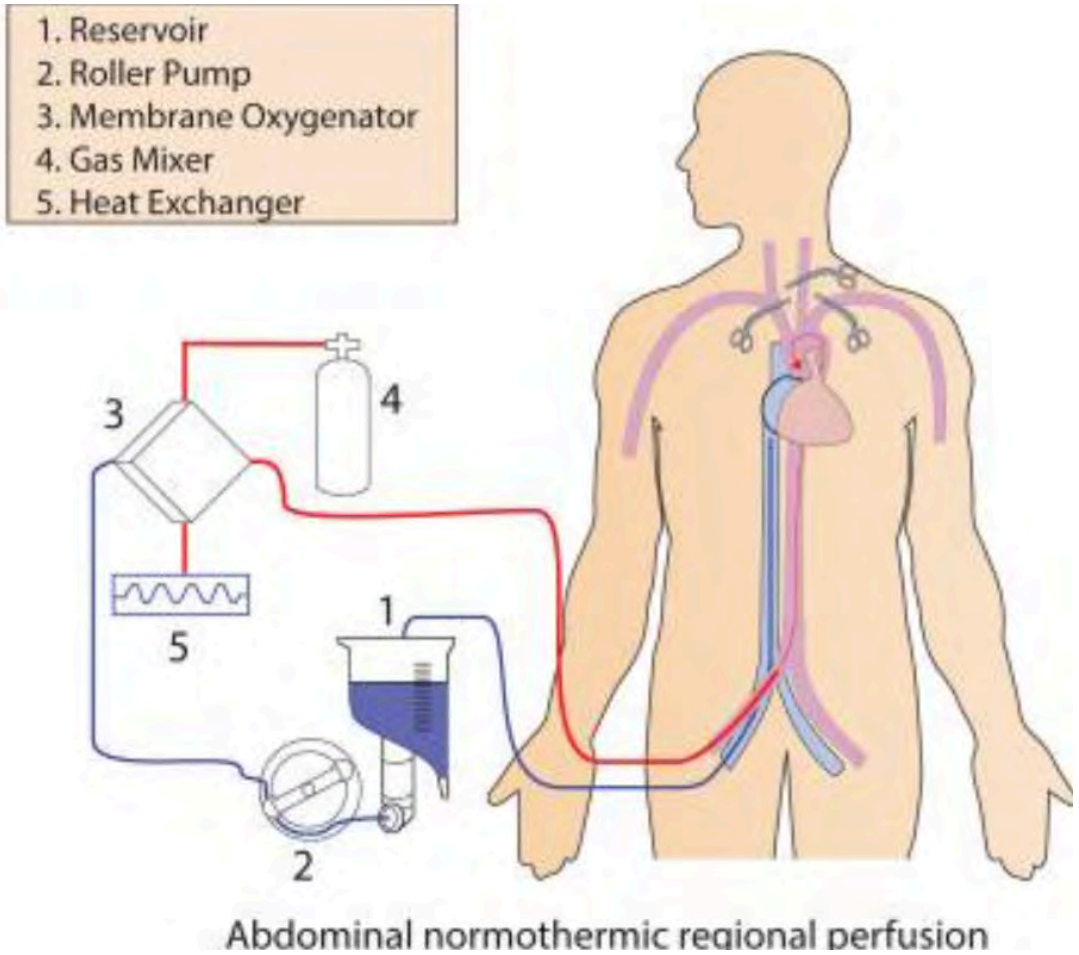
Normothermic Regional Perfusion

- A technique of in-situ resuscitation of a donor after circulatory death (DCD) using extracorporeal support
  - Venoarterial membrane oxygenation (VA ECMO) or cardiopulmonary bypass (CPB)
- Restoration and maintenance of organ perfusion with oxygenated blood
- Decreased ischemic injury
- Replenishment of energy stores (ATP)
- Increased time for the assessment of organ function and quality
- Converts a DCD rapid recovery procurement into a BDD-type procurement

Types of NRP



Thoraco-abdominal normothermic regional perfusion



Abdominal normothermic regional perfusion

Jacob, S et al Cureus. 2022 Jun; 14(6): e26437.

Role of NRP in Liver and Kidney Transplantation

- NRP has been shown to increase the utilization of all abdominal organs, and significantly improve the outcomes of liver and kidneys, with no adverse effects on the pancreas.

Liver: better transplant survival and a very low incidence of cholangiopathy when compared to conventional DCD donor livers

In situ normothermic perfusion of livers in controlled circulatory death donation may prevent ischemic cholangiopathy and improve graft survival

Christopher J. E. Watson[1,2,3] | Fiona Hunt[4] | Simon Messer[5] | Ian Currie[4] | Stephen Large[5] | Andrew Sutherland[4] | Keziah Crick[3] | Stephen J. Wigmore[4,6] | Corrina Fear[3] | Sorina Cornateanu[4] | Lucy V. Randle[7] | John D. Terrace[4] | Sara Upponi[8] | Rhiannon Taylor[9] | Elisa Allen[9] | Andrew J. Butler[1,2,3] | Gabriel C. Oniscu[4,6]

Kidney: better renal function at 12 months and earlier recovery in renal function after transplantation compared to in-situ cold perfusion

Kidney Transplant From Uncontrolled Donation After Circulatory Death: Contribution of Normothermic Regional Perfusion

Corinne Antoine [1], Emilie Savoye [1], François Gaudez [2], Gaelle Cheisson [3], Lionel Badet [4], Michel Videcoq [5], Camille Legeai [1], Olivier Bastien [1], Benoit Barrou [6]; National Steering Committee of Donation After Circulatory Death

Affiliations + expand

PMID: 30985577 DOI: 10.1097/TP.0000000000002753

Role of DCD Donors in Heart Transplantation

- The first adult heart transplant in the world was performed by Barnard at the Groote Schuur Hospital in 1967 from a DCD donor
- Noterdaeme *et al.* demonstrated that DCD hearts that met criteria (DBD criteria + donation withdrawal ischemia time less than 30 minutes) could increase the number of heart transplants by 11%
- Concerns about the risk of warm ischemic damage to the cardiac tissue
- No way to assess the heart function prior to utilization for transplantation
- Luckily, *ex vivo* perfusion platforms are now available with more in development

Evaluation Options for DCD Hearts: DPP and NRP

- Direct procurement and ex-situ machine perfusion (DPP) versus in-situ normothermic regional perfusion (NRP)
- Messer et al. compared the outcomes between DCD heart transplants performed with DPP and NRP, they showed no significant difference in outcomes with the two techniques
- NRP can be used in two ways:
  1. normothermic regional perfusion followed by static cold storage (NRP-SCS)
  2. normothermic regional perfusion followed by machine perfusion (NRP-MP)

Effects of TA-NRP on Thoracic Organs: What About the Lungs!

- Elevated pulmonary vascular resistance due to atelectatic lung
- Ongoing lung ischemia: lung perfusion limited to bronchial circulation, non-pulsatile flow, unknown perfusion with MAP goals of 65
- Stasis of blood in pulmonary vascular bed and pulmonary edema from dysfunctional left ventricle

Two Circulations

- Pulmonary Circulation
  - From Right Ventricle
  - Receives 100% of blood flow
- Bronchial Circulation
  - From the aorta, intercostal, subclavian, or internal mammary arteries
  - 2% of left ventricular output

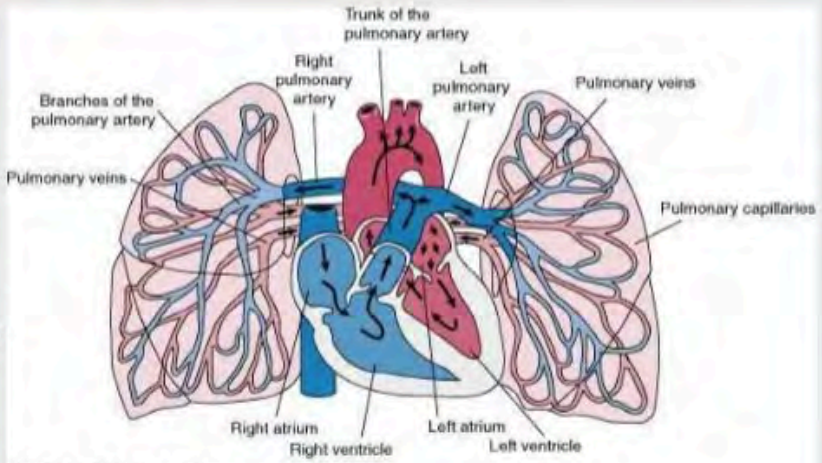
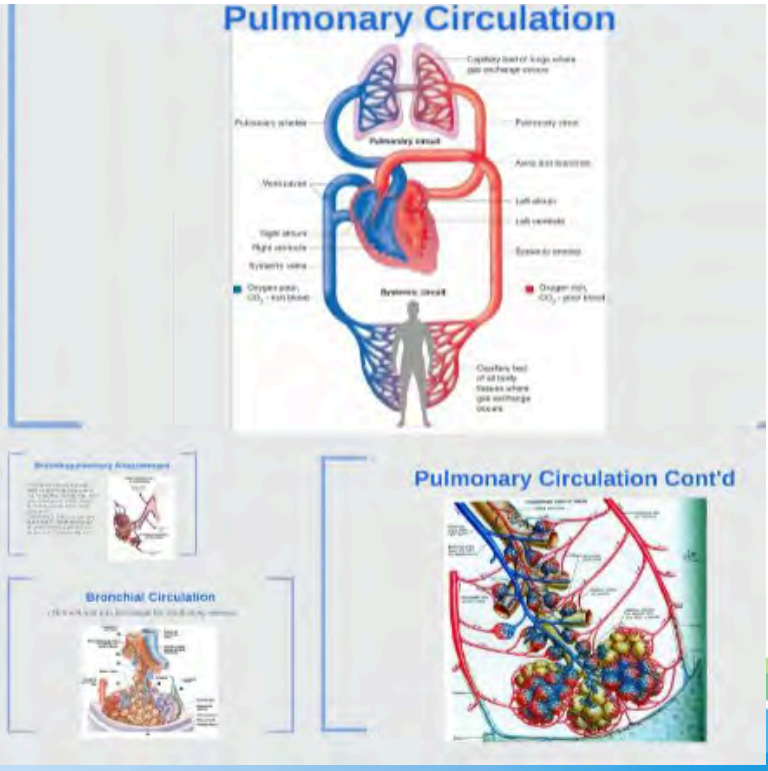


FIGURE 8-30 The pulmonary circulation.

(From Hicks GH: Cardiopulmonary anatomy and physiology, Philadelphia, 2000, WB Saunders.)



NRP and Lung Utilization: Effects of Blood Transfusion

Massive intraoperative red blood cell transfusion during lung transplantation is strongly associated with 90-day mortality

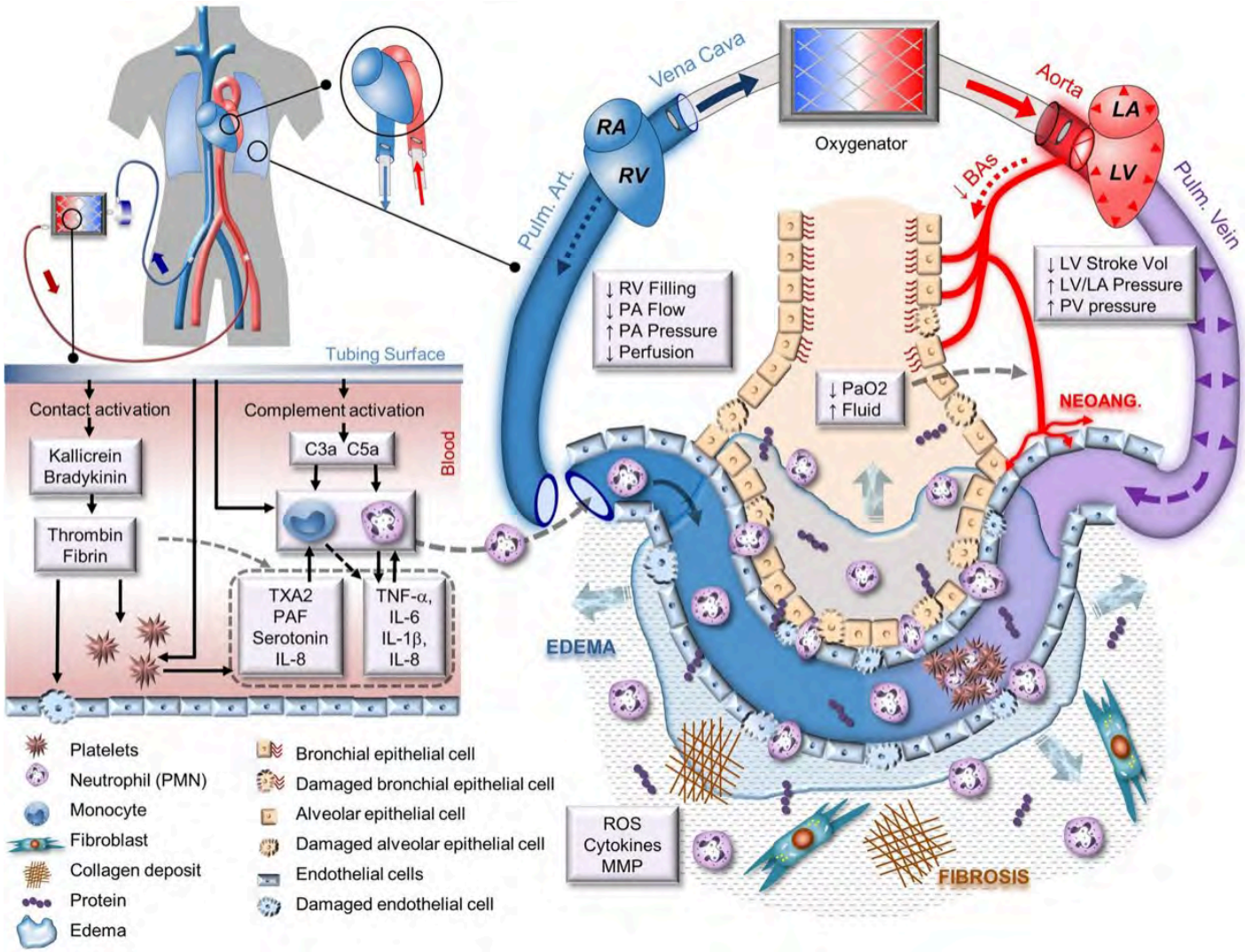
Enora Atchade [1], Yoann Elmaleh [2], Nathalie Zappella [2], Sylvain Jean-Baptiste [2], Alexis Tran-Dinh [3], Sébastien Tanaka [4], Aurélie Snauwaert [2], Brice Lortat-Jacob [2], Orlando Goncalves [5], Cendrine Godet [6], Hervé Mal [6], Yves Castier [7], Christian de Tymowski [8], Philippe Montravers [9]

Massive donor transfusion potentially increases recipient mortality after lung transplantation

Catherine F. Borders, BA,[1] Yoshikazu Suzuki, MD,[1] Jared Lasky, BA,[1] Christian Schaufler, BA,[1] Djamila Mallem, MA,[1] James Lee, MD,[2] Kevin Carney, NP,[3] Scarlett L. Bellamy, ScD,[4] Christian A. Bermudez, MD,[1] A. Russell Localio, JD, MA, MPH, MS, PhD,[4] Jason D. Christie, MD, MSCE,[2,4] Joshua M. Diamond, MD, MSCE,[2,*] and Edward Cantu, MD, MSCE[1,*]

NRP and Lung Utilization

- **Pulmonary complications associated with ECMO and CPB**
- **Reperfusion injury during NRP weaning trial**



Current Studies on NRP and Lung Utilization

- Although already being used for heart donors clinically there is still no pre-clinical data showing the impact of this procedure on donor lungs
- Significant limitations
- Data are not tracked in national databases
- Current animal studies do NOT accurately replicate NRP conditions
  - Blood utilization
  - Use of EVLP
- Early studies have limited case numbers

What is the right way to do TA-NRP?

Various protocols:

- Definitions of the agonal phase or WIT, SBP < 50 or 60, addition of sats < ?
- Hands off/observation period
- Cannulation strategy, steps of the operation, reintubation, ventilation, presence of a PA cannula, components of ECMO/CPB circuit
- Perfusion time: 30min, 45 min, 60 min, targeted blood flow? liters/min or % of cardiac output
- Transfusion of blood products: Crossmatched or un-crossmatched, 4, 6 or 8 PRBC
- Hemodynamic goals during perfusion: MAP of > 55 or 70?
- Conduct of weaning from MCS

Future: Are We Asking the Right Questions?

- Current studies of DCD Heart transplants do not examine the effects on the donor lungs or outcomes of NRP lung recipients
- Should protocols be standardized?
- What data should be collected?
- How do we know we aren't sacrificing quality of one organ in order to transplant another?

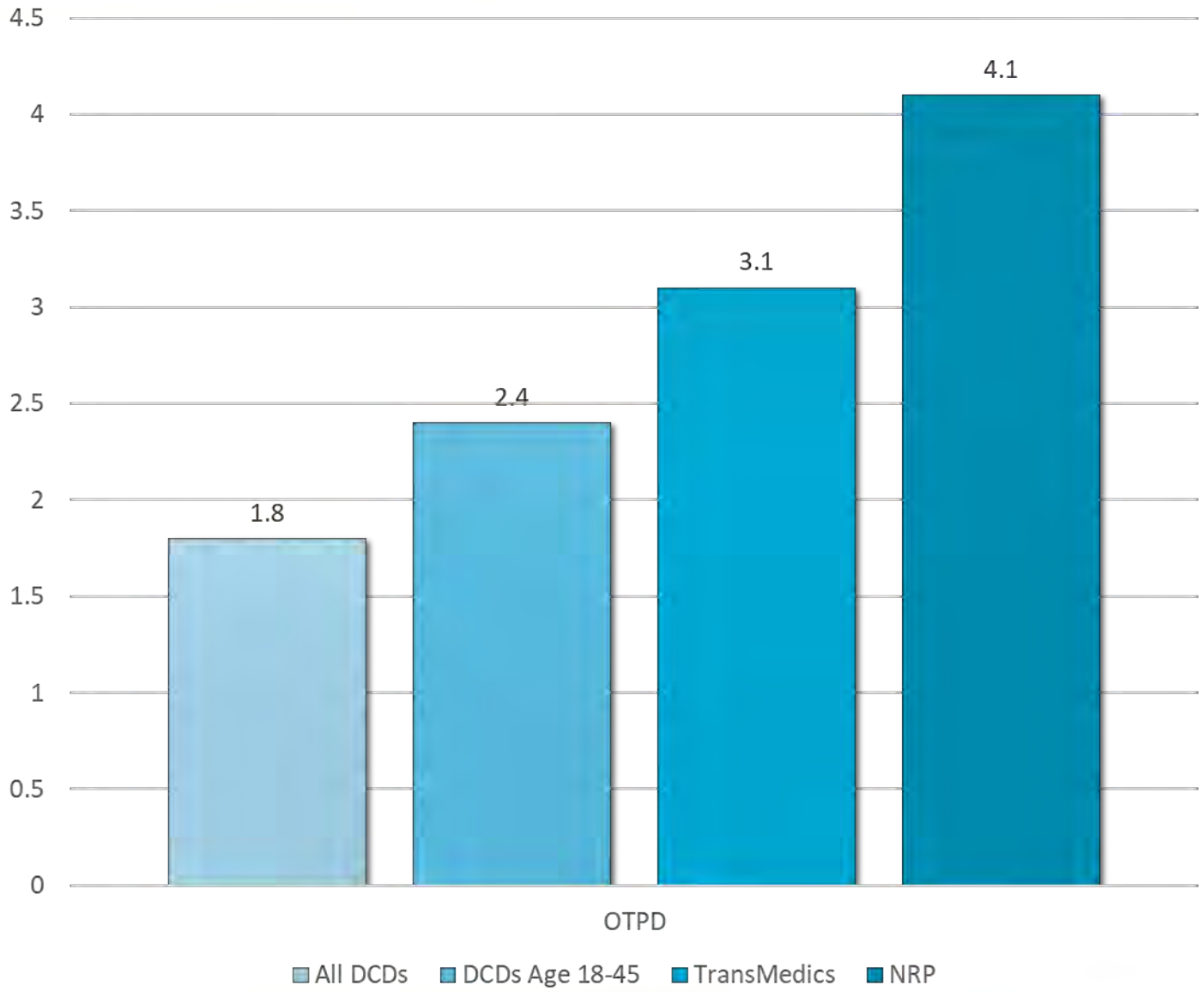
Best Practices

Sara Bowman, RN, BSN, CPTC

Clinical Manager, Organ Recovery

DonorConnect

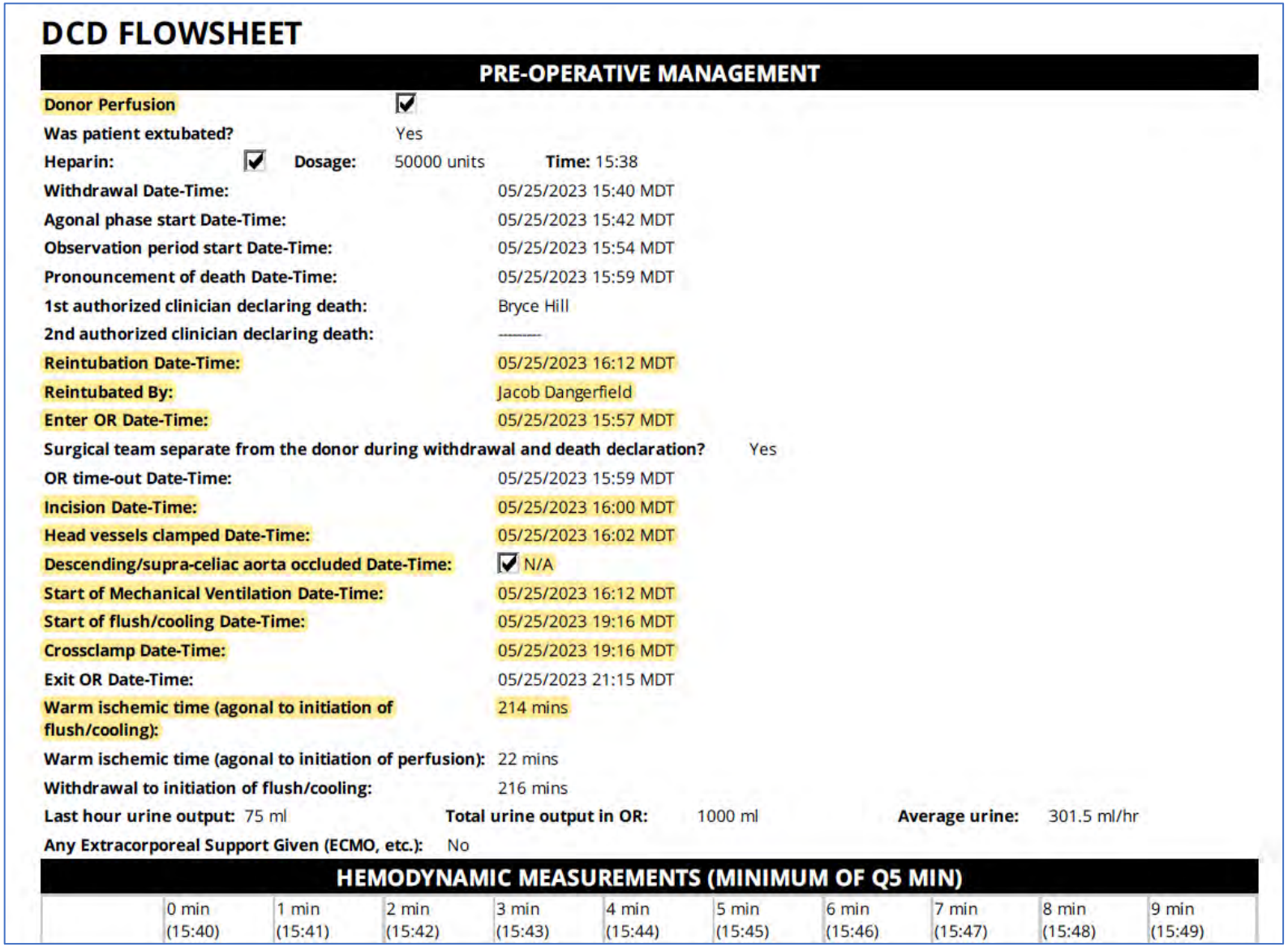
DonorConnect Average OTPD



Continuing Education

- ***Be flexible, think outside of the box and Make Things Happen!***
- Role Clarity & Ownership
  - Huddles (ICU & OR Staff)
  - Withdrawal Sequence & Roles
- NRP Taskforce (DonorConnect)
  - Representatives from multiple teams
  - Monthly check-ins
  - Pop-Up Education in ICUs
- Continued discussion with Local Tx Centers
  - Assisting 2nd Transplant Center with NRP Process
  - Pediatric Hospital Admin discussions
- Collaboration with Hospital Partners to update DCD Policies
  - Understanding of NRP Process
  - OR & ICU Withdrawal Process
  - Observation or Standoff Period: Transition to 5 minutes

iTransplant DCD Flowsheet Changes



DCD FLOWSHEET

PRE-OPERATIVE MANAGEMENT

Donor Perfusion	☑
Was patient extubated?	Yes
Heparin: ☑ **Dosage:**	50000 units **Time:** 15:38
Withdrawal Date-Time:	05/25/2023 15:40 MDT
Agonal phase start Date-Time:	05/25/2023 15:42 MDT
Observation period start Date-Time:	05/25/2023 15:54 MDT
Pronouncement of death Date-Time:	05/25/2023 15:59 MDT
1st authorized clinician declaring death:	Bryce Hill
2nd authorized clinician declaring death:	--------
Reintubation Date-Time:	05/25/2023 16:12 MDT
Reintubated By:	Jacob Dangerfield
Enter OR Date-Time:	05/25/2023 15:57 MDT
Surgical team separate from the donor during withdrawal and death declaration?	Yes
OR time-out Date-Time:	05/25/2023 15:59 MDT
Incision Date-Time:	05/25/2023 16:00 MDT
Head vessels clamped Date-Time:	05/25/2023 16:02 MDT
Descending/supra-celiac aorta occluded Date-Time:	☑ N/A
Start of Mechanical Ventilation Date-Time:	05/25/2023 16:12 MDT
Start of flush/cooling Date-Time:	05/25/2023 19:16 MDT
Crossclamp Date-Time:	05/25/2023 19:16 MDT
Exit OR Date-Time:	05/25/2023 21:15 MDT
Warm ischemic time (agonal to initiation of flush/cooling):	214 mins
Warm ischemic time (agonal to initiation of perfusion):	22 mins
Withdrawal to initiation of flush/cooling:	216 mins

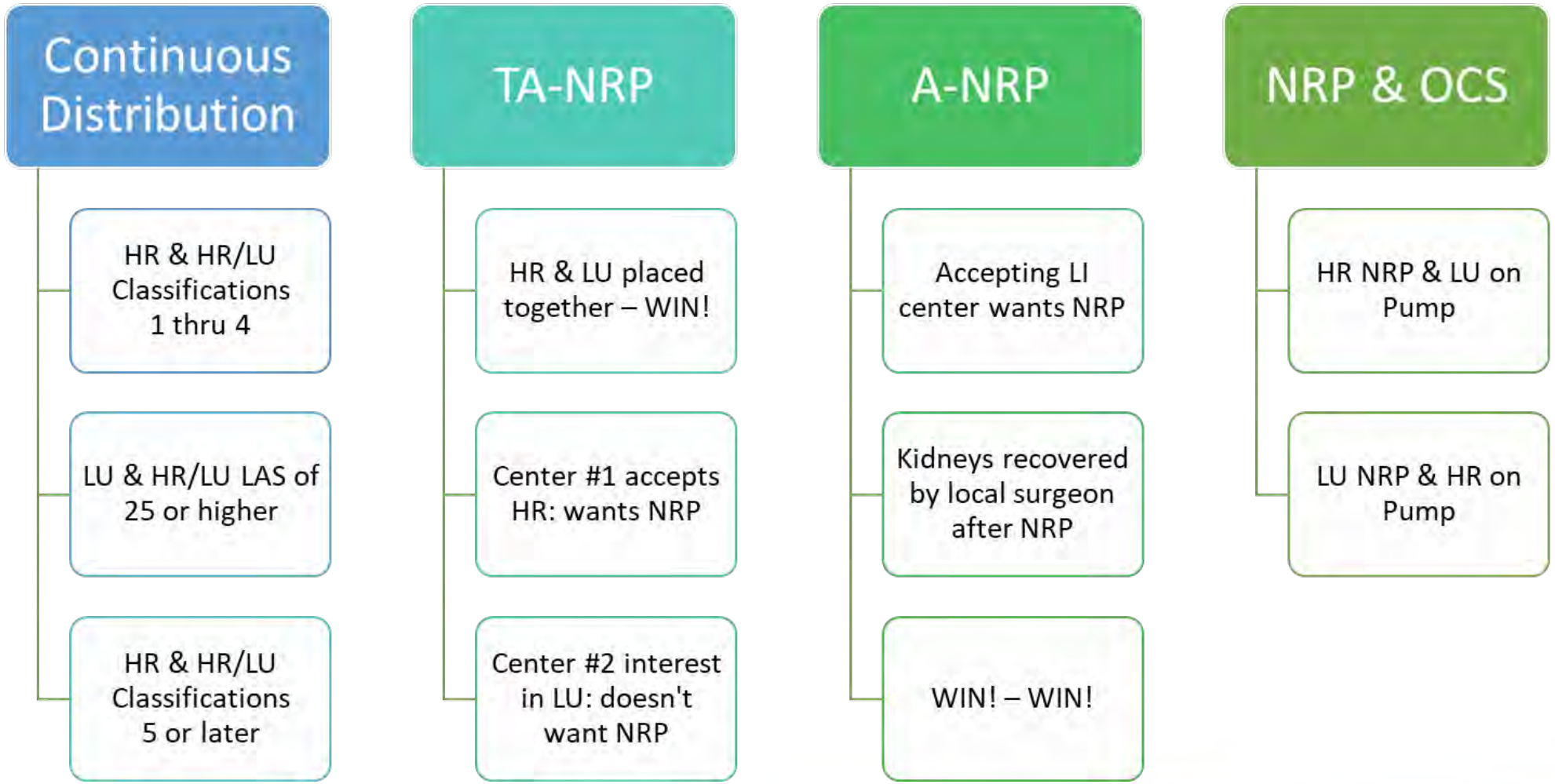
Last hour urine output: 75 ml **Total urine output in OR:** 1000 ml **Average urine:** 301.5 ml/hr

Any Extracorporeal Support Given (ECMO, etc.): No

HEMODYNAMIC MEASUREMENTS (MINIMUM OF Q5 MIN)

	0 min (15:40)	1 min (15:41)	2 min (15:42)	3 min (15:43)	4 min (15:44)	5 min (15:45)	6 min (15:46)	7 min (15:47)	8 min (15:48)	9 min (15:49)

Allocation Considerations



Making Things Happen!

VA ECMO to A-NRP

(Placed on VA ECMO & IABP on admission)

- 62/M: Cardiac arrest unknown etiology
  - Increased Risk d/t unreliable DRAI
  - PMH: HTN, LAD Stent, Meth use
  - Admit Cr 2.18
  - Terminal Cr 1.26
  - KDPI 89%
  - Severe moderate plaque & Fibrosis
  - 10-35% Glom Sclerosis
  - Local cardiac NRP team assisted

Kidneys Transplanted

DCD Transfer for TA-NRP

(Hospital not supportive of Thoracic DCD Recovery)

- 48/M: Cardiac arrest/Drug OD
  - Increased Risk d/t IV drug use & unreliable DRAI
  - PMH: IV Drugs, 16 pack year smoker, 5+ drinks/day
  - Admit Cr 2.53
  - Terminal Cr 1.16
  - KDPI 51%
  - Severe, hard plaque
  - No Bxs performed

Heart, Liver & Kidneys Transplanted

Group Discussion

Contact Information

- Lara Schaheen, MD
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- Sara Bowman, RN, BSN, CPTC
  sara.bowman@donorconnect.life
- Elizabeth Shipman, MBA
  shipman@nvdonor.org
- Heather Osipowicz, BA, MSBS, CTBS
  hosipowicz@nvdonor.org

Challenges and Insights with the New Lung Transplant Composite Allocation Score

Jody Kieler BSN,RN,CCRN

Clinical Program Coordinator, Lung and Heart-Lung Transplant Program

Cedars Sinai

cedars-sinai.org

Increased Distance to Donor

Figure 27: Distribution of Distance from Donor Hospital to Transplant Program for Lung Transplants by Era

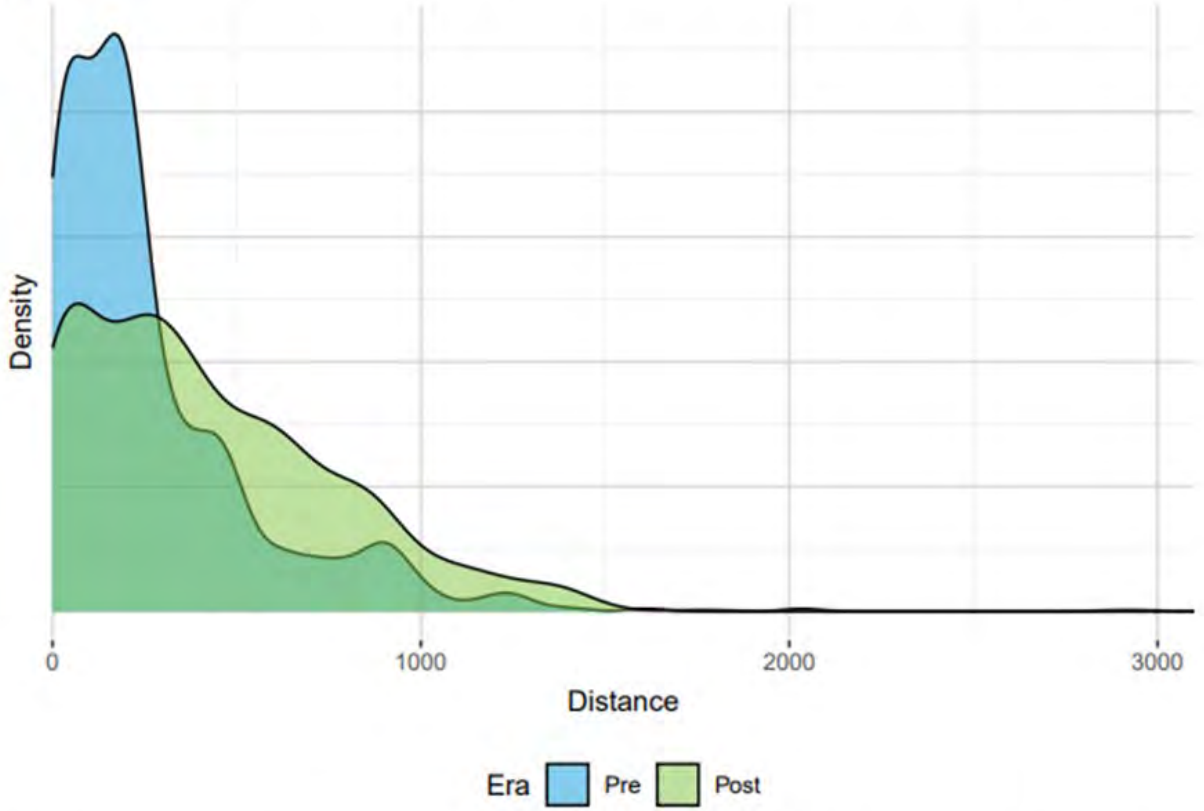


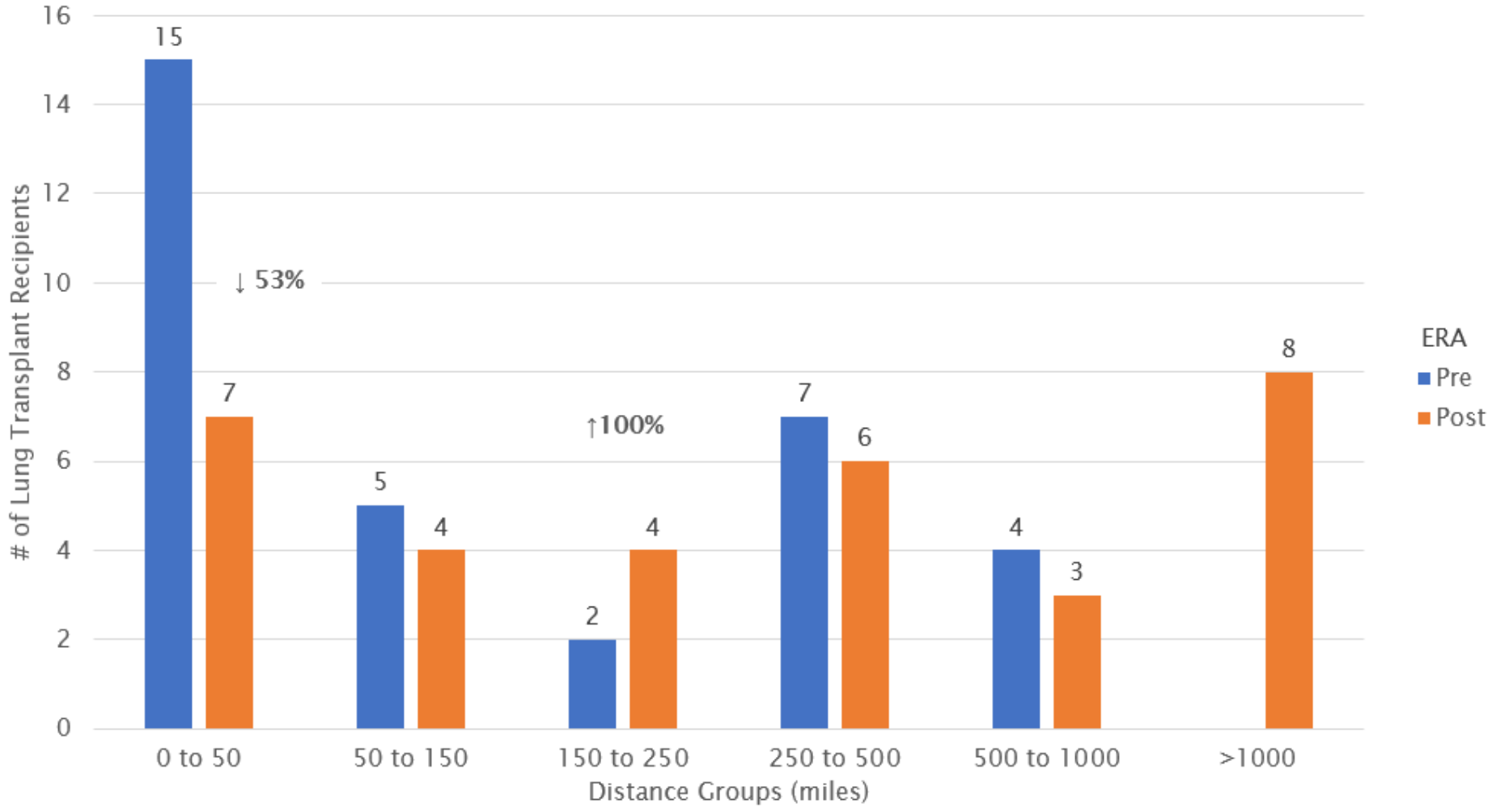
Table 27: Distribution of Distance from Donor Hospital to Transplant Program for Lung Transplants by Era

Era	N	Min	25th Percentile	Median	75th Percentile	Max	N Missing
Pre	672	0	75	193	370.5	2036	0
Post	779	0	138	344	633.5	2920	0

Cedars Sinai

Source: OPTN

Increased Distance to Donor



Source: OPTN

Increased Distance to Donor

- Increased cost of transplant
- More time with valuable staff being out of service
- Less time to prepare team/set up transportation
- Unable to complete prospective crossmatches on patients that are outside of CA, AZ, Las Vegas
- Increased number of organ offers

Cedars Sinai

Things to Consider or Unknowns

- Marginal offers
- National Distance
- Recipient impact with increased cold ischemic times
- Disadvantage for coastal transplant centers

Cedars Sinai

Age Disadvantage

Figure 20: Number of Lung Transplants by Era and Age Group

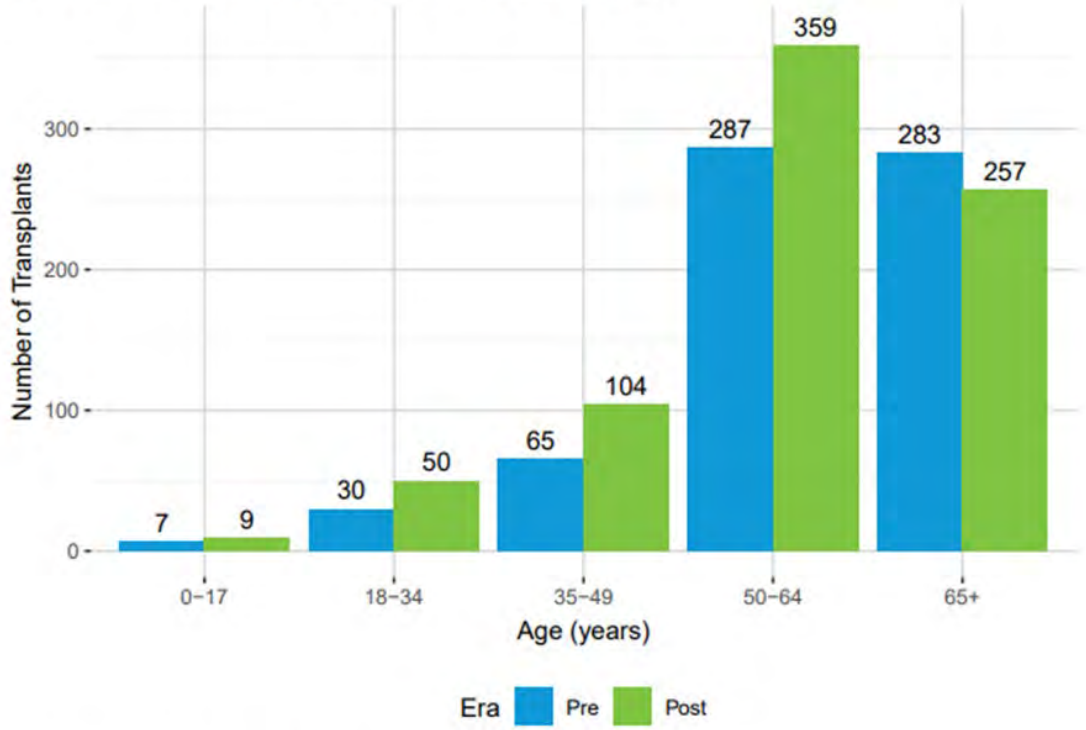


Table 20: Number of Lung Transplants by Era and Age Group

Age (years)	Pre	Post
0-17	7 (1.0%)	9 (1.2%)
18-34	30 (4.5%)	50 (6.4%)
35-49	65 (9.7%)	104 (13.4%)
50-64	287 (42.7%)	359 (46.1%)
65+	283 (42.1%)	257 (33.0%)
Total	672 (100.0%)	779 (100.0%)

Cedars Sinai

Source: OPTN

Increased Number of Patients on Waitlist

Waiting List

Candidates Ever Waiting and Waiting List Additions

There was a slight increase in the number of candidates ever waiting in the post policy era.

Figure 1: Number of Lung Candidates Ever Waiting by Era

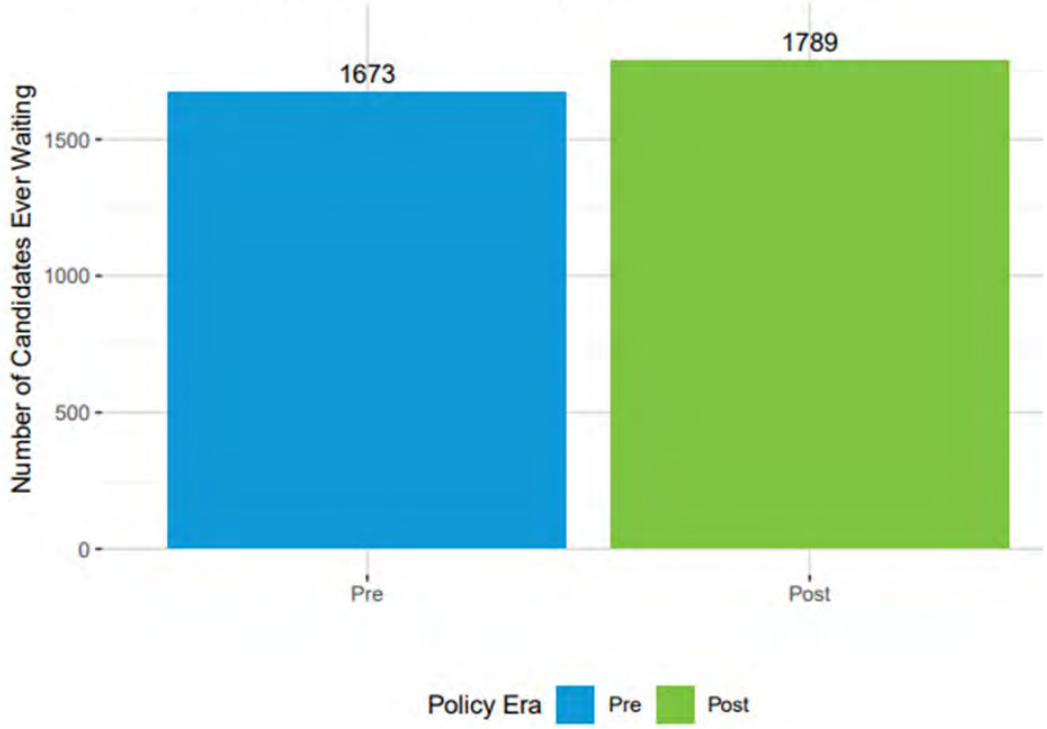


Table 1: Number of Lung Candidates Ever Waiting by Era

Era	N
Pre	1673
Post	1789

Cedars Sinai

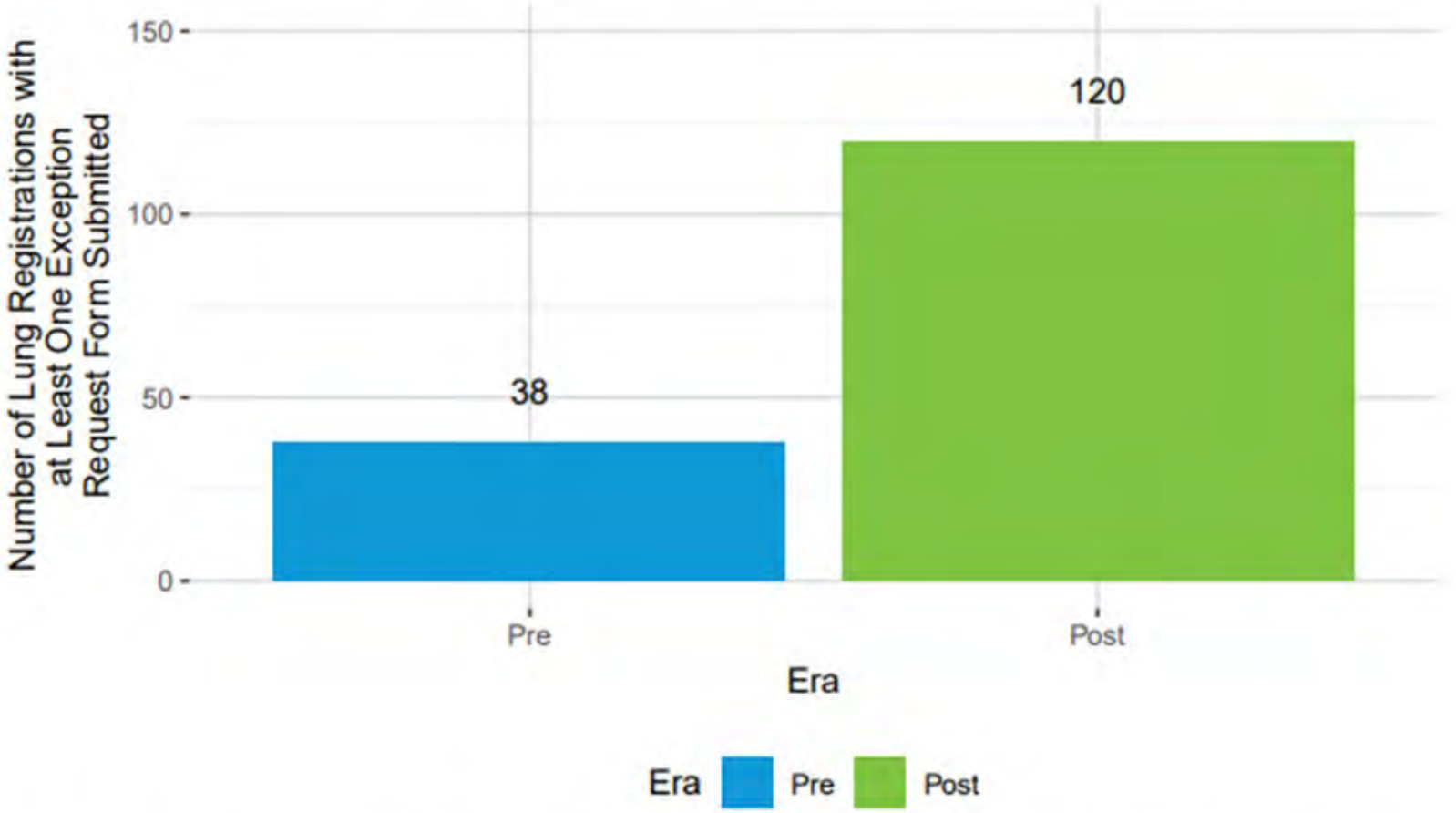
Source: OPTN

CAS Less Predictable

- Some patients with decreased score over time
- 6MWT as predictor of 5 year survival
- Increased exception requests

Cedars Sinai

Figure 11: Number of Lung Waiting List Registrations with at Least One Submitted Exception Request Form by Era

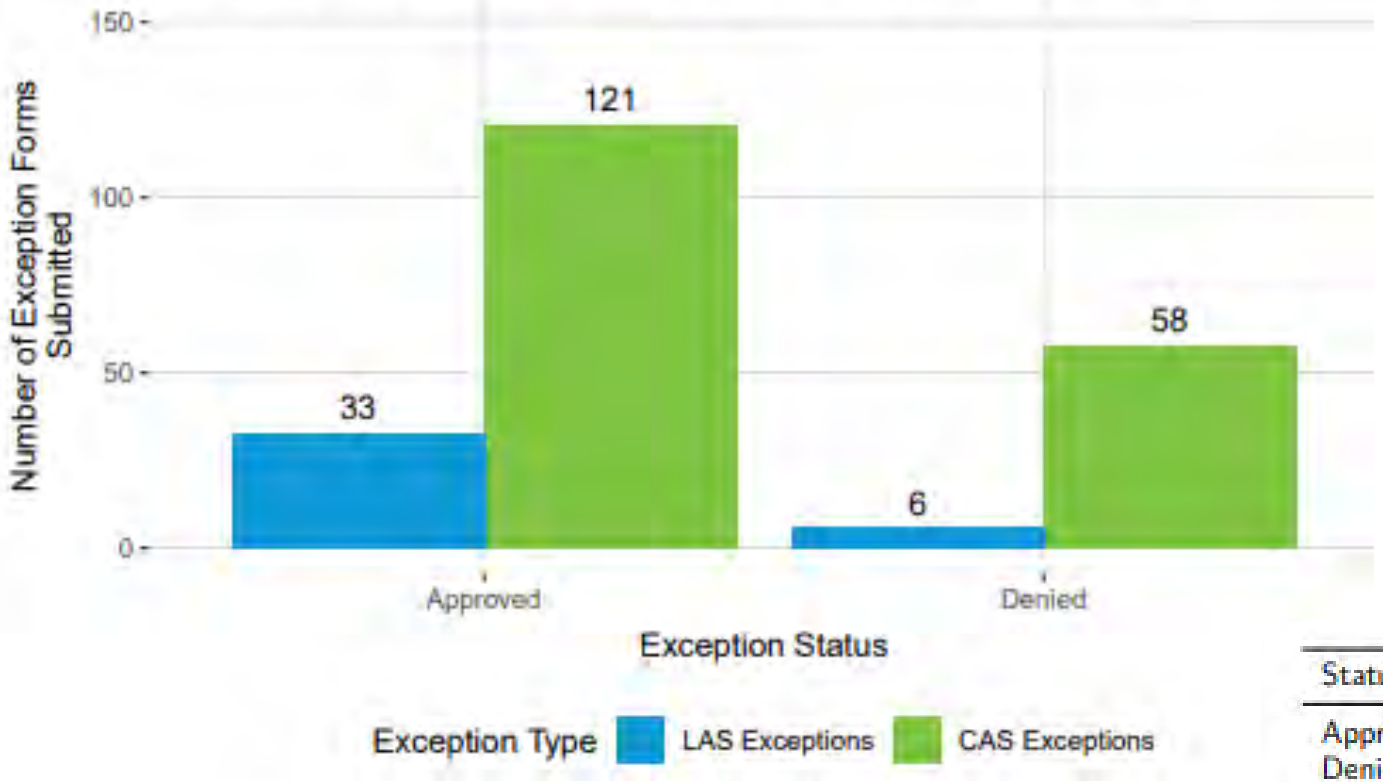


This chart does not include the 26 exceptions that were submitted to the National Lung Review Board prior to the implementation of Lung Continuous Distribution on 3/9/23. Under LAS, a single registration could only have one exception but under CD, a single registration can have multiple exceptions. Results include exceptions for multiorgan candidates but excludes exceptions on heart/lung (HL) registrations. Exceptions submitted on the lung registration of a HL candidate are included.

Cedars Sinai

Source: OPTN

Figure 14: Number of Lung Exception Request Forms Submitted by Era and Status



Status	LAS Exceptions	CAS Exceptions
Approved	33 (84.6%)	121 (67.6%)
Denied	6 (15.4%)	58 (32.4%)
Total	39 (100.0%)	179 (100.0%)

[a] This table does not include the 26 exceptions that were submitted to the National Lung Review Board prior to the implementation of Lung Continuous Distribution on 3/9/23.

[b] Under LAS, a single registration could only have one exception but under CD, a single registration can have multiple exceptions.

[c] Results include exceptions for multiorgan candidates but excludes exceptions on heart/lung (HL) registrations. Exceptions submitted on the lung registration of a HL candidate are included.

Cedars Sinai

Source: OPTN

References

-Weiss, S., Weibel, C., & Mupfudze, T. (2023, July 13) Lung Continuous Distribution Three Month Monitoring Report*. OPTN Lung Transplantation Committee.* https://optn.transplant.hrsa.gov/media/fzhh1e5r/data_report_lung_committee_cd_07_13_2023.pdf

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Thank you!

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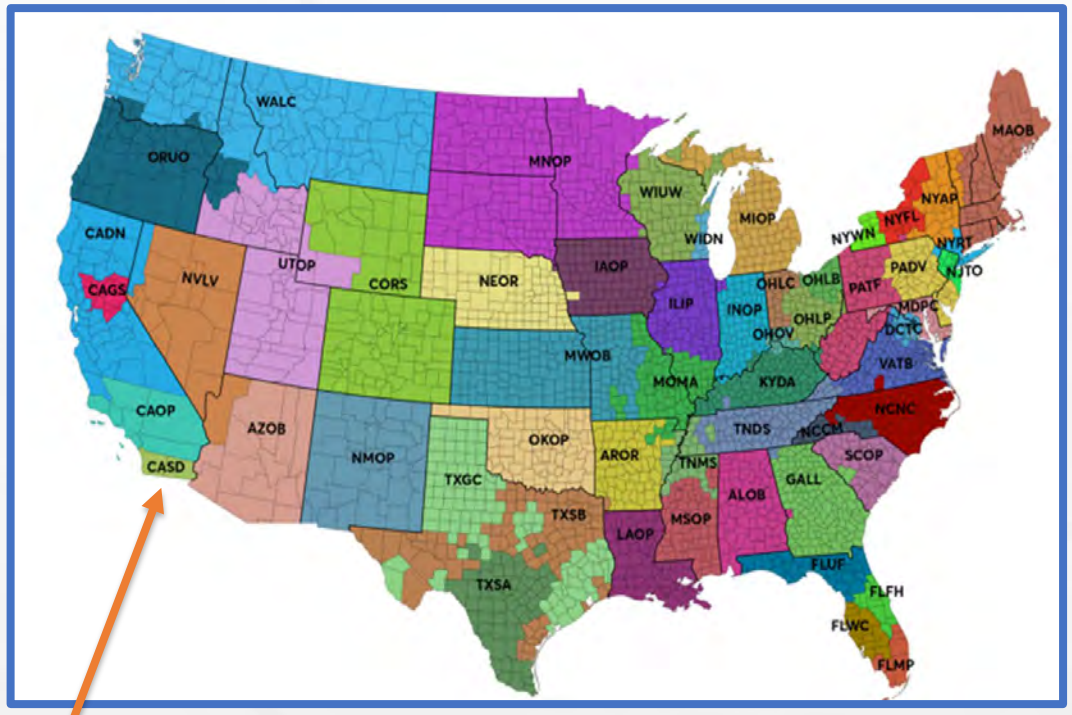
CAS: Geographical Challenges in Lung Transplant – an OPO perspective

Jaclyn Russe MSN, RN, CCRN, CPTC

Lead Organ Procurement Coordinator

LIFESHARING™



Serves a 3.3 million population

29 Hospitals with 4 local transplant programs

Allocation Changes

- March 2023: Change in lung allocation policy
- Removed local and regional candidates in favor of the continuous allocation model

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Multiple Challenges

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Transplant Center Challenges

- Working with centers we have not previously worked with
- Unknown logistics and timing
- Responsibilities
- Center familiarity
- Buy-in

Family & Hospital Challenges

- Longer allocation times
- Families want to move quickly
- Hospitals unwilling to wait
- Potential for instability

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Logistical Challenges

- More frequent pumping
- More transportation needs

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Policy Challenges

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Policy Challenges

- New policies require multiple eyes to ensure we are proceeding correctly
- The more organs being allocated, the more confusion exists
- Multi-organ policies have also added to the confusion

6.6.F Allocation of Heart-Lungs

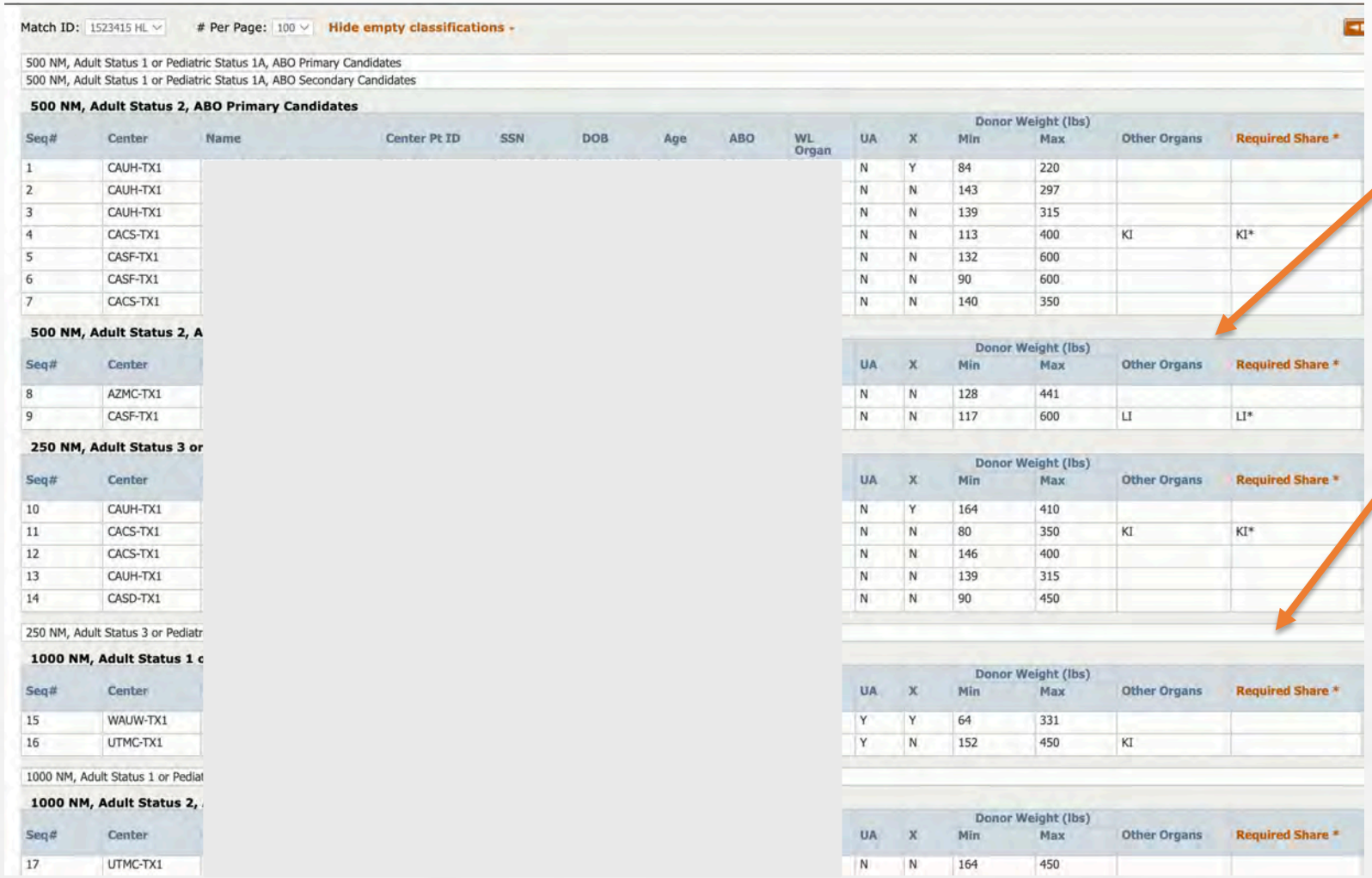
6.6.F.i Allocation of Heart-Lungs from Deceased Donors at Least 18 Years Old

If a host OPO is offering a heart and lung from the same deceased donor, then the host OPO must offer the heart and lung in the following order:

1. To all heart and heart-lung PTRs in allocation classifications 1 through 4 according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*
2. To all lung and heart-lung PTRs according to *Policy 10.1 Lung Composite Allocation Score* until offers have been made to all heart-lung PTRs with a lung composite allocation score of 25 or higher
3. To heart and heart-lung PTRs in classifications 5 or later according to *Policy 6.6.D: Allocation of Hearts from Donors at Least 18 Years Old*.

The host OPO must follow the order on each match run, including heart-lung, heart, and lung candidates.

Allocation Example



Match ID: 1523415 HL # Per Page: 100 Hide empty classifications

500 NM, Adult Status 1 or Pediatric Status 1A, ABO Primary Candidates
500 NM, Adult Status 1 or Pediatric Status 1A, ABO Secondary Candidates

500 NM, Adult Status 2, ABO Primary Candidates

Seq#	Center	Name	Center Pt ID	SSN	DOB	Age	ABO	WL Organ	UA	X	Donor Weight (lbs) Min	Max	Other Organs	Required Share *
1	CAUH-TX1								N	Y	84	220		
2	CAUH-TX1								N	N	143	297		
3	CAUH-TX1								N	N	139	315		
4	CACS-TX1								N	N	113	400	KI	KI*
5	CASF-TX1								N	N	132	600		
6	CASF-TX1								N	N	90	600		
7	CACS-TX1								N	N	140	350		

500 NM, Adult Status 2, A

Seq#	Center	UA	X	Donor Weight (lbs) Min	Max	Other Organs	Required Share *
8	AZMC-TX1	N	N	128	441		
9	CASF-TX1	N	N	117	600	LI	LI*

250 NM, Adult Status 3 or

Seq#	Center	UA	X	Donor Weight (lbs) Min	Max	Other Organs	Required Share *
10	CAUH-TX1	N	Y	164	410		
11	CACS-TX1	N	N	80	350	KI	KI*
12	CACS-TX1	N	N	146	400		
13	CAUH-TX1	N	N	139	315		
14	CASD-TX1	N	N	90	450		

250 NM, Adult Status 3 or Pediatr

1000 NM, Adult Status 1 c

Seq#	Center	UA	X	Donor Weight (lbs) Min	Max	Other Organs	Required Share *
15	WAUW-TX1	Y	Y	64	331		
16	UTMC-TX1	Y	N	152	450	KI	

1000 NM, Adult Status 1 or Pediat

1000 NM, Adult Status 2,

Seq#	Center	UA	X	Donor Weight (lbs) Min	Max	Other Organs	Required Share *
17	UTMC-TX1	N	N	164	450		

- Required to offer the lungs out to classification 4 (no lungs on this list)
- Then must allocate liver until status 3, 500 NM

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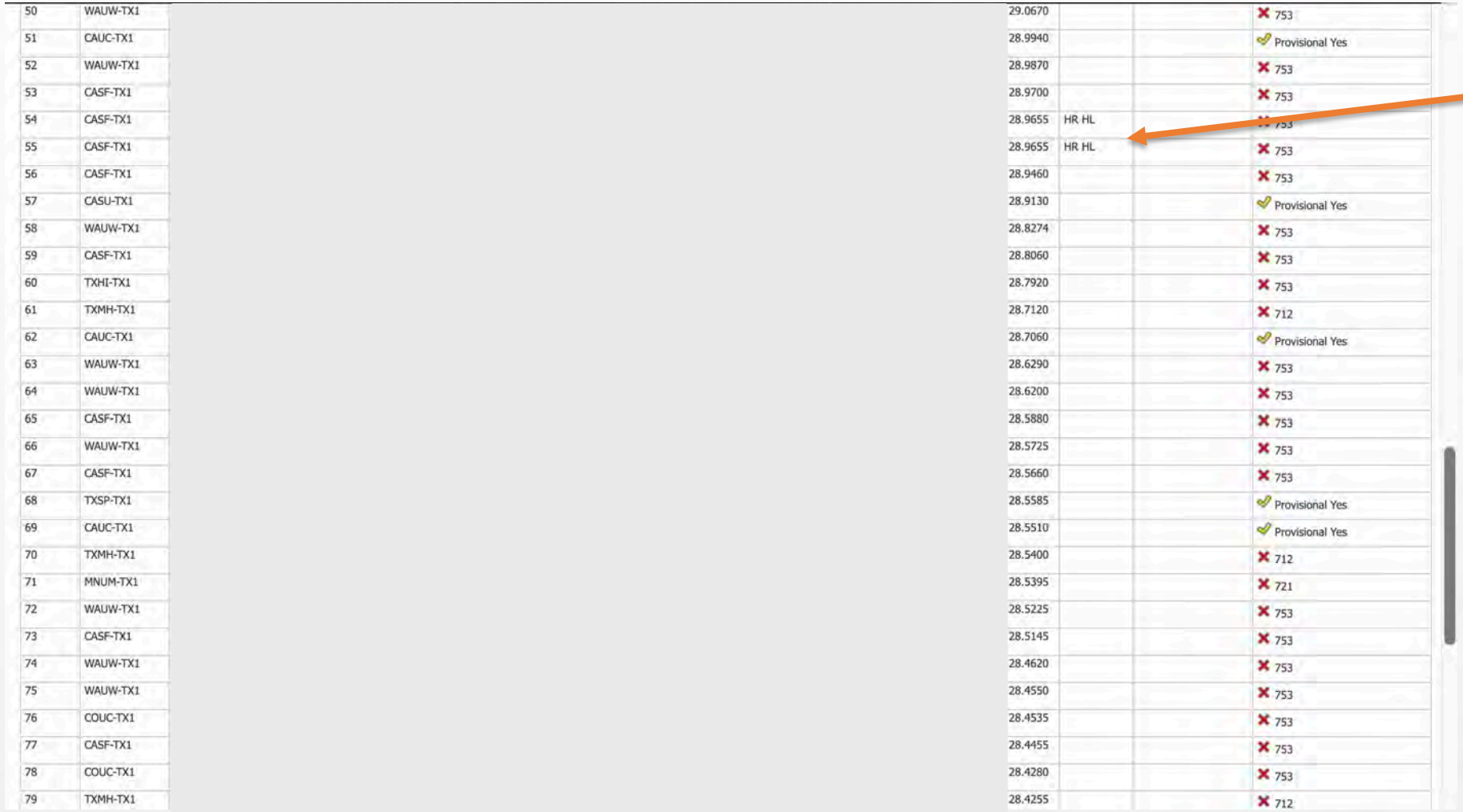
Allocation Example



50	WAUW-TX1	29.0670			753
51	CAUC-TX1	28.9940			Provisional Yes
52	WAUW-TX1	28.9870			753
53	CASF-TX1	28.9700			753
54	CASF-TX1	28.9655	HR HL		
55	CASF-TX1	28.9655	HR HL		753
56	CASF-TX1	28.9460			753
57	CASU-TX1	28.9130			Provisional Yes
58	WAUW-TX1	28.8274			753
59	CASF-TX1	28.8060			753
60	TXHI-TX1	28.7920			753
61	TXMH-TX1	28.7120			712
62	CAUC-TX1	28.7060			Provisional Yes
63	WAUW-TX1	28.6290			753
64	WAUW-TX1	28.6200			753
65	CASF-TX1	28.5880			753
66	WAUW-TX1	28.5725			753
67	CASF-TX1	28.5660			753
68	TXSP-TX1	28.5585			Provisional Yes
69	CAUC-TX1	28.5510			Provisional Yes
70	TXMH-TX1	28.5400			712
71	MNUM-TX1	28.5395			721
72	WAUW-TX1	28.5225			753
73	CASF-TX1	28.5145			753
74	WAUW-TX1	28.4620			753
75	WAUW-TX1	28.4550			753
76	COUC-TX1	28.4535			753
77	CASF-TX1	28.4455			753
78	COUC-TX1	28.4280			753
79	TXMH-TX1	28.4255			712

- Then we must offer the heart off the lung list until CAS < 25
- There is a liver/lung listed at seq 211 that we must allocate to prior to offering primary liver offers

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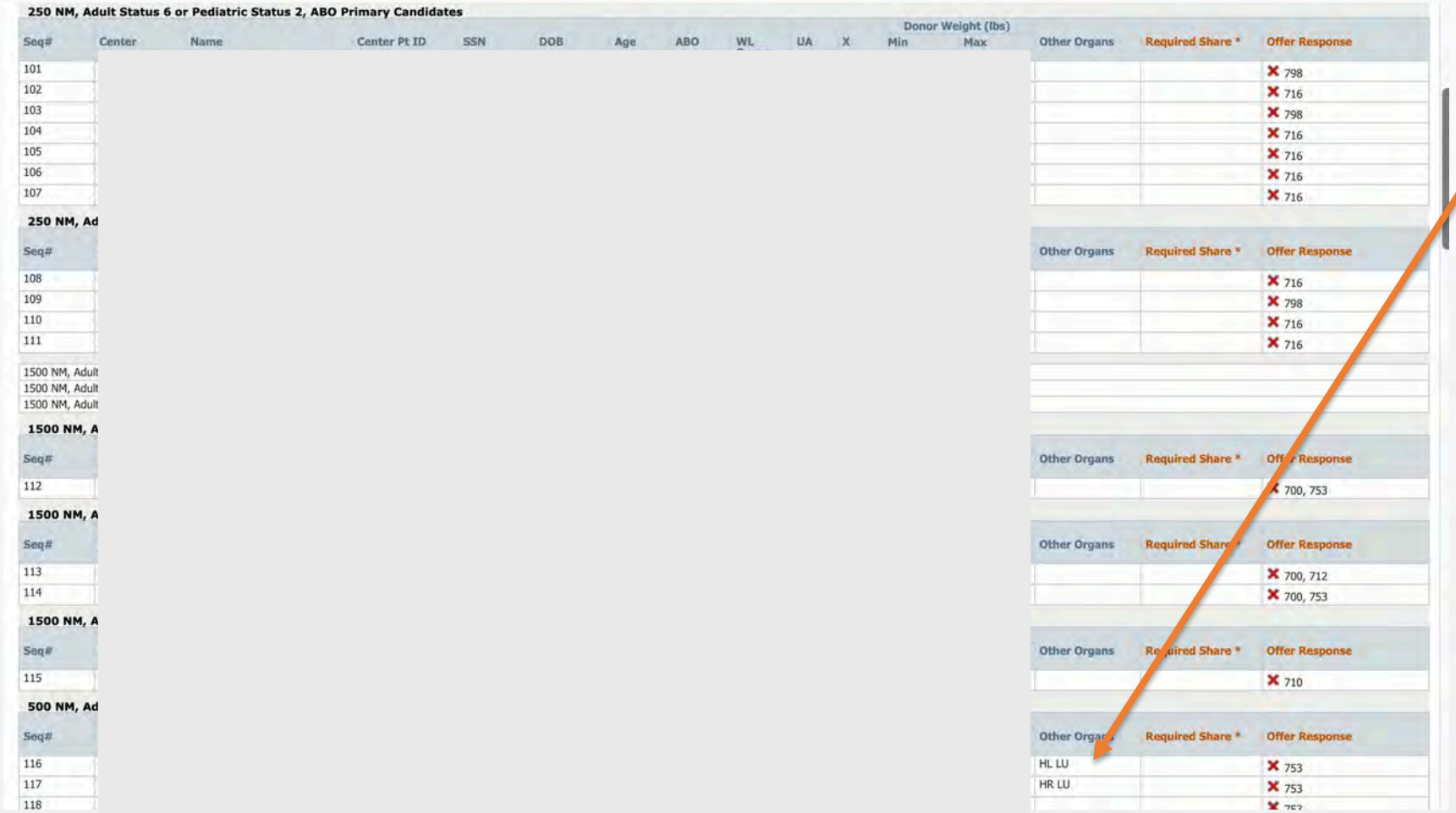
Allocation Example



- Must now allocate the lungs off the heart list until seq 117 (the last HL on the list)

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Allocation Example

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The Way Forward

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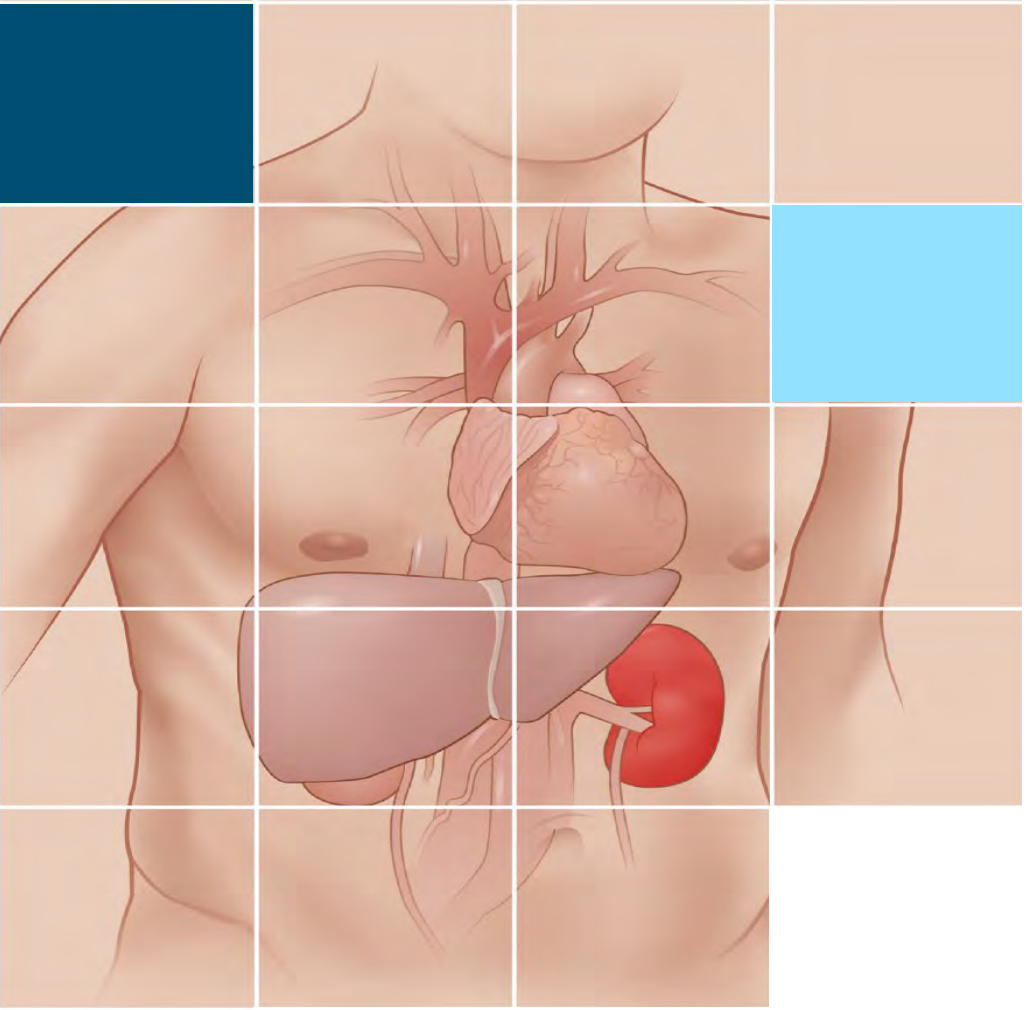

Enhancing Evaluation of Living Kidney Donors: Road to Improving Donor Education and Risk Assessment

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Disclosure

- This program is sponsored by Sanofi. I am being compensated and/or receiving an honorarium from Sanofi in connection with this presentation
- The content contained in this presentation was developed by Sanofi and is not eligible for continuing medical education (CME) credits

Questions We'll Explore

- How do racial disparities affect the living kidney donor evaluation process, and what could contribute to this?
- What new tools are available to evaluate the risk of end-stage renal disease (ESRD) for living kidney donors, and how can these tools facilitate the donor evaluation process?
- How do differences in transplant center practices impact their number of living kidney donor transplants?
- What is the role of genetic testing in the living kidney donor evaluation process?
- What steps can be taken within the transplant community to better support living kidney donors and emphasize the need for living kidney donor follow-up?

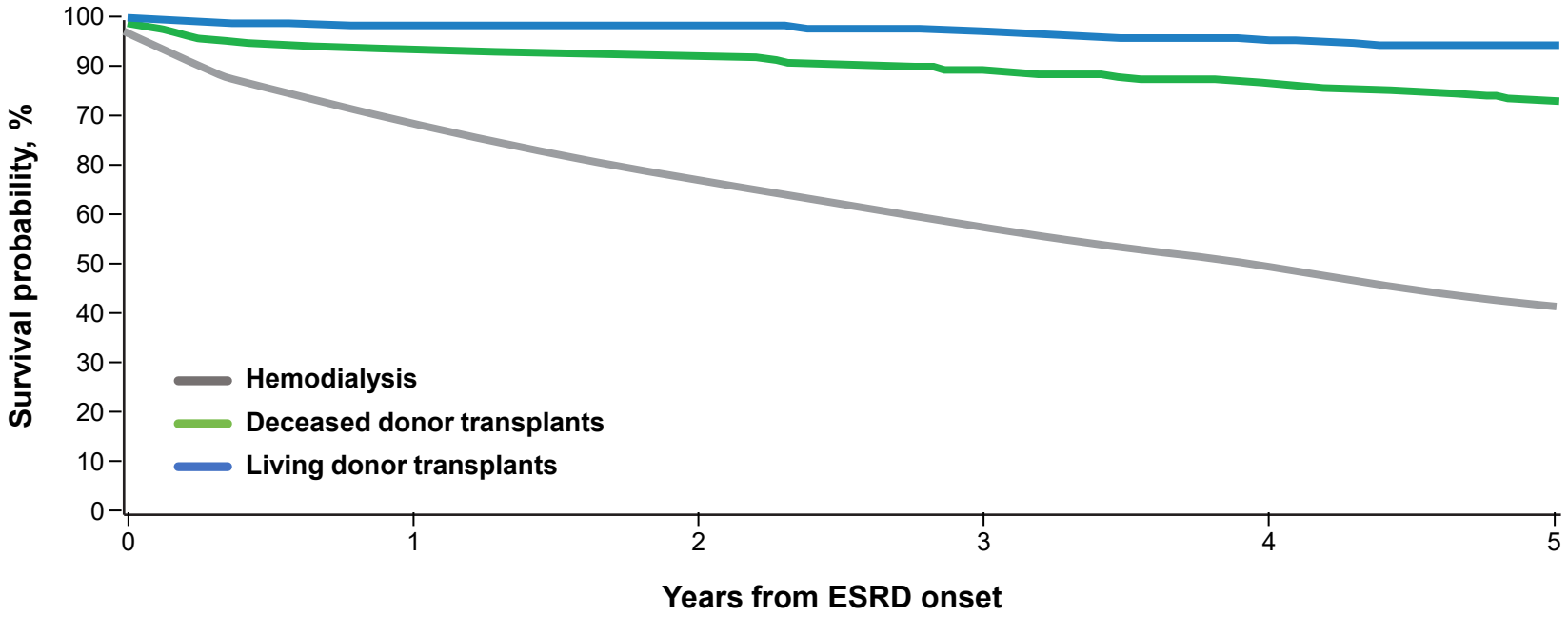
"You have 2 kidneys, and you only need one. The power of the extra one is that it can allow someone to live a whole new life."

***- Hendrik Gerrits**, Organ donor*

Why I became a living organ donor. NewYork-Presbyterian Health Matters website. https://healthmatters.nyp.org/why-i-became-a-donor/. Accessed September 29, 2022.

LDKT Is Associated With Greater 5-Year Patient Survival Than Other Treatments

Adjusted 5-Year Survival of Incident ESRD Patients After Onset of ESRD in 2013[1]



LDKT is the preferred treatment option for patients with ESRD, but is limited by availability of donors[2]

LDKT, living donor kidney transplant.

1. United States Renal Data System. *2020 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases: Bethesda, MD; 2020:ESRD vol, chap 5. https://adr.usrds.org/2020. Accessed July 21, 2022. **2.** Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation. *Transplantation.* 2020;104(4S1 Suppl 1):S1–S103.

Racial and Ethnic Disparities Exist With Living Kidney Donation

- Numbers of Black, Hispanic, or Asian living kidney donors have remained stable over the last 10 years and are ***substantially lower*** than their White counterparts[1,2]
- Over the past 2 decades, increased attention and efforts have aimed to reduce racial/ethnic disparities in living donor kidney transplants (LDKTs) within the US[1]
- Compared with receipt of LDKTs among White patients, **the incidence among other races has continued to decrease over time**[1]

These findings suggest that other national evidence-based strategies are needed to more effectively address these racial/ethnic disparities[1]

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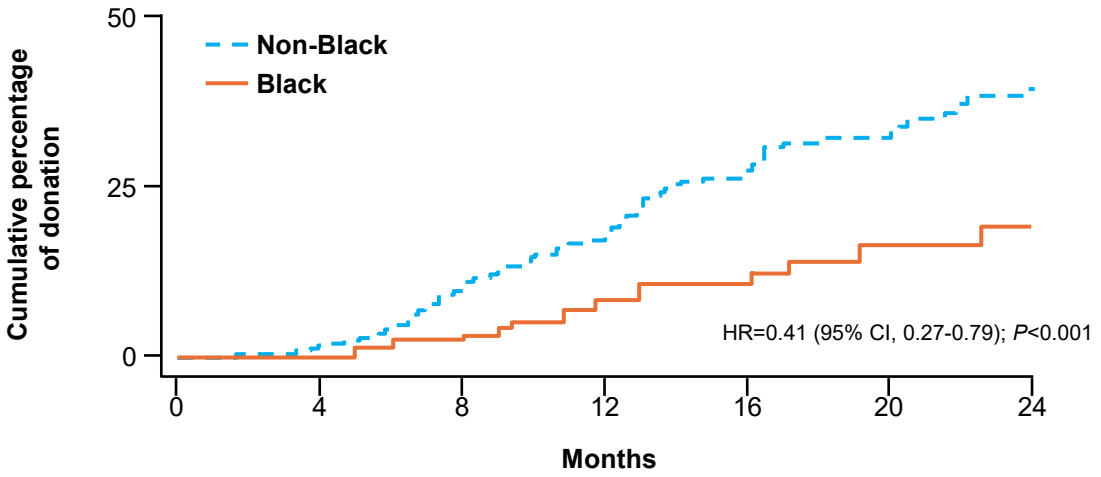
1. Purnell TS, et al. *JAMA*. 2018;319(1):49-61. **2.** Lentine KL, et al. *Am J Transplant*. 2022;22(suppl 2):21-136.

The Evaluation Process May Also Contribute to the Racial Disparities in Living Kidney Donation

- Evaluation of potential living kidney donors involves a complex, multistep screening process and medical examinations that may be a **source of racial disparities in LDKTs**[1]
  - Compared with non-Black donor candidates, Black candidates experienced **longer delays** following referral and during the evaluation process **and were less likely to progress** through the evaluation process
- In a recent policy change, OPTN has begun to require the use of **race-neutral eGFR calculations** to more accurately estimate eGFR values and reduce existing disparities[2]

Cumulative Incidence of Donation: Time From Donor Candidate Referral to Donation by Race[1]



Standardizing the evaluation process for all living kidney donor candidates across centers may increase LDKTs overall while also reducing racial disparities[1,3]

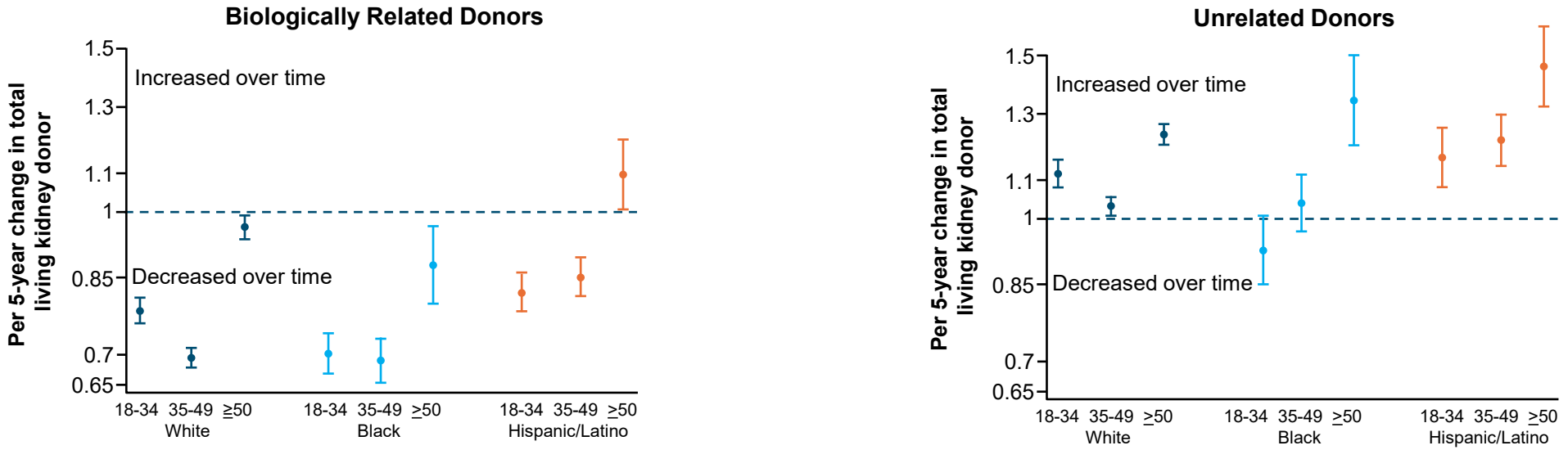
eGFR, estimated glomerular filtration rate; HR, hazard ratio; OPTN, Organ Procurement and Transplantation Network.

1. Kumar K, et al. *Clin Transplant*. 2018;32(7):e13291. doi: 10.1111/ctr.13291. **2.** Organ Procurement and Transplantation Network. Establish OPTN requirement for race-neutral estimated glomerular filtration rate (eGFR) calculations. https://optn.transplant.hrsa.gov/media/xn3nhhjr/policy-notice_establish-optn-req-for-race-neutral-egfr-calcls_mac.pdf. Accessed July 25, 2022.
3. Waterman AD, et al. *Clin J Am Soc Nephrol*. 2013;8(6):995-1002.

Donation by Biologically Related Individuals Has Declined Over Time

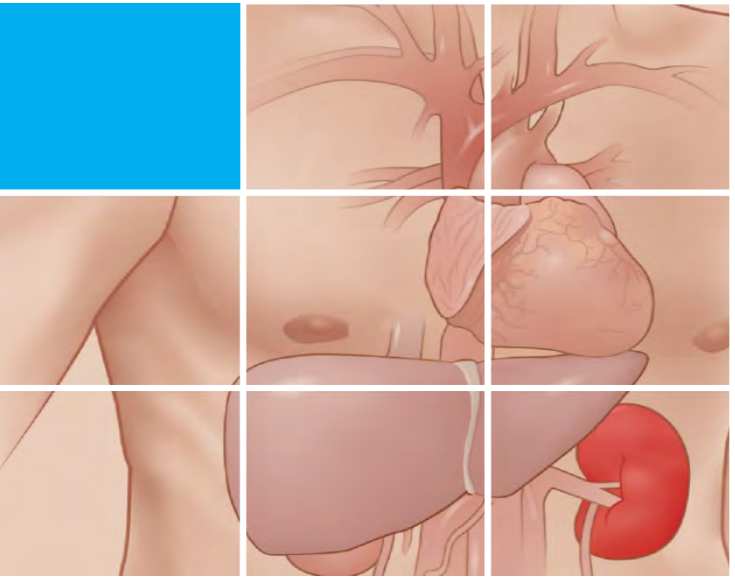
- A national study of living kidney donors from 2005 to 2017 reported a **significant decline** in most groups of biologically related donors, while the number of unrelated donors increased[1]
- Similarly, in the most recent OPTN/SRTR data report, the number of related donors **continued to decline from 2018 to 2019**, while the numbers of other donor types increased[2]
- This decline in donors parallels the increased knowledge of risk for biologically related, Black, and younger donors[1]

Incident Rate Ratio of Living Kidney Donation from 2005 to 2017 Based on Relationship With Recipient[1]



Biologically related older individuals are potentially a lower-risk subgroup of donors who could be possible targets for interventions to promote live kidney donation[1]

SRTR, Scientific Registry of Transplant Recipients.
1. Al Ammary F, et al. *Am J Transplant.* 2019;19(9):2614-2621. **2.** Lentine KL, et al. *Am J Transplant.* 2022;22(suppl 2):21-136.



Living Kidney Donors: New Ways to Evaluate Risk of ESRD

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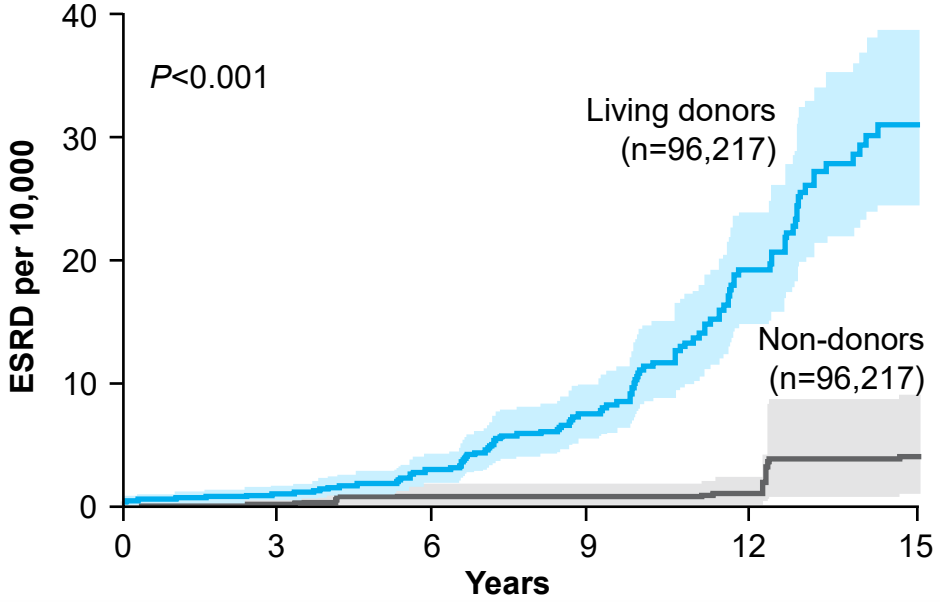
The Risk of ESRD Is Higher in Living Kidney Donors Than in Similarly Healthy Non-donors

- When donating a kidney, living kidney donors accept the long-term risk of developing ESRD[1]
- Living kidney donors (Black, Hispanic, and White donors) had a **higher estimated lifetime-risk of ESRD** than similarly healthy non-donors, as examined in a cohort study[2]

Cumulative Risk Incidence of ESRD in Living Kidney Donors vs Similarly Healthy Non-donors[2]



Absolute Risk of ESRD per 10,000[2]

Race/ Ethnicity	Donors	Non-Donors	*P* Value
Black	74.7	23.9	<0.001
Hispanic	32.6	6.7	0.002
White	22.7	0.0	<0.001

Having a clear understanding of the risk of ESRD may help to inform discussions with individuals who are considering living kidney donation[2]

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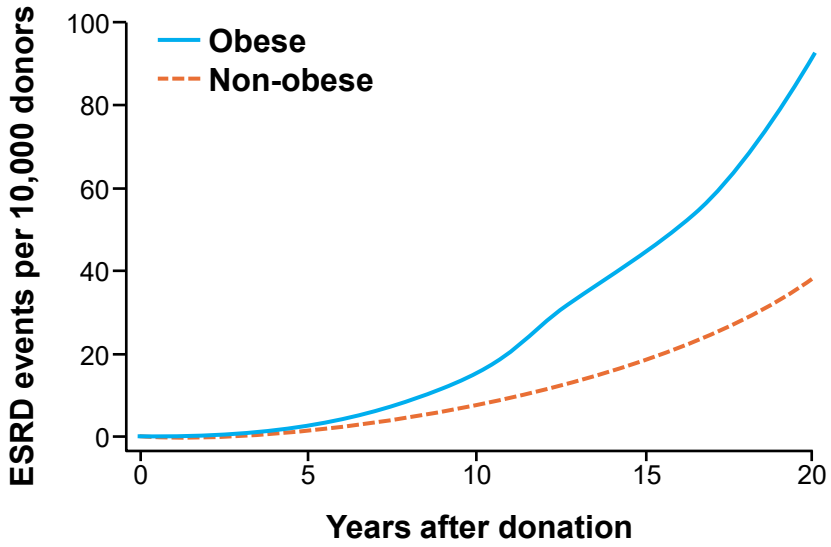
1. Lentine KL, et al. *Transplantation.* 2017;101(8S suppl 1):S1-S109. **2.** Muzaale AD, et al. *JAMA*. 2014;311(6):579-586.

Obesity Is a Major Risk Factor for ESRD

- Evidence supports that obesity is associated with an **increased risk of nonalcoholic fatty liver disease**, which has been linked to the development of CKD[1,2]
- In a study of 119,769 living kidney donors, the estimated risk of ESRD 20 years after donation was **significantly greater for obese living kidney donors** (BMI >30 kg/m^2) vs non-obese living kidney donors[3]
  - The risk was similar for male and female donors, Black and White donors, and across the baseline eGFR spectrum

Cumulative Incidence of Post-donation ESRD Events Among Living Kidney Donors by Obesity Status at Time of Donation[3]



Reprinted from *Kidney Int*, 91(3), Locke JE, et al. 699-703, © 2017, with permission from Elsevier.

Long-term lifestyle modifications may help ameliorate risks of ESRD associated with obesity[3]

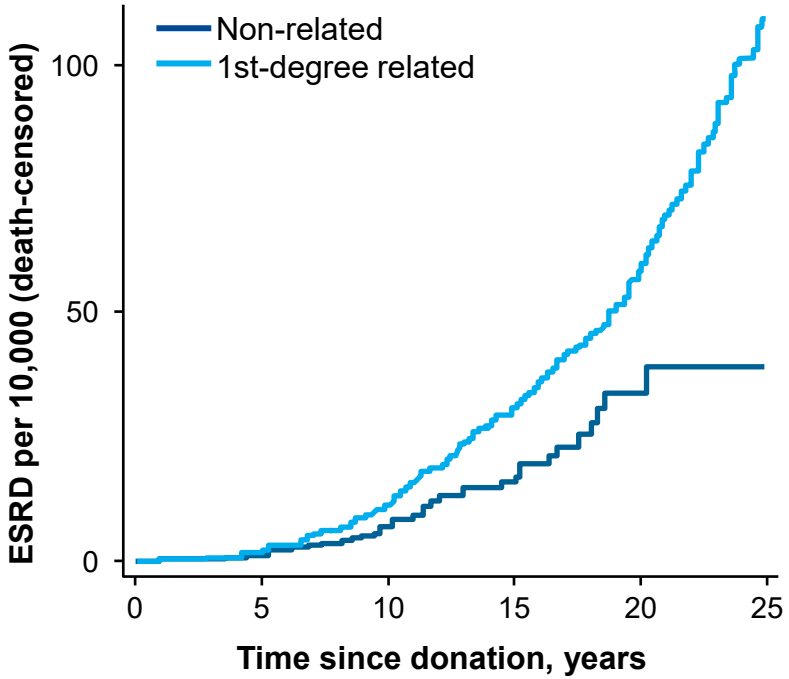
BMI, body mass index; CKD, chronic kidney disease.

1. Fabbrini E, et al. *Hepatology.* 2010;51(2):679-689. **2.** Marcuccilli M, et al. *Int J Mol Sci.* 2016;17(4):562. doi: 10.3390/ijms17040562. **3.** Locke JE, et al. *Kidney Int.* 2017;91(3):699-703.

Estimated Risk of ESRD in Living Kidney Donors Varies According to Donor Characteristics

- Analysis of national registry data in 133,824 living kidney donors revealed[1]
  - **Male sex and greater BMI** were associated with higher risk of ESRD
  - **Older age** was associated with higher risk of ESRD in non-Black donors, but the association between age and risk was not statistically significant in Black donors
  - Donors who were **closely related to their recipient** had higher risk of ESRD
- A separate analysis of 1,901 living kidney donors found that a total of 9 donors (0.47%) developed ESRD, all of whom were biologically related to their recipients, suggesting that **risk of ESRD may be influenced by hereditary factors**[2]

Incidence of ESRD Stratified by Relatedness to Recipient[1]



Providing accurate estimates of risk to potential living kidney donors may help improve the shared decision-making process and lend support to clinical decisions made during donor evaluation[1]

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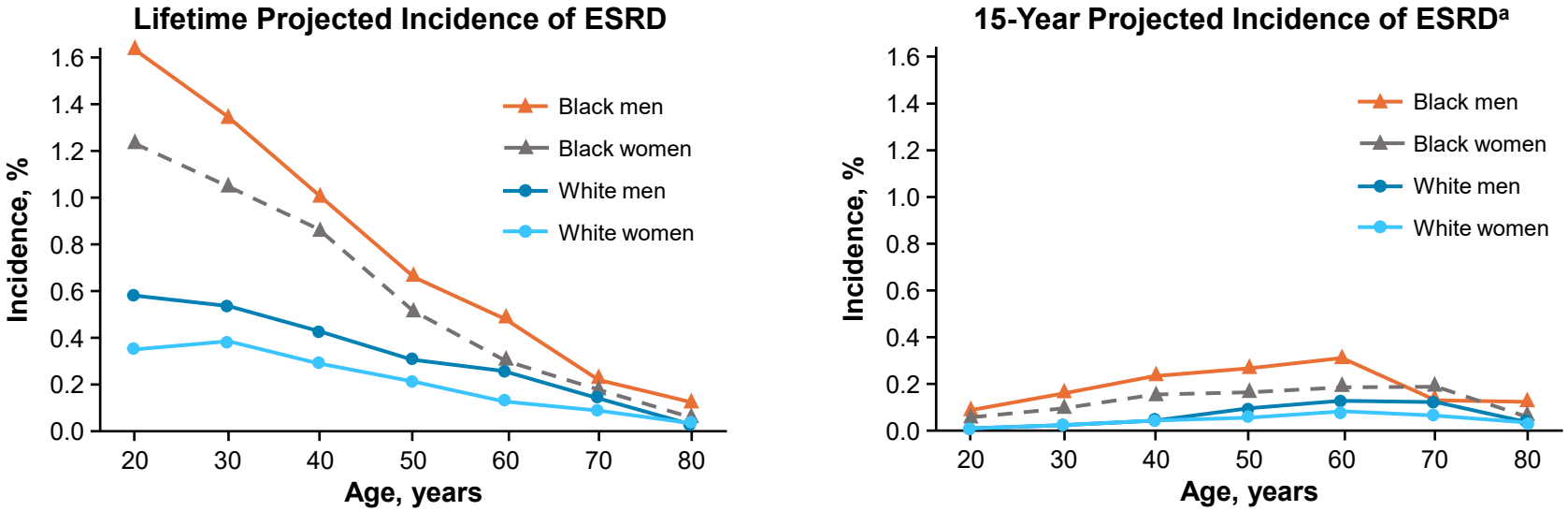
1. Massie AB, et al. *J Am Soc Nephrol*. 2017;28(9):2749-2755. **2.** Mjøen G, et al. *Kidney Int*. 2014;86(1):162-167.

Paradigm-Shifting Tools Are Now Available to Help Evaluate Baseline Risk of ESRD Prior to Donation

- A tool to predict living kidney donor candidates' long-term risk of ESRD in the absence of kidney donation could help make the criteria by which a candidate is accepted or declined more empirical and transparent[1]
- Johns Hopkins developed an online risk tool (www.transplantmodels.com) to help evaluate living kidney donor candidates and quantify the pretransplant risk of ESRD based on demographic and health characteristics[1,2]

Projections of the Incidence of ESRD in the US According to Age, Race, and Sex for the Base-Case Scenario[1]



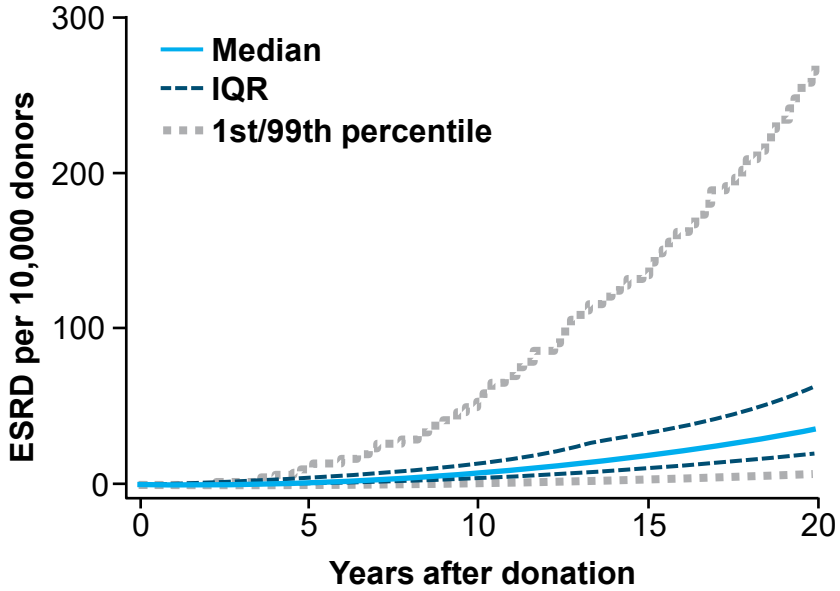
[a]The base-case scenario for the 15-year projected risk is the following: an age-specific eGFR (114, 106, 98, 90, 82, 74, and 66 mL per minute per 1.73 m^2 for an age of 20, 30, 40, 50, 60, 70, and 80 years, respectively), systolic blood pressure of 120 mm Hg, a urinary albumin-to-creatinine ratio of 4, a BMI of 26, and no diabetes mellitus or use of antihypertensive medication.

1. Grams ME, et al. *N Engl J Med*. 2016;374(5):411-421. **2.** Lentine KL, et al. *Transplantation*. 2017;101(8S suppl 1):S1-S109.

Tools to Help Evaluate Post-donation Risk of ESRD in Living Kidney Donation

- True risk prediction for living kidney donors must also include absolute risk if the individual does donate his/her kidney
- A prediction model has been constructed using national registry data to estimate the absolute risk of ESRD
  - The risk calculator can be found at http://www.transplantmodels.com/donesrd/
- The full range of predicted 20-year risk of ESRD (per 10,000 donors) post-donation **was wide and varied according to donor characteristics**, with median (IQR) of
  - 1 (1-2) cases per 10,000 donors at 5 years
  - 6 (4-11) per 10,000 at 10 years
  - 16 (10-29) per 10,000 at 15 years
  - 34 (20-59) per 10,000 at 20 years

Distribution of Predicted ESRD in Living Kidney Donors Post-donation



Predicted ESRD risk is calculated for each individual.
50% of predicted survival curves fall between the dashed lines, but a few individuals have substantially higher predicted risk.

These paradigm-shifting tools may help improve the accuracy of long-term ESRD risk assessment and support living kidney donor candidates in making educated decisions about donation

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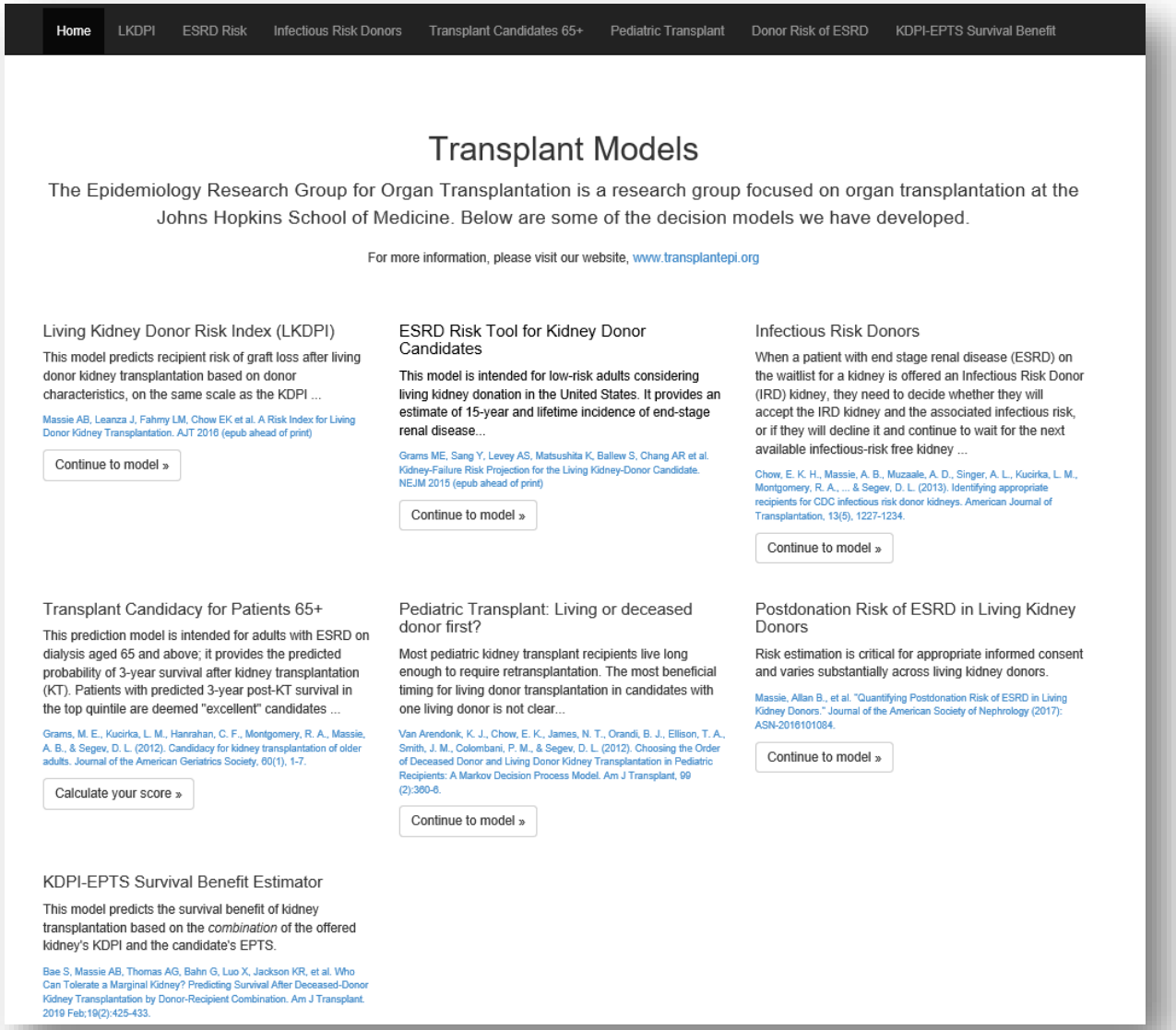
Massie AB, et al. *J Am Soc Nephrol*. 2017;28(9):2749-2755.

Online Risk Tool (www.transplantmodels.com)

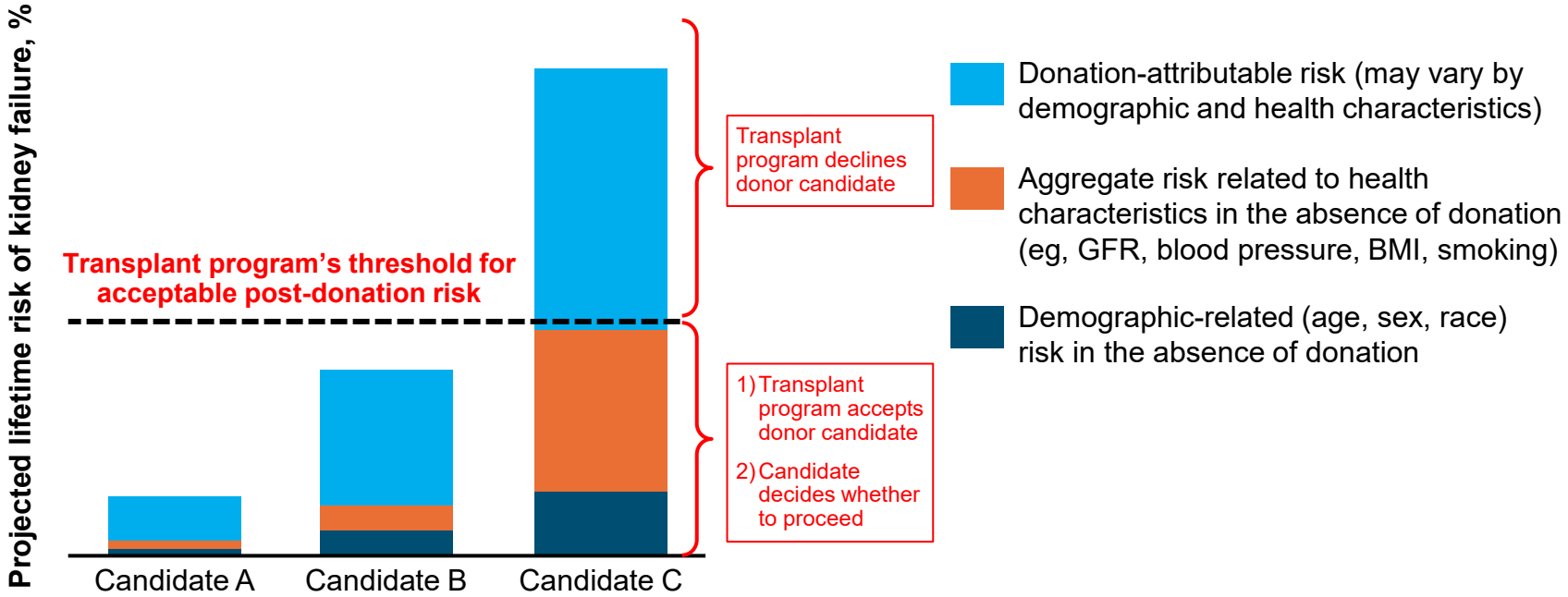


Epidemiology Research Group for Organ Transplantation at the Johns Hopkins School of Medicine. Transplant models. http://www.transplantmodels.com/. Accessed January 13, 2020. .

Educating Living Kidney Donors About the Potential Risk of ESRD Can Help in the Decision-Making Process

- In 2022, OPTN updated the living donor exclusion criteria to **remove type 2 diabetes as an absolute contraindication.** As these criteria continue to evolve, transplant programs have a responsibility to **support donor candidates and ensure that they are aware of potential risks** as part of their decision-making process[1-3]
- In 2017, KDIGO published clinical practice guidelines on the evaluation and care of living kidney donors, including weighing risks of ESRD[1]

Framework to Accept or Decline Donor Candidates Based on Transplant Program's Threshold of Acceptable Projected Lifetime Risk of Kidney Failure[1]



KDIGO, Kidney Disease: Improving Global Outcomes.

1. Lentine KL, et al. *Transplantation*. 2017;101(8S suppl 1):S1-S109. **2.** Muzaale AD, et al. *JAMA*. 2014;311(6):579-586. **3.** Organ Procurement and Transplantation Network. Modify living donor exclusion criteria. https://optn.transplant.hrsa.gov/media/d2hlvxv1/policy-notice_modify-ld-excl-crit_ldc.pdf. Accessed August 17, 2022.

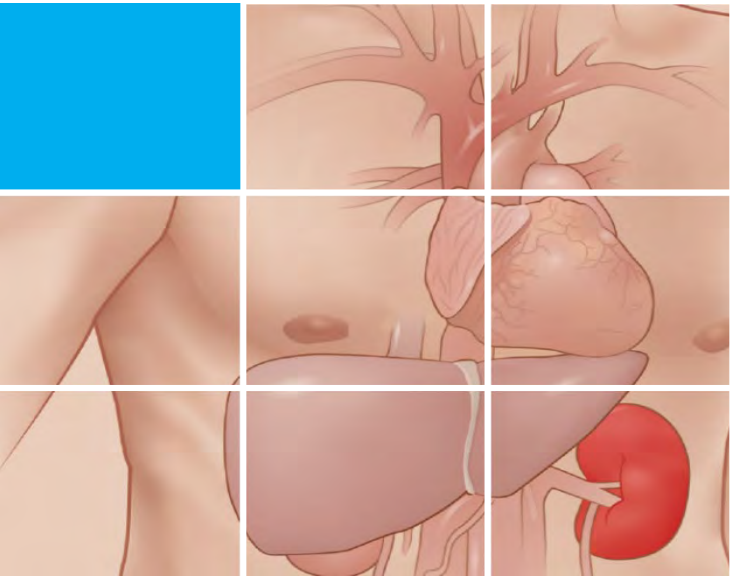
Introducing a Risk-Benefit Framework Into the Donor Evaluation Process

- The current model of donor evaluation and selection focuses on **minimizing the acceptable risk** to the donor and does not consider any potential **benefit of donation**[1]
- Using a risk-benefit framework, donors who are likely to experience **greater tangible benefits*** might be permitted to donate when previously their risk profile would have been beyond a center's threshold of acceptable[1]
  - A donor who is in a close, interdependent relationship with his/her recipient may gain more tangible benefits from donating than a donor who has less contact with the recipient[1]
  - An analysis of donor evaluations found that greater relationship closeness was independently associated with a **greater willingness to accept post-donation kidney failure**[2]

Implementation of a risk-benefit framework—taking into account donor-recipient relationships and potential benefits from donation—would more accurately reflect the real lives of donors and recipients[1]

* Refers to more benefits or more significnat benefit than under evaluation and selection approaches not taking such benefits into account.

1. Van Pilsum Rasmussen SE, et al. *Am J Transplant*. 2017;17(10): 2567-2571. **2.** Thiessen C, et al. *Am J Kidney Dis*. 2021;78(2):246-258.



Genetic Testing in Living Kidney Donor Risk Assessment

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Benefits and Risks of Genetic Testing in Living Kidney Donors

- Recent advances in sequencing technology have highlighted the importance of genetics in kidney diseases
  - Evidence supports that physiologic parameters of the kidney are **partially inheritable**, and **familial clustering of nephropathy has been observed** in 10% to 29% of adults with CKD
- Given that living kidney donors are at increased risk of ESRD compared with healthy nondonors and many living kidney donors are first- or second-degree relatives of the recipients, genetic testing can play an **important role in the evaluation and care of living kidney donors**

Key Benefits and Risks of Genetic Testing

Benefits	Risks
Assess potential risk of inherited kidney disease such as risk of CKD or ESRD following donation	Reduce opportunities for living donation in those who may never develop CKD
Improve safety of kidney donation through precision-medicine testing	Increase cost of donor evaluation/motivate need for additional testing
	Create potential for center paternalism based on genetic test results

Genetic testing may provide further risk stratification, facilitating living kidney donor assessment and informing the candidate's decision to proceed with donation

From Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.

Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.

Multiple Testing Modalities Are Available to Assess Genetic Kidney Diseases

- Various genetic testing modalities are available, which include
  - Karyotyping
  - Chromosomal microarray (CMA)
  - Sanger sequencing
  - Next-generation sequencing (NGS)
  - Whole exome sequencing (WES)
  - Whole genome sequencing (WGS)
- Selection of testing modalities may depend on the donor's **clinical picture, preferences, insurance coverage, and out-of-pocket costs**

Genetic Kidney Diseases and Genes Involved

Disease	Genes involved	% of ESRD	Clinical features
ADPKD	*PKD1, PKD2*	5	Bilateral renal cysts, hepatic cysts, intracranial aneurysms
FSGS (genetic forms) and SRNS	*NPHS1* (nephrin), *NPHS2* (podocin), *APOL1, ACTN4, INF2, COL4A3, COL4A4, COL4A5, TRPC6*	Unclear, all FSFS (genetic and non-genetic forms) accounts~2.3%	Isolated proteinuria, nephrotic syndrome
Alport syndrome	*COL4A3, COL4A4, COL4A5*	0.3-2.3%	Hematuria, ocular abnormalities, sensorineural hearing loss
Thin basement membrane disease	*COL4A3, COL4A4,*	Unclear, rarely leading to ESRD	Asymptomatic hematuria, possible progression to CKD/ESRD
ADTKD	*UMOD, MUC1, REN HNF1B, Sec61A1*	Unclear, likely underdiagnosed	Progressive CKD leading to ESRD, bland urine, renal biopsy often non-specific, some associated with maturity onset diabetes of young, gout arthropathy
aHUS	*CFH, CFI, CFB, C3, MCP, DGKE, CFHR1-5, THBD*	Unclear, likely underdiagnosed	MAHA, thrombocytopenia, TMA on kidney biopsy, kidney dysfunction

From Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.

ADPKD, autosomal dominant polycystic kidney disease; ADTKD, autosomal dominant tubulointerstitial kidney disease; aHUS, atypical hemolytic uremic syndrome; ESRD, end-stage renal disease; FSGS, focal segmental glomerulosclerosis; MAHA, microangiopathic hemolytic anemia; SRNS, steroid-resistant nephrotic syndrome; TMA, thrombotic microangiopathy.
Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.

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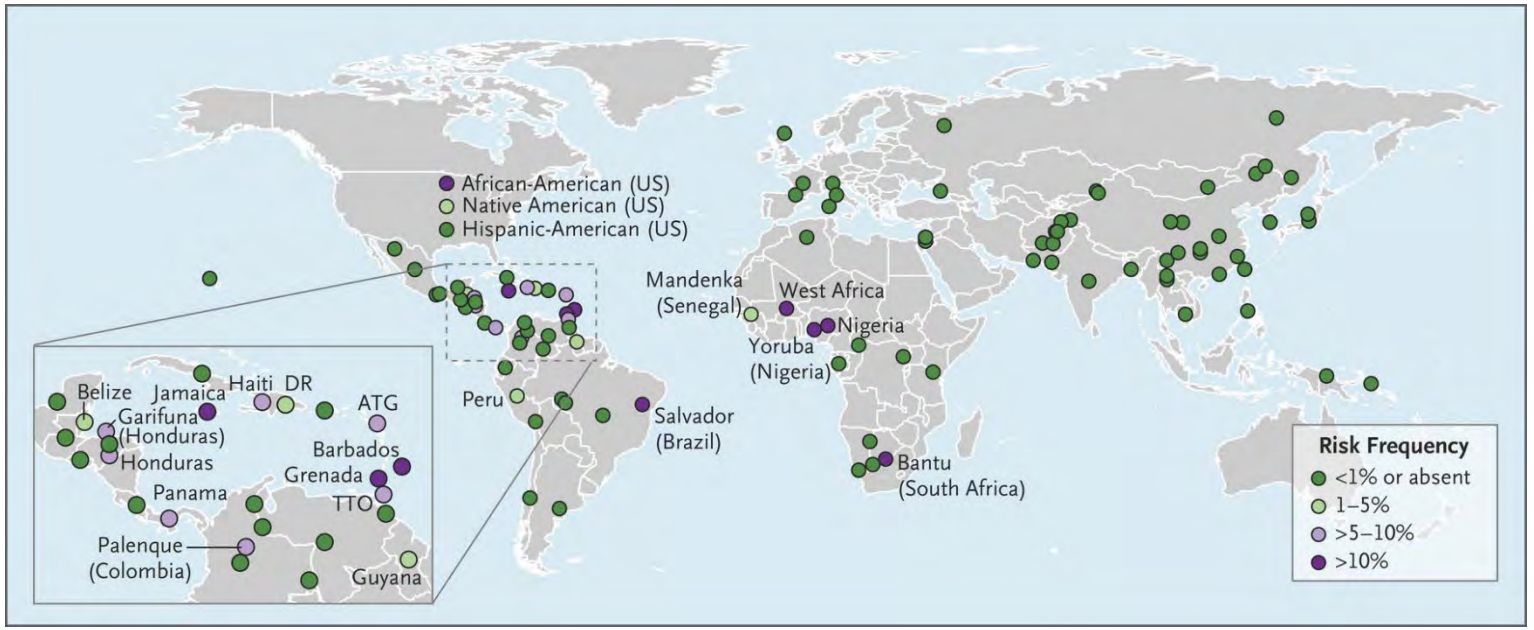
Prospective Data Are Needed to Better Understand the Role of *APOL1* Genetic Testing in Living Kidney Donor Evaluations

- Retrospective data have shown that the **presence of two *APOL1* gene renal-risk variants** contributes to living kidney donors of African ancestry having a **higher risk of developing ESRD** compared with healthy nondonors[1]
- Due to a lack of prospective data, the role of *APOL1* genotyping in living kidney donor evaluation **remains uncertain**[2]
  - However, it is generally recommended to **inform all living kidney donor candidates of appropriate ancestry about the *APOL1* gene and the potential risk of renal disease**
  - If genetic testing is deemed appropriate, it should only be offered following genetic counseling

Frequencies of *APOL1* Renal-Risk Variants[3]



From Nadkarni GN, et al. *N Engl J Med*. 2018;379(26):2571-2572. A more detailed map is available at http://APOL1.org. opens in new tab

APOL1, apolipoprotein L1.

1. Doshi MD, et al. *Transplantation*. 2021;105(10):2132-2134. **2.** Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142. **3.** Nadkarni GN, et al. *N Engl J Med*. 2018;379(26):2571-2572.

Broad Utilization of Genetic Testing in Transplant Evaluation Is Associated With Various Challenges

- While genetic testing is becoming a more familiar tool in nephrology practice, there is still **limited evidence regarding best practices and clinical application of actionable genetic findings**

Considerations for Implementation of Genetic Testing

- ☑ Maintaining an up-to-date list of nephropathy-associated genes
- ☑ Establishing best practice guidelines
- ☑ Obtaining third-party payer coverage for necessary follow-up care associated with detecting medically actionable genetic findings
- ☑ Addressing physician knowledge gaps
- ☑ Developing decision support tools for electronic health records
- ☑ Identifying long-term effects of genetic findings on nephrologic care

From Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.

Routine use of genetic testing in transplant evaluation is associated with technical, logistical, and ethical challenges that need to be addressed for wider implementation

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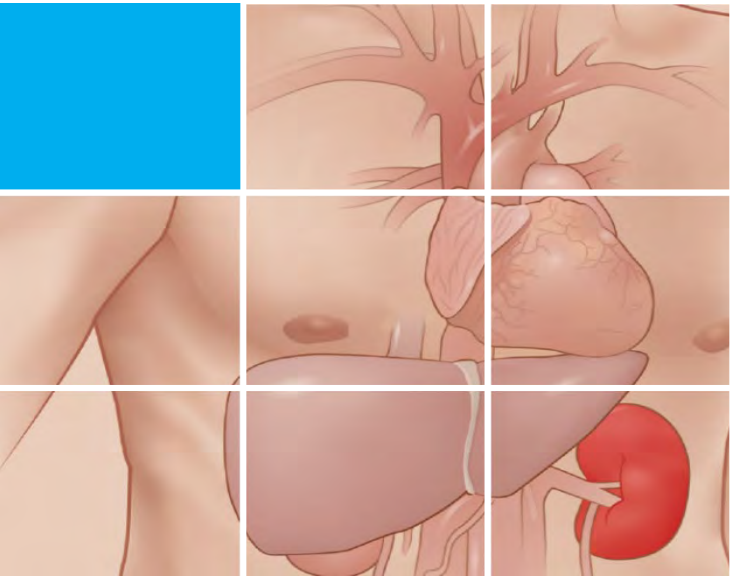
Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.



Considering Other Risks of Living Kidney Donation

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Development of Hypertension Is Common in Living Kidney Donors Post-donation

- Within 2 years of nephrectomy, **3.1% of living kidney donors developed hypertension and 0.15% developed new-onset diabetes**, both of which are predominant but manageable causes of post-donation ESRD[1]
- An analysis of 24,533 older (aged ≥50 years) living kidney donors found that while the **risk of ESRD was higher in donors with vs without hypertension**, the absolute risk was small and there was no increase in mortality risk 15 years post-donation[2]

Incidence of Hypertension and Diabetes per 10,000 Living Kidney Donors at 6 Months, 1 Year, and 2 Years Post-donation[1]

	Complete Case Estimate	Estimate by Inverse Probability Weighting	Estimate by Multiple Imputation
New-onset hypertension			
6 months post-donation	74	98	78
1 year post-donation	162	200	164
2 years post-donation	310	362	319
New-onset diabetes			
6 months post-donation	2	2	4
1 year post-donation	6	6	6
2 years post-donation	15	15	15

Early post-donation care for donors should emphasize healthy lifestyle practices, management of modifiable risk factors (eg, obesity), and early detection/management of comorbidities[1]

1. Holscher CM, et al. *Transplantation.* 2019;103(6):1216-1223. **2.** Al Ammary F, et al. *Clin J Am Soc Nephrol*. 2019;14(7):1048-1055.

Living Kidney Donors May Experience Positive and/or Negative Psychosocial Effects

- On average, **living kidney donors report having positive feelings** about their organ donation experience, but it may also cause negative psychosocial effects

Living Kidney Donor Positive Experiences

- Little to no regret about donating
- Would make the same decision to donate again
- Deep sense of fulfillment
- Very favorable levels of HRQOL (pretransplant and posttransplant)
- Improved relationship with recipient
- Highly positive average levels of psychosocial outcomes

Living Kidney Donor Negative Experiences

- Fair to poor, or much worse, physical health since donation
- Persistent fatigue and pain
- Current or future health concerns as a result of donation
- Changes in donor's body image
- Worsened relationship with other family members
- Elevated emotional distress and/or psychiatric disorders

Understanding both the positive and negative psychological effects of living kidney donation is important

HRQOL, health-related quality of life.

Dew MA. Psychosocial risks of living kidney donation. AST Live Donor. https://www.myast.org/sites/default/files/Chapter%2013%20%20Psychosocial%20Risks%20of%20kidney%20donation_0.pdf. Accessed September 29, 2022.

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Feelings of Regret May Be Present in Living Kidney Donors Following Donation

- Feelings of regret may occur after living kidney donor, and limited evidence showed that **those experiencing regret post-donation reported increased negative health perceptions and worse social functioning**[1]
- Clinical tools are available to identify feelings of regret post-donation
  - The **Decision Regret Scale** is a 5-item assessment tool that can be used to evaluate distress or remorse after a health care decision[2,3]
  - Anxiety may be closely associated with feelings of regret, and thus, the **GAD-2 screening tool**, a 2-item anxiety assessment scale, may be used to evaluate regret[4]

Decision Regret Scale[3]

1. It was the right decision	*1 Strongly Agree*	*2 Agree*	*3 Neither Agree Nor Disagree*	4 Disagree	5 Strongly Disagree
2. I regret the choice that was made	*1 Strongly Agree*	*2 Agree*	*3 Neither Agree Nor Disagree*	4 Disagree	5 Strongly Disagree
3. I would go for the same choice if I had to do it all over again	*1 Strongly Agree*	*2 Agree*	*3 Neither Agree Nor Disagree*	4 Disagree	5 Strongly Disagree
4. The choice did me a lot of harm	*1 Strongly Agree*	*2 Agree*	*3 Neither Agree Nor Disagree*	4 Disagree	5 Strongly Disagree
5. The decision was a wise one	*1 Strongly Agree*	*2 Agree*	*3 Neither Agree Nor Disagree*	4 Disagree	5 Strongly Disagree

GAD-2 Tool[5]

Generalized Anxiety Disorder 2 item (GAD-2)				
Over the last 2 weeks how often have you been bothered by the following problems?	*Not at all*	*Several days*	*More than half the days*	Nearly every day
1. Feeling nervous, anxious or on edge	0	*1*	*2*	3
2. Not being able to stop or control worrying	0	*1*	*2*	3
GAD-2 score obtained by adding score for each question (total points)				
A score of 3 points is the preferred cut-off for needing further identifying evaluation[23]				

1. Wirken L, et al. *Nephrol Dial Transplant.* 2019;34(6):1045-1055. **2.** Patient decision aids. The Ottawa Hospital Research Institute website. https://decisionaid.ohri.ca/eval_regret.html. Accessed August 2, 2022.
3. Sample Tool: Decision Regret Scale. The Ottawa Hospital Research Institute website. https://decisionaid.ohri.ca/docs/develop/Tools/Regret_Scale.pdf. Accessed August 2, 2022.
4. Holscher CM, et al. *BMC Nephrol.* 2018;19(1):218. doi: 10.1186/s12882-018-1024-0. **5.** Sapra A, et al. *Cureus.* 2020;12(5):e8224. doi: 10.7759/cureus.8224.

Anxiety and Depression May Occur in Living Kidney Donors Post-donation

- Living kidney donors may **experience anxiety and depression post-donation**, which can be associated with higher rates of disability, illness, and death
  - In a study of 825 living kidney donors, 5.5% screened positive for anxiety and 4.2% for depression

Risk Factors Associated With Positive Generalized Anxiety Disorder-2 (GAD-2) Anxiety Screening in Living Kidney Donors

	aRR (95% CI)	*P* Value
Positive PHQ-2 screen	13.72 (6.78-27.74)	<0.001
Years since donation (by year)	0.93 (0.89-0.98)	0.006
Married/living with a partner	0.52 (0.26-1.05)	0.07
Hypertension	1.54 (0.96-2.48)	0.08
Recipient alive	0.82 (0.38-1.78)	0.6

- A positive PHQ-2 depression screen was **more likely in living kidney donors** whose recipients experienced graft loss (aRR=5.38 [95% CI, 1.29-22.32]; *P*=0.02)
- In the US, **pre-donation psychiatric assessments are mandated** by the OPTN for all living kidney donors

Psychological screening at follow-up may help support living kidney donors, particularly those with risk factors for anxiety and/or depression

aRR, adjusted relative risk; PHQ-2, Patient Health Questionnaire-2.

Holscher CM, et al. *BMC Nephrol*. 2018;19(1):218. doi: 10.1186/s12882-018-1024-0.

Prevalence of Regret of Donation Is Low and Continued Efforts Should Aim to Limit This Outcome

- **2.1% of living kidney donors** reported regretting their donation, according to a questionnaire study
- Studies have reported that most living kidney donors would be willing to donate again, but **donors with negative psychosocial outcomes post-donation may be at higher risk for regret**

Risk Factors Associated With Regret of Donation in Living Kidney Donors

	aRR (95% CI)	*P* Value
Black	3.78 (0.75-18.92)	0.1
Age at survey completion (per 10 years)	0.98 (0.58-1.65)	0.9
Positive GAD-2 screen	5.68 (1.20-26.90)	0.03
Development of any comorbidity	1.53 (0.35-6.74)	0.6
Trouble obtaining or changing insurance	3.13 (0.75-12.98)	0.1
Recipient graft loss	4.59 (0.57-36.81)	0.2

Anxiety was the only factor significantly associated with regret of donation

Given the association between anxiety and regret, careful psychosocial evaluation and management may further decrease the numbers of living kidney donors who experience regret

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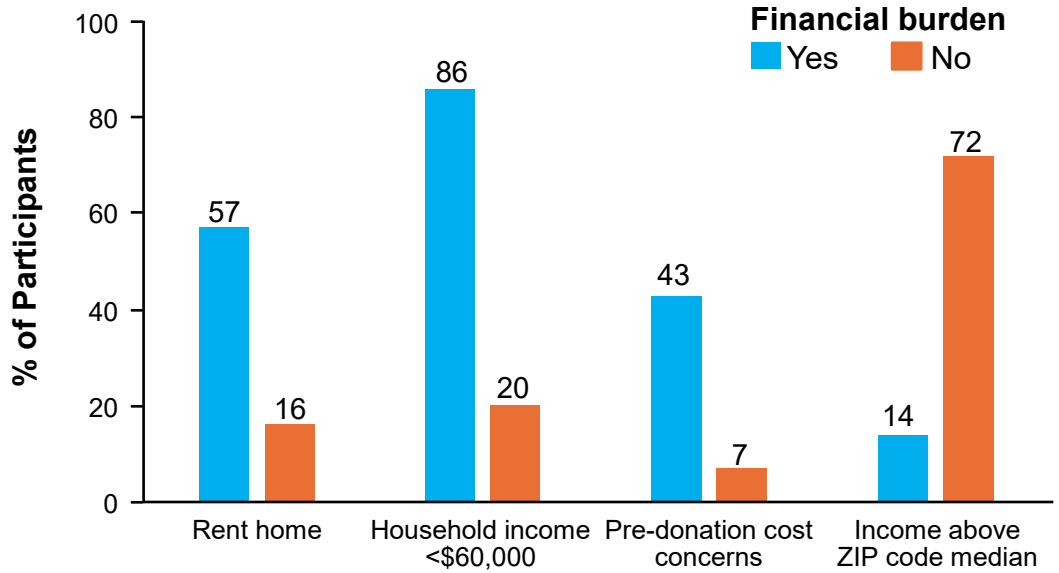
1. Holscher CM, et al. *BMC Nephrol*. 2018;19(1):218. doi: 10.1186/s12882-018-1024-0.

Risk of Financial Burden Is Another Consequence to Living Kidney Donation

- Candidate living kidney donors who were more likely to perceive donation as a financial burden were **less likely to own a home**, had a **lower individual household income** overall and relative to ZIP code median, and were **more likely to be concerned about pre-donation costs**

Factors Associated With Perceived Donation-Related Financial Burden



Adjusted higher risk of perceived financial burden is

- **3.7-fold** for pre-donation cost concerns
- **10.6-fold** for household income <$60,000

Transplant centers can use these factors to identify potential donors at higher risk of perceived financial burden and help them achieve financial neutrality

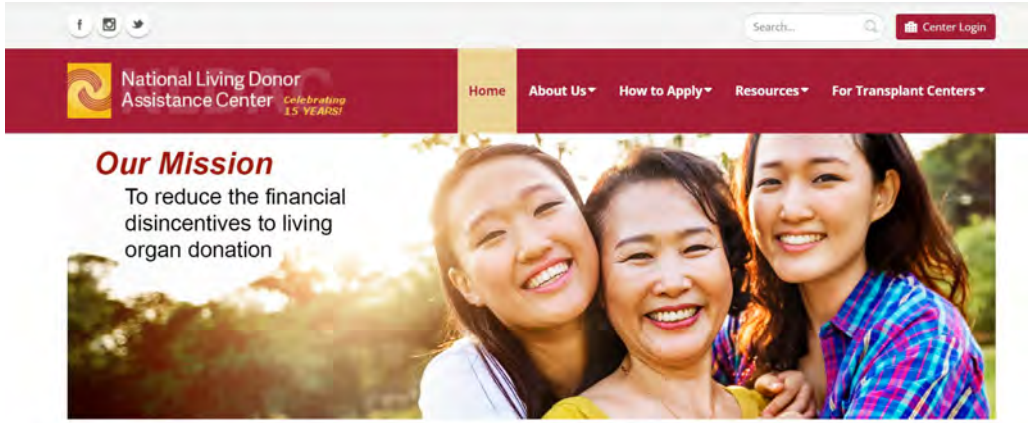
Ruck JM, et al. *Am J Transplant*. 2018;18(3):715-719.

Audience Question

What is financial neutrality and what does it encompass?

Financial Assistance Is Available to Help Living Kidney Donors Achieve Financial Neutrality

- The **National Organ Transplant Act (NOTA) of 1984 outlawed the buying and selling of organs**, thus eliminating financial benefits from organ donation. However, **donations can remain financially neutral,** without imposing financial burdens on living kidney donors[1]
- Various resources are available for living kidney donors to achieve financial neutrality[2,3]
  - **National Living Donor Assistance Center** helps cover travel and lodging expenses for eligible donors, up to $6,000
  - **National Foundation for Transplants** offers fundraising assistance for living donors to help with medical and nonmedical expenses
  - **American Transplant Foundation** offers grants to eligible donors
- Additionally, there are federal and state laws around tax deductions, paid leave, and disability programs that help support living donation[4]
- In 2020, **AST introduced the LDCOE program** to recognize employers who help eliminate barriers to living donation by providing salary support to their employees who choose to be a living donor[5]



https://www.livingdonorassistance.org/

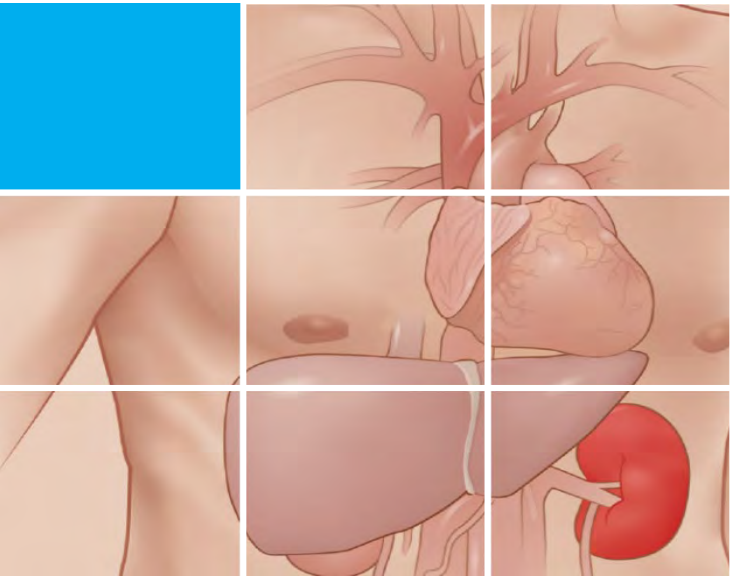
PATIENT ASSISTANCE PROGRAM

The American Transplant Foundation is proud to be able to provide real help to real families when they need it the most. We go beyond awareness by providing emotional and financial support to patients and their families.

https://www.americantransplantfoundation.org/programs/pap/

LDCOE, Living Donor Circle of Excellence.

1. Delmonico FL, et al. *Am J Transplant*. 2015;15(5):1187-1191. **2.** Nonprofit financial aid programs for living donors. American Society of Transplantation website. https://www.livingdonortoolkit.com/financial-toolkit/nonprofit-financial-aid-programs-living-donors. Accessed August 3, 2022. **3.** Living donation resources. National Kidney Foundation website. https://www.kidney.org/patients/resources_LivingDonation. Accessed August 3, 2022. **4.** Federal and state laws about living donation. American Society of Transplantation website. https://www.livingdonortoolkit.com/financial-toolkit/federal-and-state-laws-about-living-donation. Accessed August 3, 2022. 5. AST announces new living donor circle of excellence program. https://www.myast.org/ast-announces-new-living-donor-circle-excellence-program#:~:text=MOUNT%20LAUREL%2C%20NJ%20(Oct.,be%20a%20living%20organ%20donor. Accessed October 31, 2022.



Follow-up Is Critical in Managing Living Kidney Donors

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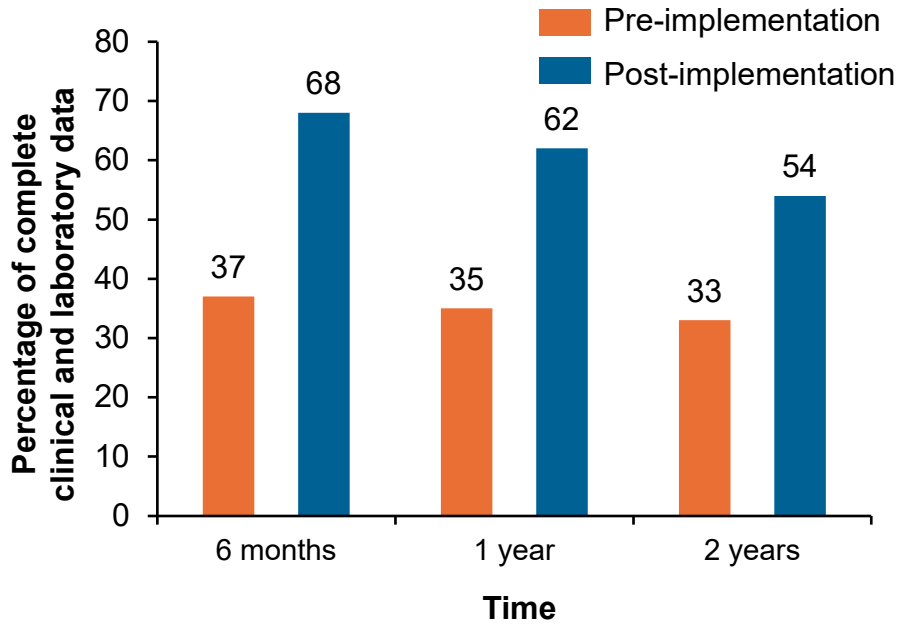
Transplant Centers Are Required to Collect Follow-up Data on Living Kidney Donors for 2 Years

- In 2013, OPTN/UNOS mandated that transplant centers meet thresholds for collecting and reporting clinical and laboratory data for living kidney donors at **6 months, 1 year, and 2 years post-donation**[1]
- An analysis of SRTR data for 31,615 living kidney donors found that complete and timely follow-up **significantly increased from 33% in 2013 to 54% in 2015**[1]
- This increase was observed with only **43% of centers being compliant**[1]

Proportions of Complete and Timely Clinical and Laboratory Follow-up in Living Kidney Donors Before and After Policy Implementation[1]



Increasing compliance with follow-up may enhance living kidney donor outcomes[1,2]

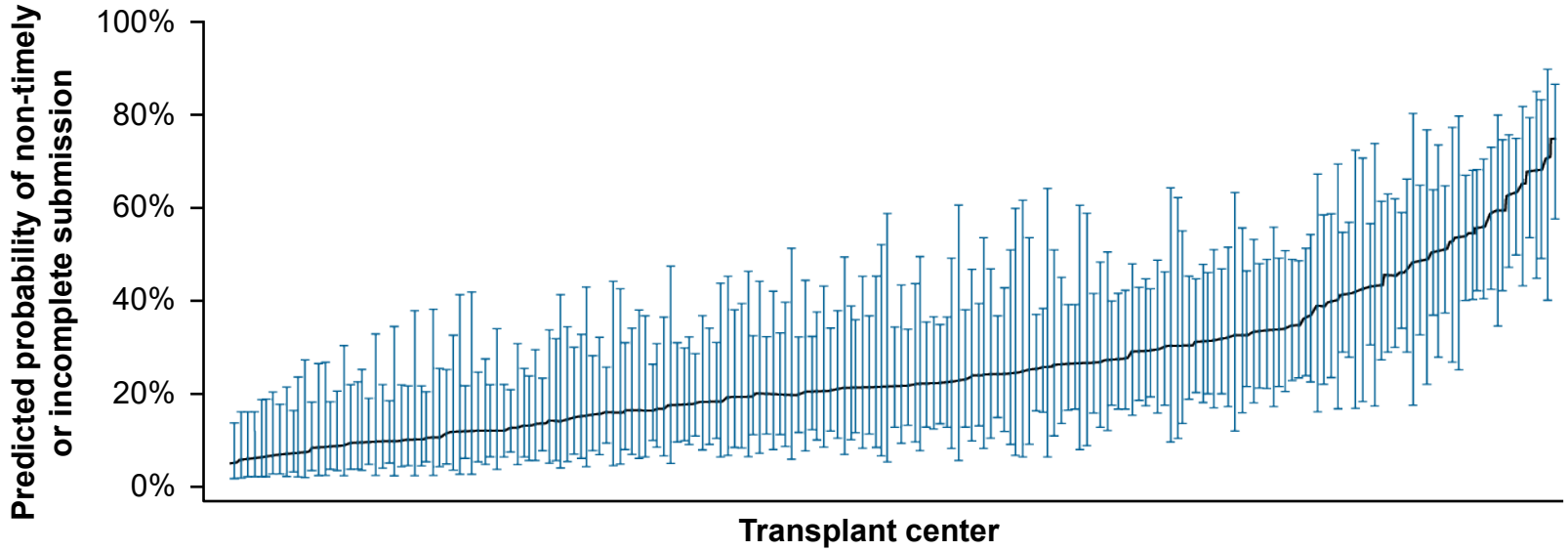
UNOS, United Network for Organ Sharing.

1. Henderson ML, et al. *Am J Transplant.* 2017;17(12):3131-3140. **2.** Kulkarni S, et al. *Am J Transplant.* 2016;16(12):3385-3391.

Transplant Centers Have Significant Variability in Living Donor Follow-up

- Analysis of SRTR data also showed that the odds of non-timely or incomplete living donor follow-up (LDF) at 6 months ***varied significantly*** by transplant center
- For 6-month LDF, center-level variation accounted for **19% of the variance of non-timely or incomplete submission** of clinical data (interclass correlation=0.19 [95% CI, 0.15-0.24])
- Overall, **57% of centers** did not meet the national reporting thresholds in the 2013 OPTN/UNOS mandate

Transplant Center Variability in Non-timely or Incomplete LDF Clinical Data



Henderson ML, et al. *Am J Transplant.* 2017;17(12):3131-3140.

Annual Primary Care Physician Visits Are Important to Monitor Living Kidney Donors Post-donation

- Post-donation counseling is necessary to promote the health of all living kidney donors, but especially living kidney donors at **increased risk of not receiving regular monitoring**

Risk of Having Fewer-Than-Annual PCP Visits Post-donation With Pre-donation PCP Visit Frequency

	Odds Ratio	*P* Value
Male	1.1	0.6
Less than college education	1.8	<0.01
Black	1.6	0.1
Smoking history	1.1	0.7
Time to follow-up (per year)	1.0	0.08
Fewer than annual PCP visits before donation	14.4	<0.001

Pre-donation PCP visit frequency was the strongest predictor of post-donation PCP visit frequency

New, non-traditional follow-up methods may be needed to ensure living kidney donors receive appropriate post-donation monitoring and care

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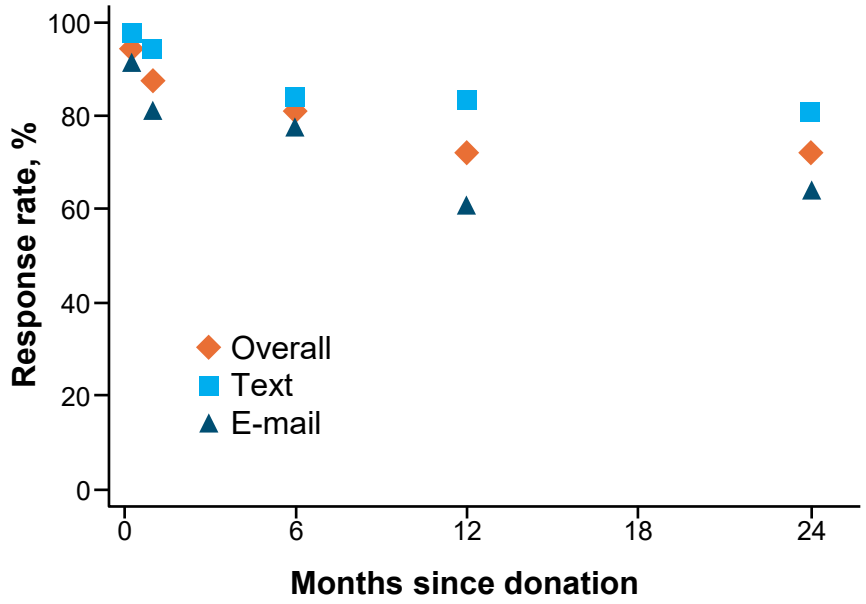
PCP, primary care physician.

Alejo JL, et al. *Clin Transplant*. 2017;31(7). doi:10.1111/ctr.12992.

Electronic Mobile Messaging May Be a Useful Tool for Follow-up of Living Kidney Donors

- Living kidney donor in-person follow-up presents a number of challenges[1]
- Electronic mobile messaging may be a useful tool to reduce burden of follow-up among living kidney donors post-donation, for donors and centers[1,2]
  - Text messaging had **consistently higher response rates** up to **24 months post-donation vs e-mail** in a study of 67 living kidney donors[2]
  - **94% of 100 living kidney donors** surveyed **owned a smartphone**[1]
  - **79%** of smartphone-owning participants perceived it would be **useful to complete their required post-donation follow-up** with resources on their smartphones[1]

Response Rate by Contact Method For Living Kidney Donors[2]



Used with permission from Ruck JM, et al. *Clin Transplant*. 2018;32(2).

Electronic messaging tools may facilitate follow-up and help improve communication between living kidney donors and transplant centers[1]

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1. Eno AK, et al. *JMIR Mhealth Uhealth.* 2018;6(10):e11192. doi: 10.2196/11192. **2.** Ruck JM, et al. *Clin Transplant*. 2018;32(2).

Additional Methods to Help Improve Post-donation Follow-up Compliance in Living Kidney Donors

- In a guidance document, OPTN provides strategic recommendations to maintain contact with living donors to help facilitate timely post-donation follow-ups[1]
- Studies are currently being conducted to assess novel strategies to improve adherence with post-donation follow-ups in living kidney donors, including[2,3]

Providing small financial incentives to promote compliance

Utilizing mobile health app to improve compliance and post-donation care

Key OPTN Recommendations[1]

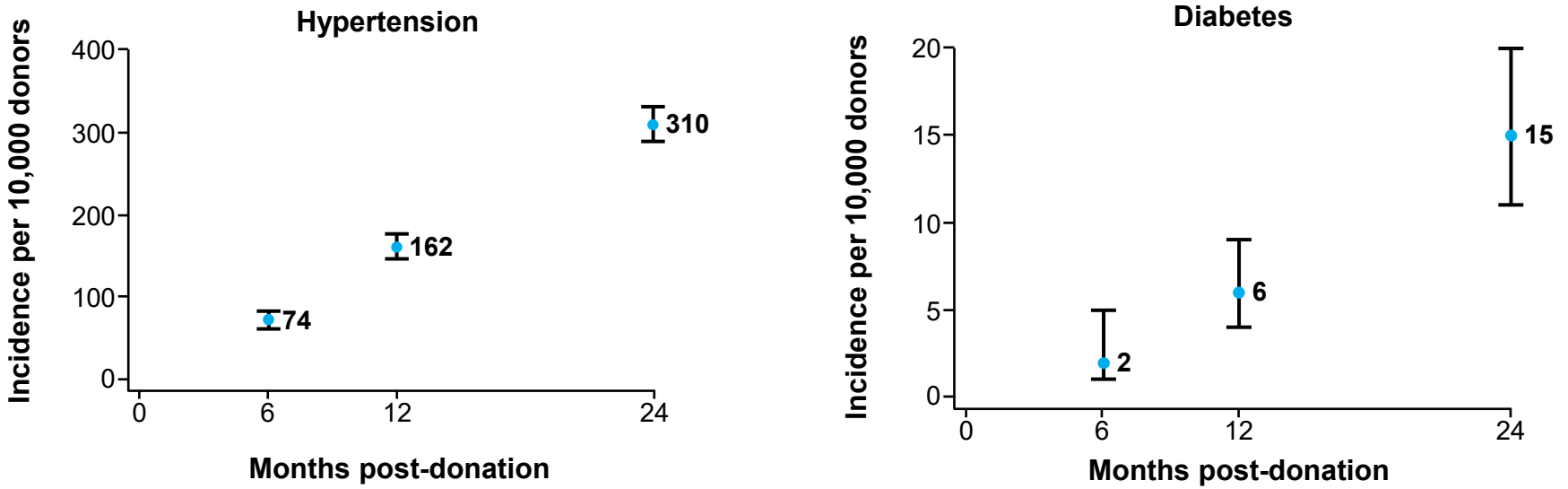
Use not only regular mail and telephone contacts but also emails and texts to communicate with donors	Consider calling donors using a cell phone rather than the medical center's main line	Use internet search strategies to locate difficult-to-find donors
Develop plans for repeated attempts at contact that span at least 1 month and potentially several months	If the donor misses an appointment unexpectedly, try to reach the donor within 24 hours to reschedule the appointment	Routinely review and update donors' contact information each time they are successfully contacted post-donation

1. Procedures to collect post-donation follow-up data from living donors. Organ Procurement and Transplantation Network website. https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/#rec3/. Accessed August 4, 2022.
2. Levan ML, et al. *BMC Nephrol*. 20209;21(1):465. doi: 10.1186/s12882-020-02117-9. **3**. Henderson ML, et al. *JMIR Res Protoc*. 2019;8(1):e11000. doi: 10.2196/11000.

The Risk of Medical Problems Increases as Living Kidney Donors Grow Older

- In a US-based cohort study of 41,260 living kidney donors, it was found that the **incidence of developing hypertension and diabetes increased as months post-donation increased**
  - **Donors who were older** at donation were more likely to develop hypertension and diabetes

Post-donation Incidence of Hypertension and Diabetes per 10,000 Living Kidney Donors



As donors age, they will be at increased risk for medical problems.
Routine follow-up will be important to preserve donor health and well-being

Holscher CM, et al. *Transplantation.* 2019;103(6):1216-1223.

Summary

- Racial disparities in the evaluation process could account for the **substantially lower numbers** of Black, Hispanic, or Asian living kidney donors vs White living kidney donors observed over the last 10 years[1,2]
- **Educating donors** about the risk of ESRD and **providing accurate risk estimates** can help inform decisions during donor evaluation[3,4]
- **Balanced risk-benefit evaluation** may help transplant centers in assessing living kidney donors[5]
- Incorporating **genetic testing** in the living kidney donor evaluation process may help **assess for risk of kidney diseases**, including CKD and ESRD, post-donation; however, additional challenges will need to be addressed to facilitate the implementation of genetic testing in transplant practice[6]
- **Post-donation follow-up** of living kidney donors is critical to **ensure early detection** of any health concerns and subsequent clinical management[7]
- **Electronic messaging tools** may facilitate follow-up and help improve communication between living kidney donors and transplant centers[8]

1. Purnell TS, et al. *JAMA*. 2018;319(1):49-61. **2.** Kumar K, et al. *Clin Transplant*. 2018;32(7):e13291. doi: 10.1111/ctr.13291. **3.** Muzaale AD, et al. *JAMA*. 2014;311(6):579-586.
4. Massie AB, et al. *J Am Soc Nephrol*. 2017;28(9):2749-2755. **5.** Van Pilsum Rasmussen SE, et al. *Am J Transplant*. 2017;17(10):2567-2571. **6.** Caliskan Y, et al. *Curr Transplant Rep*. 2022;9(2):127-142.
7. Alejo JL, et al. *Clin Transplant*. 2017;31(7). doi: 10.1111/ctr.12992. **8.** Eno AK, et al. *JMIR Mhealth Uhealth*. 2018;6(10):e11192. doi: 10.2196/11192.

sanofi

Moving Forward: Impact of Living Kidney Donation

- What role do you and your center play in increasing LDKTs at your center?
- What are some ways you and your center can support living donations and living kidney donors?
- What does your center do to overcome the racial and ethnic disparities related to living kidney donation?
- How do you educate living kidney donors about the risk of ESRD?
- Does your center use genetic testing for living kidney donors? If so, how is genetic testing used at your center?
- How does your center support living kidney donors who need financial assistance?
- What role does your center play in post-donation follow-up of living kidney donors?

Questions?

Living Donor: Increased Utilization and Experience

Ellen Shukhman, RN, MSN, AMB-BC, CCTC
Assistant Nurse Manager | KidneyTransplant & Living Donation Programs
Cedars-Sinai Comprehensive Transplant Center

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cedars-sinai.org

Nothing to disclose

U.S. vs. Region 5 Recipients on the Waiting List

		All Organs	Kidney
All Regions		113,789	95,928
Region 1		6,544	5,309
Region 2		14,399	12,131
Region 3		12,983	11,057
Region 4		12,384	10,183
Region 5		24,243	21,174
Region 6		2,767	2,309
Region 7		8,535	6,977
Region 8		4,817	3,879
Region 9		8,322	7,057
Region 10		6,499	5,099
Region 11		12,296	10,753

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https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

U.S. vs. Region 5: Transplants

			To Date	2023	2022	2021	2020	2019	2018	2017	2016	2015
All Regions	All Donor Types		558,675	15,927	25,500	24,670	22,817	23,401	21,167	19,849	19,060	17,878
	Deceased Donor		379,649	12,349	19,636	18,699	17,583	16,534	14,725	14,038	13,431	12,250
	Living Donor		179,026	3,578	5,864	5,971	5,234	6,867	6,442	5,811	5,629	5,628
Region 5	All Donor Types		88,493	2,544	4,078	4,004	3,713	3,742	3,496	3,302	3,258	3,033
	Deceased Donor		61,537	2,003	3,185	3,140	2,920	2,771	2,584	2,457	2,448	2,133
	Living Donor		26,956	541	893	864	793	971	912	845	810	900

https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

Cedars-Sinai Programmatic Changes

Areas of Opportunity

- Kidney Recipients' knowledge, understanding, and interest in living donation
- Donor Referral and Evaluation process
- Disincentives to living donation
- Community Education and Outreach

Areas of opportunity continued:

- Alternative Donation options:
  - Blood Incompatible / Highly Sensitized Transplants
  - Kidney Paired Exchange program expansion
  - Remote Evaluation / Donation
  - Advanced Donation Voucher Program

Recipient Education Program on Living Donation

- In-person Consultation with the Living Donor Coordinator
- Facts about Living Kidney Donation Brochure*
- How-To Guide to Finding a Living Donor*
- Education Class on How-to approach the search for Living Donor Candidates.

Recipient Education

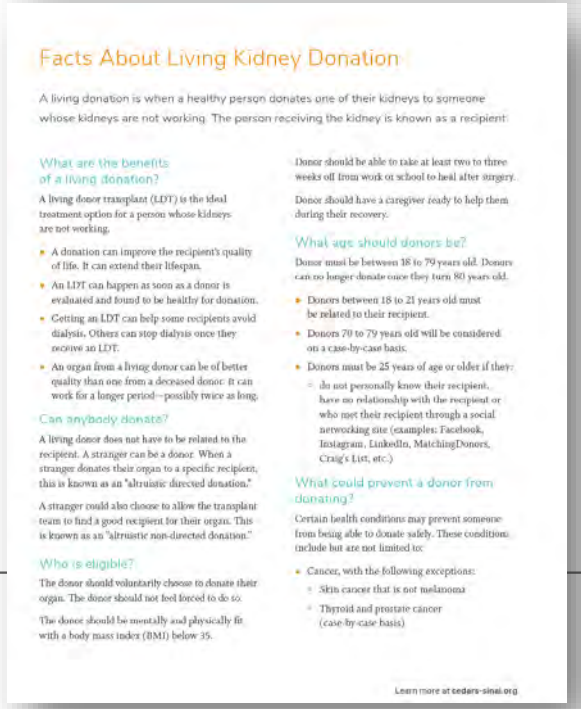
Educational Video

In-person Consultation:

- Assessment of recipient's situation and needs (Preemptive, Waitlisted, Immunologic Challenges, Limited social support)
- Assessment of knowledge about living donation
- Overview of the difference between living vs. deceased donor transplant
- Assessment of search efforts in pursuit prospective living donor candidates
- Outline steps to be taken to increase effectiveness of search efforts
- Review of Educational resources

Facts About Living Kidney Donation

- What is Living Donation
- What are the benefits of Living Donation
- Can Anybody Donate?
- Who is Eligible
- What is an acceptable age for a donor?
- What could prevent a donor from donating?
- Can more than one donor be evaluated simultaneously?
- Can an out-of-state or international donor be evaluated?
- What happens during a donor's evaluation?
- What if the donor and recipient are not compatible?
- Are there long-term problems that a donor could have after organ donation?
- Does the donor have to pay for their evaluation?
- What is the donor feels pressured to donate?
- Living Donor Self-Referral process
- How long will a donor be hospitalized?
- How long will recovery take?



How-To Guide to Finding a Living Donor

Cedars Sinai

The How-To Guide to Finding a Living Donor

Presented by: Cedars-Sinai Kidney Living Donor Program

Table of Contents

Dear Family/Friends letter template

Dear Family and/or Friend(s):

Thank you for taking the time to read this letter!

I am writing to you on behalf of ***[insert name of recipient]****, who has kindly agreed to have me share with you the struggle* ***he/she/they*** *has been going through due to an unfortunate health issue.*

In ***[insert year, insert name of recipient]*** *was diagnosed with chronic kidney disease, the cause of which (is related to* ***insert cause of kidney disease/remains unclear****). Since the initial diagnosis,* ***his/her/their*** *kidney function has continued to worsen, to a point where* ***his/her/their*** *kidneys can no longer able to support* ***his/her/their*** *body. Kidney failure, also known as end-stage renal disease, can only be treated with a kidney transplant or lifelong dialysis. A transplant will offer* ***[insert name of recipient]*** *the best long-term outcome and quality of life.*

A kidney transplant is the treatment option that has the most significant impact on a person's quality of life. However, due to a nationwide shortage of deceased organ donors, ***[insert name of recipient]*** *will have to wait approximately eight to 11 years before* ***he/she/they*** *comes up for a deceased donor transplant, unless a living donor candidate comes forward. While awaiting a transplant, dialysis is given to patients such as* ***[insert name of recipient]****; however, this treatment option can be extremely hard on the body. Even in a short duration, it has been shown to negatively impact a person's health and longevity.*

Although many of us thought we were already doing our part by declaring ourselves to be organ donors through the DMV or the U.S. Department of Health and Human Services website. Despite continuing advances in kidney disease management, demand for deceased donor organs continuous to drastically exceeds the number of organ donors, causing a national organ shortage.

[insert name of recipient]*'s health has been strongly affected by* ***his/her/their*** *illness, and I am reaching out to* ***his/her/their*** *family, friends, acquaintances, co-workers and community members to consider becoming a living organ donor.*

You can make a difference in ***[insert name of recipient]****'s or someone else's life by donating your organ while you are still alive!* ***(The following sentence should only be included if the recipient is not yet on dialysis)*** *A living donation could also allow* ***[insert name of recipient]*** *to avoid dialysis/starting dialysis, which will greatly improve* ***his/her/their*** *long-term health and quality of life. Living donation helps those in need to get a healthy living organ, preventing them from becoming sicker or dying while waiting for a deceased organ donor.*

Unfortunately, due to a ***medical condition/age/incompatibility issue(s)****, I am unable to donate my kidney to* ***[insert name of recipient]****. However, I am hopeful that you or someone you know might consider becoming a living donor for* ***[insert name of recipient]****.*

If you think you would be interested in being a living donor for ***Insert Name of Recipient****, please contact me at* ***[insert name of advocate, insert advocate's phone number and/or email]****.*

To receive additional information about living donation, please contact the Cedars-Sinai Living Donor Program at 800-303-6235, 310-423-2641 or by emailing kidney@csmc.edu.

Streamlined Self-referral Process

1

2

Become a Living Kidney Donor

If you are interested in being evaluated for living donation, please complete the Donor Self-Referral Form.

DONOR SELF-REFERRAL FORM▸

Transplant Recipient Referrals

For physicians or dialysis centers interested in referring a transplant recipient, please complete the following form.

REFERRAL FORM FOR PHYSICIAN/DIALYSIS CENTER (PDF)▸

To refer yourself for a transplant evaluation, please use the following form. A member of our team will reach out to you.

RECIPIENT SELF-REFERRAL FORM▸

3

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LIVING KIDNEY DONATION: SELF-REFERRAL FORM

*PLEASE FILL OUT THIS FORM AND ONE OF OUR TEAM MEMBERS WILL CONTACT YOU.

TITLE:
LAST NAME (AS SEEN ON DRIVER'S LICENSE OR ID CARD):
FIRST NAME:
MIDDLE NAME:
DATE OF BIRTH
SOCIAL SECURITY NUMBER:
BLOOD TYPE:
HEIGHT: WEIGHT (LBS.):
MARITAL STATUS:
GENDER:
CURRENTLY RESIDE IN THE UNITED STATES?
HOME ADDRESS:
CITY: STATE: ZIP/POSTAL CODE:
COUNTRY:
HOME PHONE NUMBER:
CELL PHONE NUMBER:
WORK PHONE NUMBER:
E-MAIL ADDRESS:
YOUR PREFERRED LANGUAGE:
INTERPRETER NEEDED?
BEST TIME TO CONTACT YOU:
YOU ARE DONATING TO:
RECIPIENT LAST AND FIRST NAMES:
RECIPIENT DATE OF BIRTH OR PHONE NUMBER:
IS YOUR RECIPIENT AWARE THAT YOU ARE INTERESTED IN BEING A LIVING DONOR?
ARE YOU COMFORTABLE WITH US SHARING YOUR NAME WITH THE RECIPIENT?
IF YOUR CHOSEN RECIPIENT NO LONGER NEEDS YOUR DONATION, WOULD YOU BE WILLING TO DONATE TO ANOTHER PATIENT WHO NEEDS AN ORGAN TRANSPLANT?
COMMENTS:

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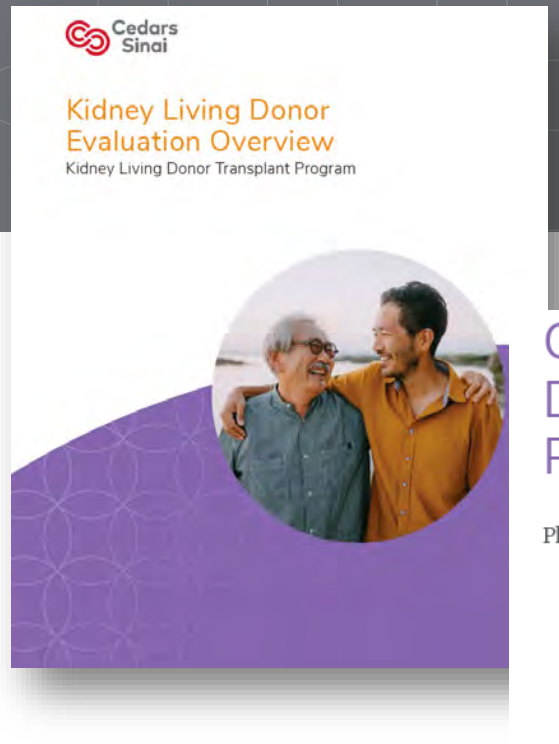
Electronic Admission Packet

Electronic Admission Packet via DocuSign:

- Kidney Living Donor Evaluation Overview
- Health History Questionnaire

Patient Communication Enhancements

- Promotion of EPIC secure patient messaging
- Patient Utilization of Group Donor Email: Groupkidneydonor@cshs.org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Kidney Living Donor Evaluation Overview

Kidney Living Donor Transplant Program

Overview of a Living Donor Evaluation Process

Phases of a donor's evaluation:

- Phase 1: Admission and Health History
- Phase 2: Lab and Compatibility Tests, Blood Pressure Monitor
- Phase 3: Age- and Disease-Related Tests, Clinical Evaluation and Selection
- Phase 4: Surgery

Phase 1: Admission and Health History

The first step of your evaluation process is a review of your health history information. Please complete the attached electronic Health History Questionnaire to provide us with your health history. The questionnaire will help us identify issues that may keep you from being a donor or increase your risk of complications after donation. You will also be asked to provide us with three separate blood pressure readings (morning reading, afternoon reading and evening reading). You can have your blood pressure checked with your personal blood pressure monitor, at your doctor's office, a medical clinic or health facility, a local fire station, or a pharmacy. If you go to a pharmacy, make

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Evaluation Changes:

Living Donor Criteria:

- Age
- BMI
- Expansion of Hypertensive donors' criteria
- PMH:
  - Renal Stones
  - Pre-diabetes
  - Gestational DM
- Use of Genetic Testing

Minimization of Logistical / Financial disincentives:

- Early involvement of ILDA and SWs
- Undocumented / International Living Donors
- Use of external Lab Providers and ABPM
- Remote Evaluation / Donation
- Early Financial Stability Assessment:
  - NALDAC: Early education and assessment of candidacy
  - Donor Shield

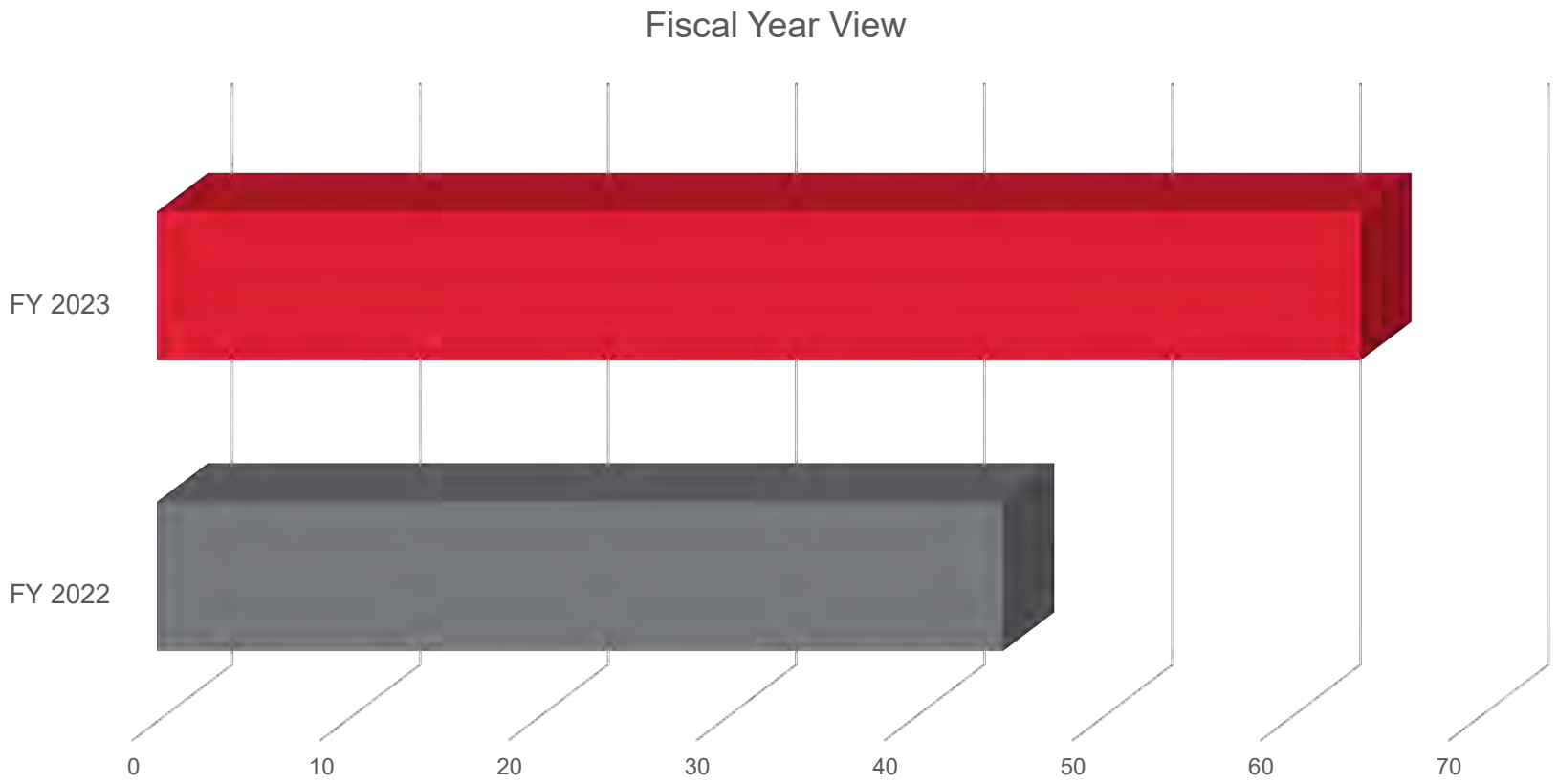
Incorporation of Alternative Donation Options

- Blood Incompatible Transplants
- Highly Sensitized Transplants
- Kidney Paired Exchange program expansion:
  - Internal Exchanges/Swaps
  - Regional and National Exchanges/Swaps
- Remote Evaluation / Donation
- Advanced Donation Voucher Program

Raising Awareness through Community Outreach

- Dedicated Outreach Coordinator
- Expanded Geographic Outreach
- Lobby Days
- Living Donor Coordinator Participation in Outreach:
  - Community Educational Seminars
  - Education for Dialysis Social Workers on the Living Donor Program and Criteria

CSMC Transplants FY 2022 vs FY 2023



	FY 2022	FY 2023
Series1	45	64

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In Summary…

- Engagement and support of Organizational / Departmental Leadership and Clinical Team will heavily influence outcomes
- Implemented changes:
  - Improved Recipient engagement and understanding of living donation
  - Increased Recipient efforts in pursuit of potential living donor candidates
- Living Donor referrals numbers will initially increase but will ultimately stabilize
- Increased number of donor referrals does not always equate to increased living donor transplants unless:
  - Donor Criteria is safely expanded
  - Donor referral and evaluation processes are efficient and optimized
  - There is sufficient staffing to manage patient volumes
  - Disincentives to living donation are minimized
  - Alternative Living Donation options are available for consideration and understood by patients

Questions?

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The CMS OPO Final Rule & Metric
How is it Measuring UP?

Presentation to UNOS Region 5 Educational Collaborative

San Diego, CA | August 23, 2023

By
Tom Mone
Chief External Affairs Officer
OneLegacy

A History of CMS OPO Metrics

- 1984 - and NOTA assignment of OPO Oversight to CMS:
  - CMS Adopted the International standard - *Donors per Million Population and CMS certified all OPOs w/in 1.5 Standard Deviations of the Mean*
- 2000 - Recognition that varying death rates (12/100,000 population in West Virginia vs 5/1000 in Utah) made DPM statistically unreliable
  - CMS adopted Donors per Eligible Death (Brain Dead without contraindicating conditions*) and CMS certified all OPOs w/in 1.5 Standard Deviations of the mean*
- 2022 – Concern that Eligible Deaths is OPO reported
  - CMS adopted Donors per Potential Donors
  - *Potential Donors estimated using CDC Mortality Data of Hospital Deaths and CMS will only certify OPOs in the top 25th Percentile*

Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F

Donation Rate Measure

The number of organ donors in the OPO's DSA as a percentage of inpatient deaths among patients 75 years old or younger with a primary cause of death that is consistent with organ donation.

A donor is now defined as a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted, not just procured for transplant, or an individual from whom a pancreas is procured and is used for research or islet cell transplantation.

Transplantation Rate Measure

The transplantation rate measure is the number of transplanted organs from an OPO's DSA as a percentage of inpatient deaths among patients 75 years old or younger with a primary cause of death that is consistent with organ donation.

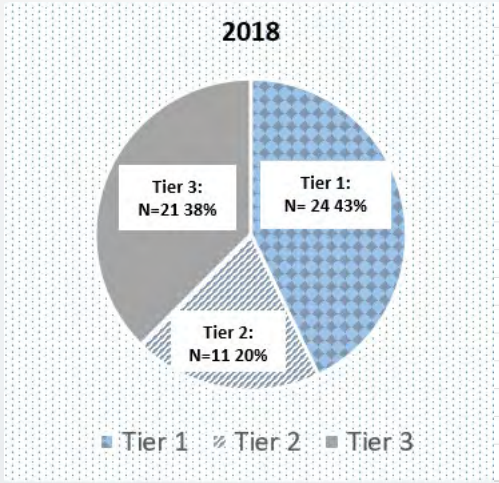
Performance Benchmark

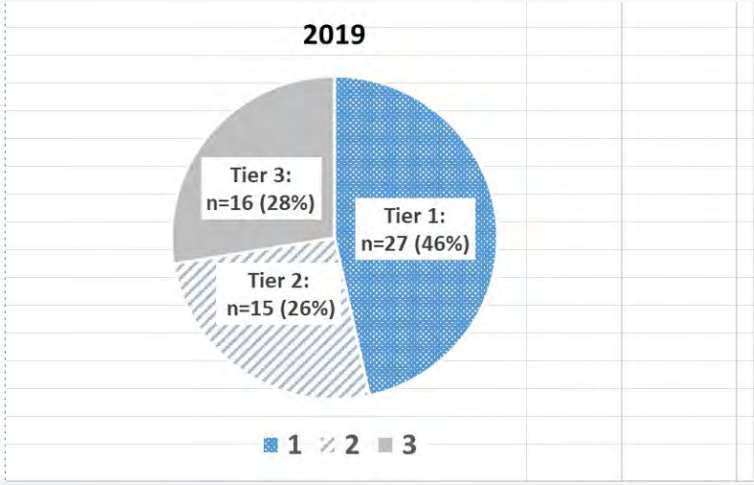
The performance rates that OPOs will be *encouraged* to meet for the donation and transplantation rates will be established by the lowest rates of the top 25 percent of OPOs from the previous 12-month period.

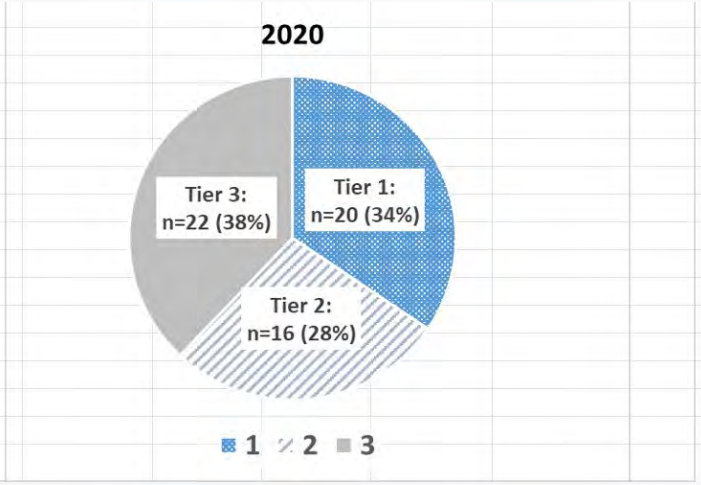
Performance Tiers

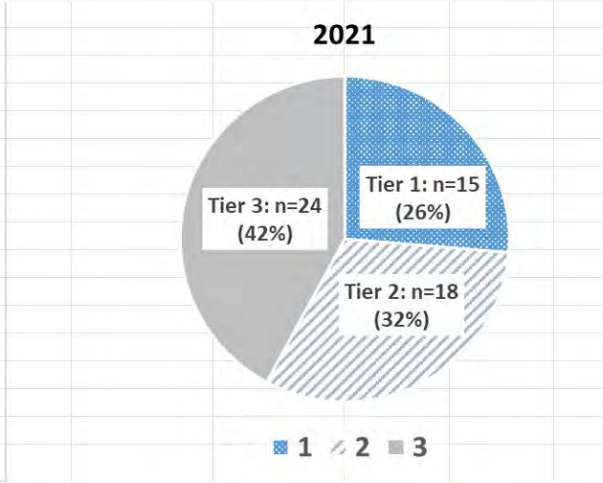
OPOs in the top 25 percent will be Tier 1 and automatically recertified for another four years. Tier 2 OPOs, where performance on both measures exceed the median but do not reach Tier 1,will not automatically be recertified and will have to compete to retain their DSAs. Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.

CMS New OPO Metric Applied to Pre-implementation Performance









- The percentage of OPOs in Tier 1 in 2021 vs 2018 has dropped from 43% to 26% (15)
- The percentage of OPOs in Tier 2 in 2021 vs 2018 has increased from 20% to 32% (18)
- The percentage of OPOs in Tier 3 in 2021 vs 2018 has increased from 38% to 41% (23) *(based on 56 OPOs)*

If 2021 were the certification year,

CMS would need to decertify or invite competition for 74% (41 of 56) of the OPOs

Volatility of Tier Rankings between 2018 and 2021 is a Concern

Tier 1 to Tier 3
- Arizona (AZOB)
- LifeBanc (OHLB)

Tier 1 to Tier 2
- Gift of Hope (ILIP)
- LifeCenter NW (WALC)
- LifeLink Florida (FLWC)
- LifeLink PR (PRLL)
- LifeShare Oklahoma (OKOP)
- New England DS (MAOB)
- Southwest Transplant (TXSB)
- Versiti of Wisc. (WIDN)

18 OPOs changed Tiers in 2021 vs 2018

59 Tier changes by 38 OPOs between 2018 and 2021

Tier 3 to Tier 1
- Iowa Donor Network (IAOP)
- Life Connection Ohio (OHLC)
- Life Center Organ Donor (OHOV)

Tier 2 to Tier 1
- Ctr for Organ Don. & Rec. (PATF)

Tier 3 to Tier 2
- Donor Alliance (CORS)
- Ctr. For Donation & Tx. (NYAP)
- Legacy of Hope (ALOB)
- Texas Org Sharing All. (TXSA)

Median Donation Rate and Top Quartile Change 2018 Vs 2023

Nation						
Year	Donation Rate			Transplant Rate		
	Donation Rate	Top 25% Cutoff[1]	Median Cutoff[1]	Observed Rate	Top 25% Cutoff[1]	Median Cutoff[1]
2018		11.37	9.72		36.10	32.05
2019		11.78	10.12		38.69	32.16
2020		12.96	11.10		41.07	36.26
2021		13.06	11.24		42.01	35.95
2022						
2023ytd						

The top 25th percentile and median growth reflect the overall growth in donation and transplantation, and undermines CMS's assumption that all OPOs could be expected to be able to move into Tier 1 as the goalpost keeps moving upward

CMS Measures Performance Projections
January to July 2023

Organ Procurement Organization (OPO)	2021 Overall Tier	2022 Overall Tier	Current Overall Tier
Tier 1 OPO names obscured while report is in draft status	2	1	1
	3	1	1
	1	1	1
	1	1	1
	2	1	1
	1	1	1
	3	2	1
	2	1	1
	1	1	1
	2	1	1
	3	1	1
	3	2	1
	2	2	1
	1	1	1
	1	1	1
	1	1	1
	1	1	1
	2	1	1
	1	1	1
	2	1	1
	3	1	1
	3	1	1
	1	1	1
	3	2	1
	1	1	1
	1	1	1
	1	1	1
	2	2	1
	1	1	1
WIDN - Versiti Organ and Tissue	2	1	1
WIUW - UW Organ and Tissue Donation	1	1	1

Organ Procurement Organization (OPO)	2021 Overall Tier	2022 Overall Tier	Current Overall Tier
Tier 2 OPO names obscured while report in draft status	3	2	2
	2	2	2
	3	2	2
	3	2	2
	3	2	2
	3	3	2
	3	3	2
	2	1	2
	2	2	2
	2	1	2
	2	3	2
Tier 3 OPO names obscured while report in draft status	3	3	3
	3	1	3
	3	2	3
	2	2	3
	2	2	3
	3	2	3
	3	3	3
	3	3	3
	2	3	3
	3	3	3
	3	3	3
	3	3	3
	2	2	3
	3	3	3

2023 Modelled Tier Ranking Insights

- 31 OPOs (55%) in Tier 1
- 11 OPOs (20%) in Tier 2
- 14 OPOs (25%) in Tier 3

- 4 OPOs in Tier 2 or 3 with 0 additional donors to be in Tier 1

Implications

1. *What's Measured Matters*
2. *The inclusion of transplant rate is clearly an issue*
3. *A single year remains unreliable*
4. *45% estimated to be in jeopardy vs 72% in 2021*

So, What do the Researchers say?

University of Colorado Research of the CMS OPO Metric: Annual Volatility

OPO Measured Donation Rate is Highly Volatile Year to Year and Not a Stable Quality Indicator

University of Colorado Anschutz Medical Campus

Jesse Schold, PhD, MStat, MEd[1]; Rocio Lopez, MS[1]; Sumit Mohan, MD[2]

[1]University of Colorado Anschutz Medical Campus, [2]Columbia University

Background

- With new 2020 CMS regulations, Organ Procurement Organizations (OPO) are to be evaluated yearly and certified or decertified every 4 years based on a single year's data.
- Threshold values used for tiering will be based on prior year values.
- Concerns have been raised that there could be year to year variations that are clinically insignificant, but sufficient to change an OPO's tier ranking.
- We aimed to assess the volatility of annual evaluations.

Methods

- We used National Center for Health Statistics' Multiple Cause of Death files and SRTR SAFs for 2017-2020
- Donor potential was determined for OPOs using CALC (Cause, Age, and Location Consistent with donation), defined in CMS Regulation as the number of inpatient deaths within an OPO's service area among patients 75 and younger with a primary cause of death consistent with organ donation.
- We calculated donation and transplant rates with one-sided 95% upper confidence intervals following CMS methodology.[1,2]
- Tiers were assigned using thresholds obtained from the prior year.[1,2]
- We compared assignments between 2018, 2019, and 2020.

Figure 1. OPO Tier Assignments by Year

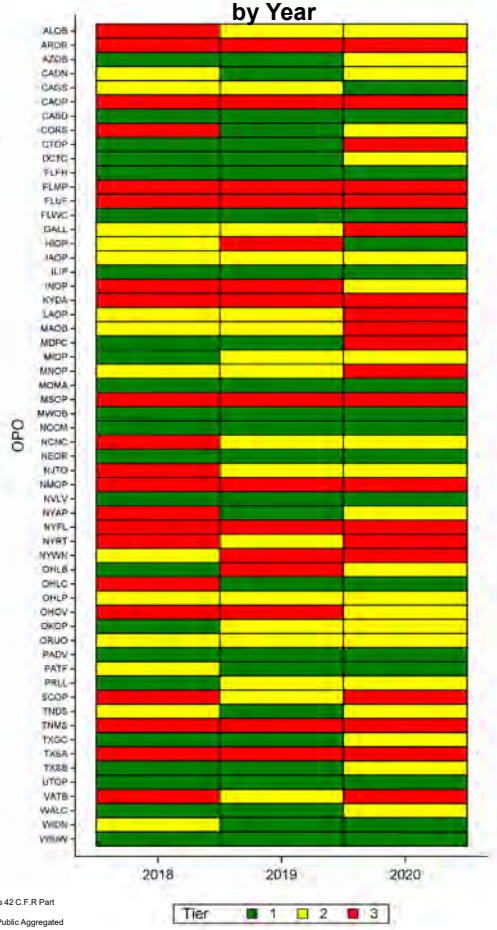


Table 1. Reclassification Rates

CALC Metric	2018 vs 2019	2019 vs 2020
	n (%) reclassified out of 58 OPOs	
Overall tier	19 (32.8%)	23 (39.7%)
Donation rate ranking	21 (36.2%)	21 (36.2%)
Transplant rate ranking	17 (29.3%)	25 (43.1%)

Either OPOs' measured performance is overly vulnerable to random fluctuations or performance is highly variable between years

Results

- Performance metrics are not stable with 30+% of OPOs changing tiers year to year.
- 9 OPOs changed tiers in both periods.
- 9 were in tier 3 in one year and tier 1 or 2 the following year and would have been decertified in the year that they were in tier 3.
- ~40% of OPOs lie within 5% of a tier edge.

Conclusions

- New CMS OPO performance metrics are not stable with many OPOs having shifts in donor potential >5% year to year.
- Yearly OPO performance evaluation may result in well-functioning OPOs inadvertently being decertified **causing unnecessary and unproductive perturbations in the transplant system** on a continuous basis.
- Using a longer 'baseline' and comparison years for measurement of quality may avoid these high levels of volatility and should be explored.

Disclosures

This work was supported by OneLegacy Foundation and Gift of Life Foundation

1. Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations 42 C.F.R Part 486 Subpart G § 436.301-486.360 (2020) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G
2. Centers for Medicare & Medicaid Services, Quality, Certification and Oversight Reports (QCOR). OPO Annual Public Aggregated Performance Report – User Guide: 2026 Certification Period. Accessed June 1, 2022. https://qcor.cms.gov/documents/OPO_Public_Performance_Report-User_Guide_for_the_2026_Certification_Period.pdf

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Stability of New CMS Metrics for Organ Procurement Organizations: Comparison of 2 Consecutive Years

Ajay Israni, MD, MS, Medical Director, Scientific Registry of Transplant Recipients

Stability of New Cms Metrics for Organ Procurement Organizations: Comparison of 2 Consecutive Years A. Israni, J. Snyder, Hennepin Healthcare, Univ of MN, Scientific Registry of Transplant Recipients, Minneapolis, MN

Purpose: The organ procurement organizations (OPOs) are evaluated by the Centers for Medicare & Medicaid Services (CMS) for quality of performance, and we compared the stability of tiers for the new CMS metrics for donation rate and transplant rate between 2019 and 2020.

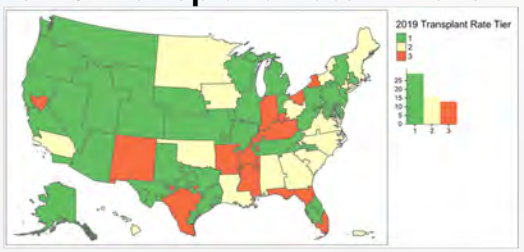
Results: For the donation rate metric, between 2019 and 2020, 67% of the OPOs stayed consistent in their tiers and 33% changed tiers (5 improved and 14 worsened) (Figure 1). For the transplant rate metric, 55% stayed consistent and 45% changed tiers (5 improved and 21 worsened). CMS's overall assessment will use the lower of the 2 tiers. For the overall tiers, 59% stayed consistent and 41% changed tiers (5 improved and 19 worsened). Tier 1 OPOs decreased from 27 to 20, while tier 2 increased from 15 to 16 and tier 3 increased from 16 to

Figure 1: New CMS metrics for Donation and Transplant Rate in 2019 & 2020

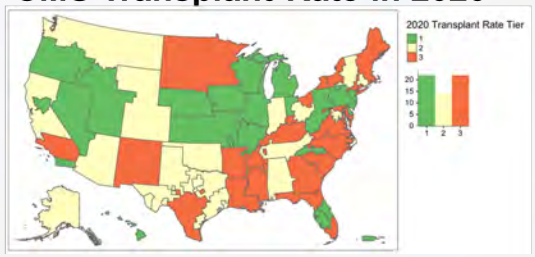
CMS Donation Rate in 2019

CMS Donation Rate in 2020

CMS Transplant Rate in 2019



CMS Transplant Rate in 2020



Conclusions: More OPOs failed CMS's performance assessment in 2020 compared with 2019. This could be an artifact of national transplant rates improving from 2018 to 2019, thereby raising the median and 75th percentiles, whereas transplant rates declined nationally from 2019 to 2020 from 37.0 to 36.5 transplants per 100 potential donors, perhaps illustrating a limitation of using the prior year to set the performance

University of Colorado Research of the CMS OPO Metric: CALC vs CALC Adj.

Significant Discrepancies to Evaluate Organ Procurement Organization Performance Based on Exclusion Criteria

University of Colorado Anschutz Medical Campus

Jesse Schold, PhD, MStat, MEd[1]; Rocio Lopez, MS[1]; David Zingmond, MD[2]

[1]University of Colorado Anschutz Medical Campus, [2]UCLA Health

Background

- In 2020, CMS updated the OPO Conditions for Coverage, choosing CALC (Cause, Age, and Location Consistent with donation), defined as the number of inpatient deaths among patients 75 or younger with a primary cause of death that is consistent with organ donation, as the measure of donor potential.
- CALC includes cases with contraindications to donation.
- CMS stated that contraindicating conditions are equally distributed across OPOs, and the more easily obtainable CALC yields an equivalent OPO rank order and tiering as CALC-adjusted, which excludes cancers, infections and non-ventilated cases.
- We sought to evaluate whether incorporating data with exclusions produce the same tier assignments.

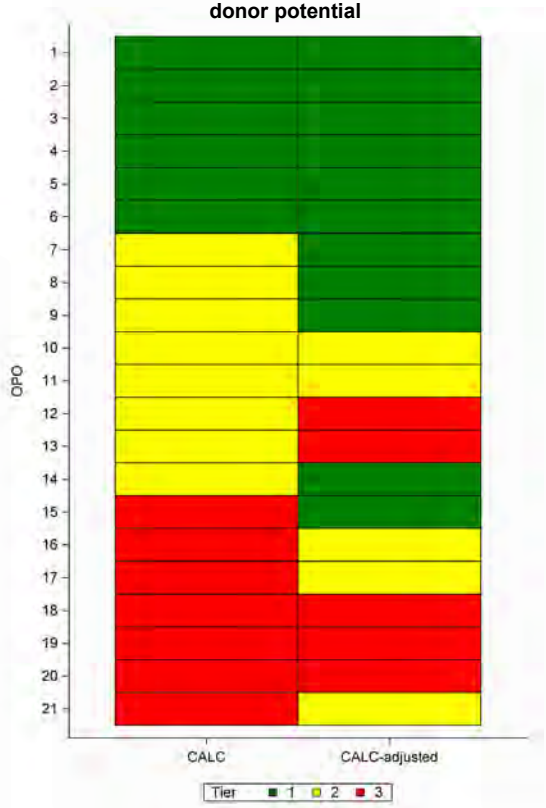
Methods

- State Inpatient Databases for 2017-2018 for 16 states served by 21 OPOs with full data.
- ICD-10 codes used to identify cases. Primary discharge diagnosis was used to identify CALC; other discharge diagnoses were used to identify cancers, infections, and non-ventilated cases excluded for CALC-adjusted.
- We calculated donation and transplant rates along with one-sided 95% upper confidence intervals following CMS methodology.[1,2]
- Tiers were assigned using thresholds obtained from the prior year.[1,2]
- 2017 data is only used to calculate threshold values used for 2018 tier assignments.
- We compared 2018 tier assignments between CALC and CALC-adjusted.

Figure 1. 21 OPOs Included in the Analysis

47% (10/21) **of OPOs change tiers** using donor potential measured by CALC compared to that measured by CALC-adjusted.

Figure 2. OPO Tier Assignments based on CALC and CALC-Adjusted donor potential



Results

- 40% (9/21) of OPOs are large (>1500 DDP).
- On average, CALC and CALC-adjusted donor potential are 4 and 2 times, respectively, higher than actual number of donors ($p<0.001$).
- CALC and CALC-adjusted donation and transplant rates highly correlate (rho=0.90 and 0.89, respectively).

Conclusions

- Contraindicating exclusion factors are not equal across OPO service areas.
- Current tier assignments using CALC may be unreliable compared to those calculated by CALC-adjusted, using a large sample of OPOs across the country.
- ***Despite CMS' assertion, CALC does not produce the same OPO tier assignments as CALC-adjusted, and therefore may not be appropriate to make OPO certification/decertification decisions.***

Disclosures

This work was supported by OneLegacy Foundation and Gift of Life Foundation

References

1. Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations 42 C.F.R Part 486 Subpart G § 436.301-486.360 (2020).https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G
2. Centers for Medicare & Medicaid Services, Quality, Certification and Oversight Reports (QCOR). OPO Annual Public Aggregated Performance Report – User Guide: 2026 Certification Period. Accessed June 1, 2022. https://qcor.cms.gov/documents/OPO_Public_Performance_Report-User_Guide_for_the_2026_Certification_Period.pdf

Conclusions

- Contraindicating exclusion factors are not equal across OPO service areas.
- Current tier assignments using CALC may be unreliable compared to those calculated by CALC-adjusted, using a large sample of OPOs across the country.
- ***Despite CMS' assertion, CALC does not produce the same OPO tier assignments as CALC-adjusted, and therefore may not be appropriate to make OPO certification/decertification decisions.***

University of Colorado Research of the CMS OPO Metric: CALC vs Hosp Dx Data

Jesse D. Schold, PhD, MStat, MEd[1]; Rocio Lopez, MS[1]; David Zingmond, MD[2] [1]University of Colorado Anschutz Medical Campus, [2]UCLA School of Medicine

Aim

To assess whether CALC is a sufficiently reliable and objective determination of donor potential on which to make OPO decertification decisions

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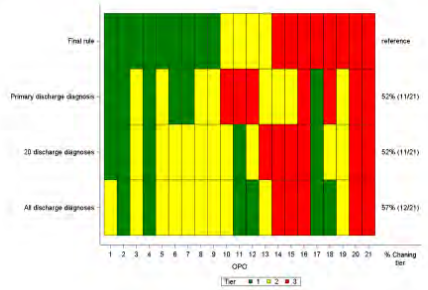
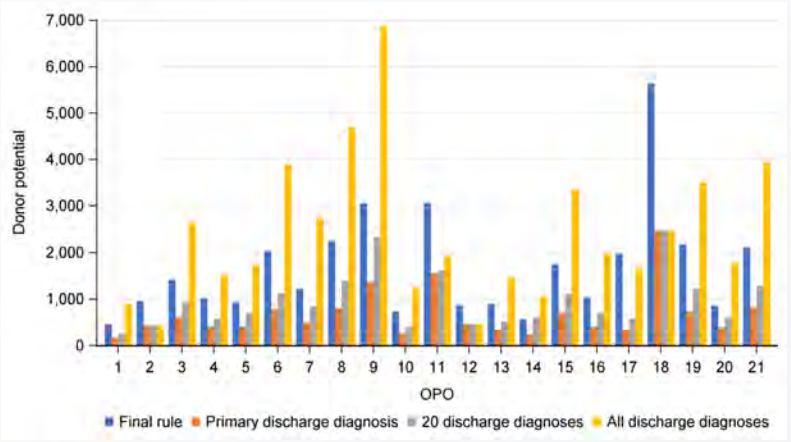
Results





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- **Differences in DDP are not consistent across OPOs.**
- **On average DDP based on the primary diagnosis is 2.6 times the final rule DDP (range is 1.9 – 5.5).**
- **On average DDP based on the 20 diagnoses is 1.7 times the final rule DDP (range is 0.93 – 3.5).**
- **On average DDP based on the all diagnoses is 0.84 times the final rule DDP (range is 0.44 – 2.3).**

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Conclusions

- OPO tier assignments determine certification status
- Different data sources produce significant differences in estimated donor potential
- Tier assignments change based on the different data sources
- Given the structure of the tiering system and the significant ramifications, CMS should revisit their decision to use CALC for certification decisions

Conclusions

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- Different data sources produce significant differences in estimated donor potential
- Tier assignments change based on the different data sources
- Given the structure of the tiering system and the significant ramifications, CMS should revisit their decision to use CALC for certification decisions

University of Colorado Research of the CMS OPO Metric: Age & ADI and Tiers

Jesse D. Schold, PhD, MStat, MEd[1]; Rocio Lopez, MS[1]; Sumit Mohan, MD, MPH[2] [1]University of Colorado Anschutz Medical Campus [2]Columbia University

Impact of Area Deprivation Index on Organ Procurement Organization Performance Metrics

Jesse D. Schold, PhD, MStat, MEd[1]; Rocio Lopez, MS[1]; Sumit Mohan, MD, MPH[2]
[1]University of Colorado Anschutz Medical Campus
[2]Columbia University

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Results - Changes in adjusted tier as compared to CALC tier

Change as compared to CALC tier	2018	2019	2020
	n (%) out of 58 OPOs		
Age and ADI-adjusted tier			
Type of change			
No change	40 (69.0%)	47 (81.0%)	46 (79.3%)
Moving into lower tier	9 (15.5%)	7 (12.1%)	8 (13.8%)
Moving into higher tier	9 (15.5%)	4 (6.9%)	4 (6.9%)
Moving into tier 1	**4 (6.9%)**	**6 (10.3%)**	**7 (12.1%)**
Moving out of tier 1	4 (6.9%)	3 (5.2%)	0 (0.0%)
Moving out of tier 3	**5 (8.6%)**	**1 (1.7%)**	**1 (1.7%)**
Moving into tier 3	5 (8.6%)	1 (1.7%)	4 (6.9%)

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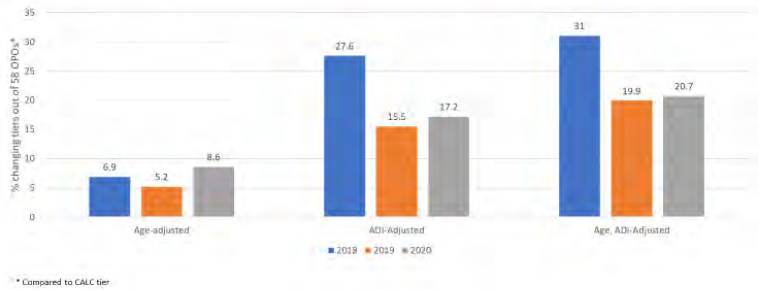
Results – Reclassification Rates



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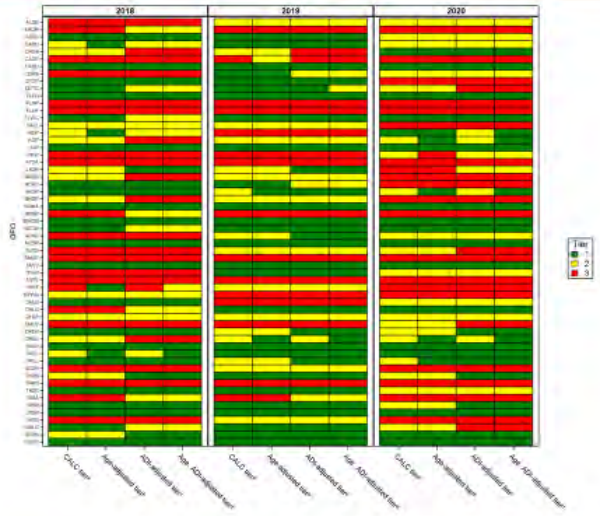

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Conclusions

- Adjusting for area deprivation and age significantly changes OPO measured performance and tier rankings
- Underlying population characteristics may alter processes of care and characterize donation and transplant rates independent of OPO performance
- ***Risk adjustment accounting for population characteristics should be considered in prospective policy***

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- Underlying population characteristics may alter processes of care and characterize donation and transplant rates independent of OPO performance
- ***Risk adjustment accounting for population characteristics should be considered in prospective policy***

SRTR Research of the CMS OPO Metric: Race and Ethnicity and Tier Rankings

SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Adjusting for Race in Metrics of Organ Procurement Organization Performance

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[1]Scientific Registry of Transplant Recipients, Hennepin Healthcare Research Institute, Minneapolis, MN; [2]Department of Medicine, Hennepin Healthcare, University of Minnesota, Minneapolis, MN; [3]Department of Epidemiology and Community Health, University of Minnesota, Minneapolis, MN

Introduction

- In December 2020, the Centers for Medicare & Medicaid Services (CMS) published a Final Rule for organ procurement organizations (OPOs) to be evaluated for recertification with new unadjusted donation and age-adjusted transplant rate metrics.
- Adjustment for race is controversial. A common concern is that it will set lower expectations and "excuse" poor performance within racial subgroups.
- Whether existing disparities within racial subgroups are "caused" by OPOs or are preexisting conditions that OPOs operate within is debatable.
- This study examined national donation and transplant rates within racial subgroups and how additional adjustment for race would affect the CMS evaluation of OPOs.

Methods

- CMS donation and transplant rates and resulting tiers for the year 2020 were calculated with CDC and SRTR data using the method defined in the CMS Final Rule.
- Race adjustment by stratification was added to the metrics (categories: White, Black, Asian or Pacific Islander, and Mixed or Other race).
- Tiers were calculated for both the race-adjusted and race-unadjusted metrics: Tier 1 OPOs had an upper 95% confidence limit for both their donation and transplant rates above the 75th percentile of 2019 rates; Tier 2 OPOs had an upper 95% confidence limit for both rates above the median of 2019 rates; all other OPOs were in Tier 3.

Table 1: National CALC potential donors, donation and transplant rates by race – 2020

Race	CALC Potential Donors	Donors (Donation Rate)	Transplants (Transplant Rate)
Asian/Pacific Islander	3,691	328 (8.89%)	1,020 (27.63%)
Black	18,967	1,889 (9.96%)	6,150 (32.42%)
Other/Mixed Race	2,445	126 (5.15%)	425 (17.38%)
White	76,476	9,260 (12.11%)	29,494 (38.57%)

Table 2: OPOs that change tier when adjusting for race and whether they over or underperform national rates – 2020

OPO	CMS Tier	Race-adjusted Tier	Percent Non-White Potential Donors	Non-White Donor Performance: (Observed/ Expected)	Non-White Transplant Performance: (Observed/ Expected)	White Donor Performance: (Observed/ Expected)	White Transplant Performance: (Observed/ Expected)
OPO1	3	2	39.14%	Overperforms (116/113.95)	Overperforms (396/370.28)	Underperforms (206/218.19)	Underperforms (637/695.18)
OPO2	1	2	6.9%	Overperforms (10/5.17)	Overperforms (42/16.82)	Underperforms (84/94.7)	Underperforms (259/301.73)
OPO3	2	3	15.16%	Overperforms (45/32.71)	Overperforms (180/106.22)	Underperforms (193/227.03)	Underperforms (682/723.34)
OPO4	3	2	44.65%	Overperforms (84/78.83)	Overperforms (298/256.46)	Underperforms (118/120.24)	Overperforms (404/383.08)
OPO5	3	2	41.3%	Underperforms (36/45.03)	Underperforms (108/146.2)	Overperforms (95/79.67)	Overperforms (298/253.84)
OPO6	3	2	35.1%	Underperforms (81/85.6)	Underperforms (248/278.6)	Overperforms (203/199.06)	Overperforms (639/634.22)
OPO7	2	3	18.95%	Underperforms (8/12.82)	Underperforms (20/41.58)	Overperforms (68/67.32)	Overperforms (225/214.49)
OPO8	2	1	22.94%	Overperforms (35/25.63)	Overperforms (104/84.48)	Overperforms (152/146.39)	Underperforms (430/466.41)

Results

- Nationally, donation rates and transplant rates were higher among White potential donors than non-White potential donors (donation rate per 100 potential donors: 12.11 versus 9.33, respectively; transplant rate per 100 potential donors: 38.58 versus 30.26, respectively).
- When adjusting for race, 8 OPOs changed tiers (5 improved their tier, 3 lowered their tier). Among the OPOs that changed tiers, 1 that moved from Tier 3 to Tier 2 had 44.65% non-White potential donors and outperformed the national donor and transplant rates for non-White potential donors and the national transplant rate for White donors.

Conclusions

- Failing to adjust for race can hide good performance relative to national averages among potential non-White donors and *risks extreme penalties* for OPOs that have high proportions of non-White potential donors.
- If reducing racial disparities is a system goal, racial substrata must be examined and OPOs compared within substrata of performance—precisely what is done through adjustment for racial groups.

The authors have no financial relationships to disclose within the past 12 months, relevant to this presentation.

This work was supported wholly or in part by HRSA contract 75R60220C00011. The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of HHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

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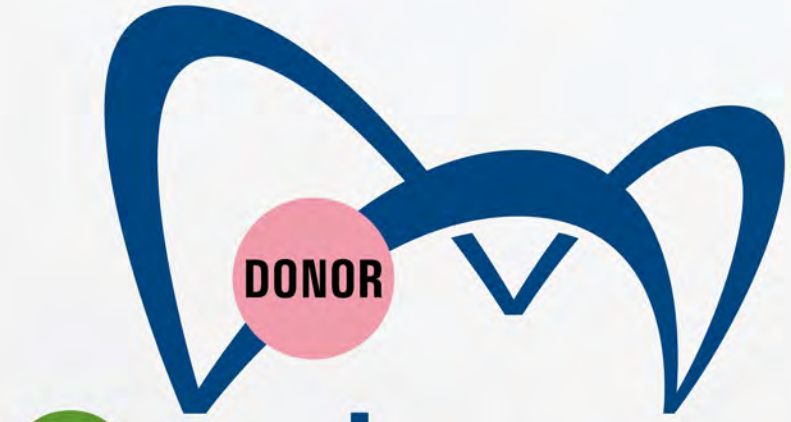
CMS OPO Metric: How is it Measuring Up?

According to the biostatisticians…Not too well

What are CMS's Options?

1. Manage the decertification or competition of 52-72% of OPOs simultaneously
2. Recertify Tier 2 OPOs with nominal performance improvement programs
3. Re-open the rule to reduce the number of OPO decertifications at one time
   a) Put all Tier 2 and 3 on performance improvement programs
   b) Keep the CDC data source, but drop the Tier "Cliffs" by returning to Standard Deviations
   c) Increase the number of years measured from 1 to 3 or 4
   d) ?



OneLegacy

saving lives through
organ, eye & tissue donation

Keeping Up with the Times-eGFR Policy Action

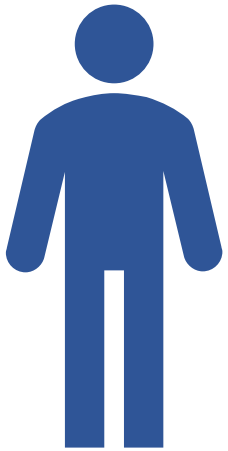
Bethany Durbin, MSN, RN, CPTC, CCTC

Denisia Chen, RN, CHC, CPC

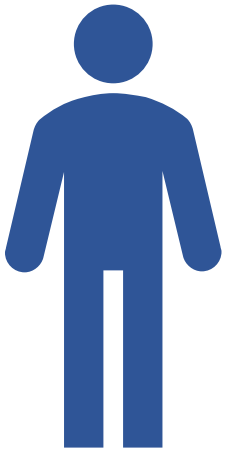
Andrew Jimenez, MHA

Background of Race-Based eGFR Calculations

- The historical use of race inclusive eGFR calculations had shown to increase eGFR values by up to 16% for African American individuals
- In July 2022, a policy change made it a requirement for transplant hospitals to use only race-neutral eGFR values for data entered into UNet



65 y/o M
Cr: 3.4
"Non-AA"
eGFR = 18
Eligible for Transplant



65 y/o M
Cr: 3.4
"AA"
eGFR = 21
Ineligible for Transplant

Policy Action: January 5, 2023

1. Notify all currently listed candidates of policy change and impending review
2. Identify African American candidates and Determine whether a race-neutral eGFR calculation shows they should have qualified sooner to start gaining waiting time for a transplant
3. Submit completed waiting time modification requests to the OPTN for those candidates
4. Send a second notification to inform each kidney candidate of their eligibility status
5. Provide an attestation to the OPTN that these requirements have been met

Initial Notification

- Keck sent out initial letter on 3/20/23
- Designated a phone line for calls and questions related to eGFR notification
- Received 45+ patient calls over span of 4 weeks
- Majority of calls requested explanation of letter; others called thinking their race was miscategorized

Keck Medicine of USC

Kidney Transplant Program

Dear Kidney Transplant Candidate:

You are receiving this letter because you are registered on the waiting list for a kidney transplant at Keck Medicine of USC. This letter contains important information about possible changes to your waiting time if you are registered as a **Black or African American candidate.**

A recent national policy change requires all kidney transplant programs to review their waiting lists to see if any registered Black or African American candidates were affected by the use of a calculation of kidney function called "eGFR", that included race in a way that might have changed their eligibility to be waitlisted for a kidney transplant. Those Black or African American candidates who were affected by the use of the eGFR calculation could potentially receive additional waiting time. The amount of waiting time a kidney candidate has is important, as it is a significant factor in determining who gets kidney transplant offers. Programs are required to submit waiting time modifications and supporting documentation for eligible candidates by January 3, 2024. If you registered for a kidney-pancreas or multiple organ transplant, you are also within the scope of eligibility if you are registered for an isolated kidney.

This letter is only to serve as a notice of the policy change. If you are **not** Black or African American, you are not eligible for a waiting time modification, as you did not have a race-inclusive calculation used to calculate your eGFR. If you are registered as **Black or African American** or if you registered with multiple races and one of those races is **Black or African American**, we will review our records to see if you are eligible for a waiting time modification. However, you can also help us by contacting the doctor who referred you to our transplant center, such as your regular kidney doctor, and ask if they have lab data that we may not be able to access. Any of your doctors (e.g., general internist, PCP, family medicine, etc.) who have your older labs may also be able to help. Forward these lab documents to your transplant coordinator and we will determine if we can apply for an adjustment in waiting time.

Please call (213) 317-4651 with any questions.

You will receive a second letter confirming your race and whether or not you are eligible for a waiting time modification. Please be patient with any delays in getting back to you promptly as we are assessing the waiting list for all registered adult and pediatric Black or African American kidney candidates that may have been affected.

How can I learn more about eGFR and this policy change?

- Go to OPTN website > Patients > Kidney > "FAQ: Understanding race-neutral eGFR calculations"
- Full URL:
  - https://optn.transplant.hrsa.gov/patients/by-organ/kidney/understanding-the-proposal-to-require-race-neutral-egfr-calculations/

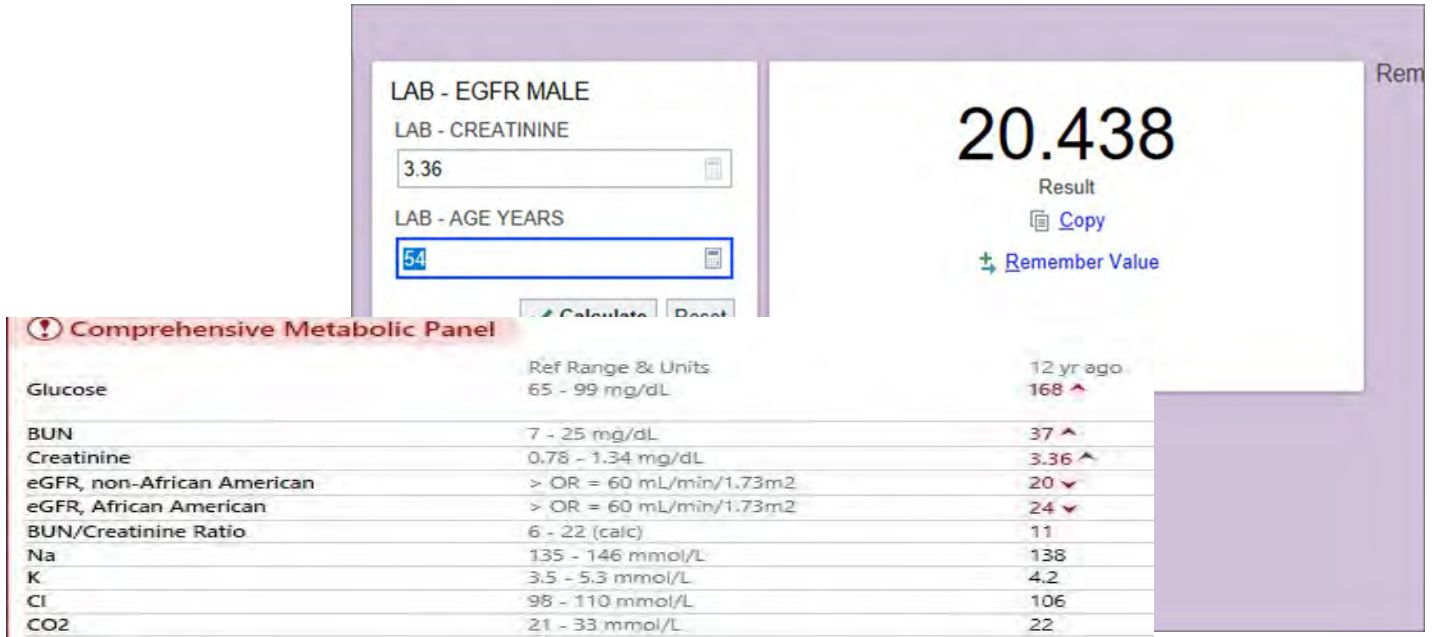
Examples for Assessment of Qualifying Documentation

- Name
- Date
- Creatinine
- eGFR African-American
- eGFR non-African-American

  OR

- The race neutral calculation with the lab report
  - Use any GFR tool

Note GFR shows one in range to qualify and one out of range



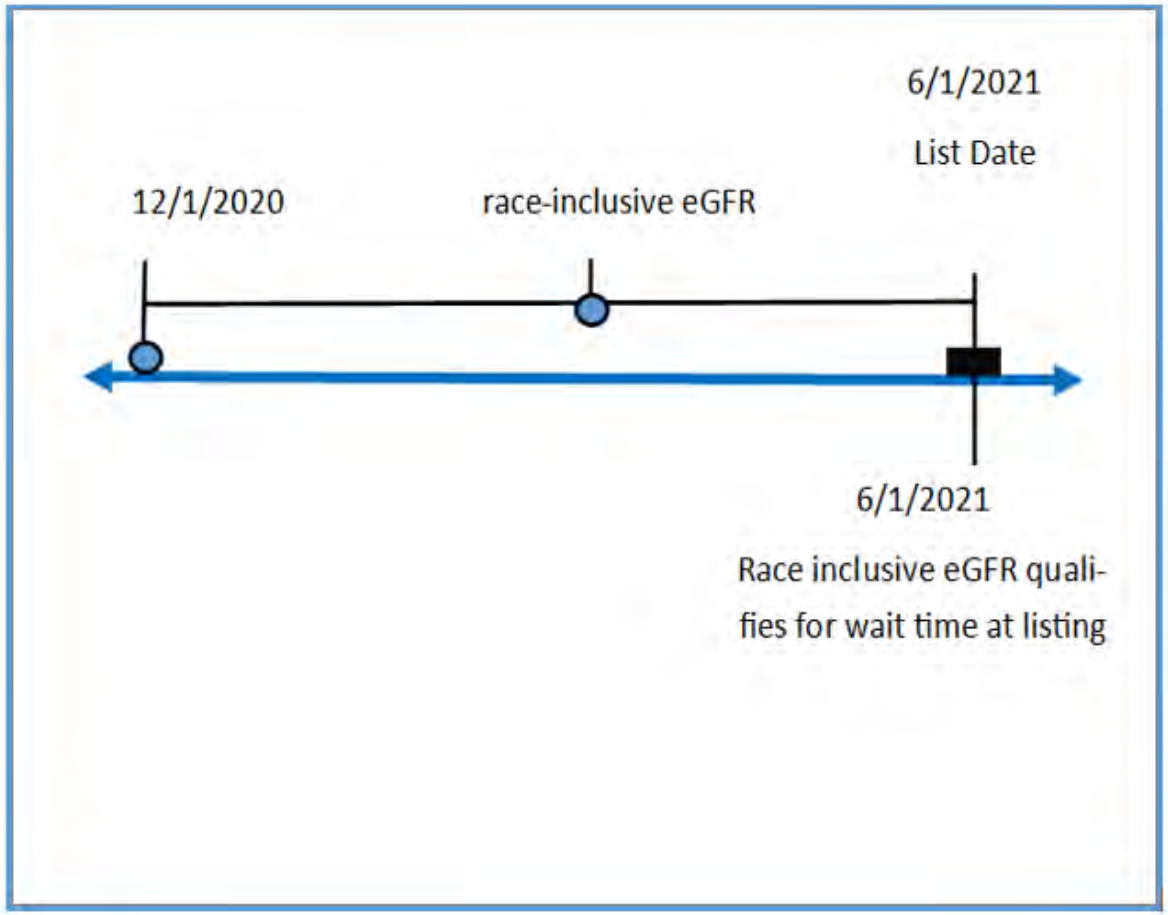
Comprehensive Metabolic Panel

	Ref Range & Units	12 yr ago
Glucose	65 - 99 mg/dL	168 ^
BUN	7 - 25 mg/dL	37 ^
Creatinine	0.78 - 1.34 mg/dL	3.36 ^
eGFR, non-African American	> OR = 60 mL/min/1.73m2	20 v
eGFR, African American	> OR = 60 mL/min/1.73m2	24 v
BUN/Creatinine Ratio	6 - 22 (calc)	11
Na	135 - 146 mmol/L	138
K	3.5 - 5.3 mmol/L	4.2
Cl	98 - 110 mmol/L	106
CO2	21 - 33 mmol/L	22
Calcium	8.6 - 10.2 mg/dL	8.8
Total Protein	6.2 - 8.3 g/dL	7.0
Albumin	3.6 - 5.1 g/dL	3.6
Globulin, Total	2.1 - 3.7 g/dL (calc)	3.4
Albumin/Globulin Ratio	1.0 - 2.1 (calc)	1.1
Bilirubin Total	0.2 - 1.2 mg/dL	0.4
Alkaline Phosphatase	40 - 115 U/L	93
AST	10 - 40 U/L	29
ALT	9 - 60 U/L	22

Resulting Agency QUEST DIAG
Specimen Collected: 11/06/10 13:45

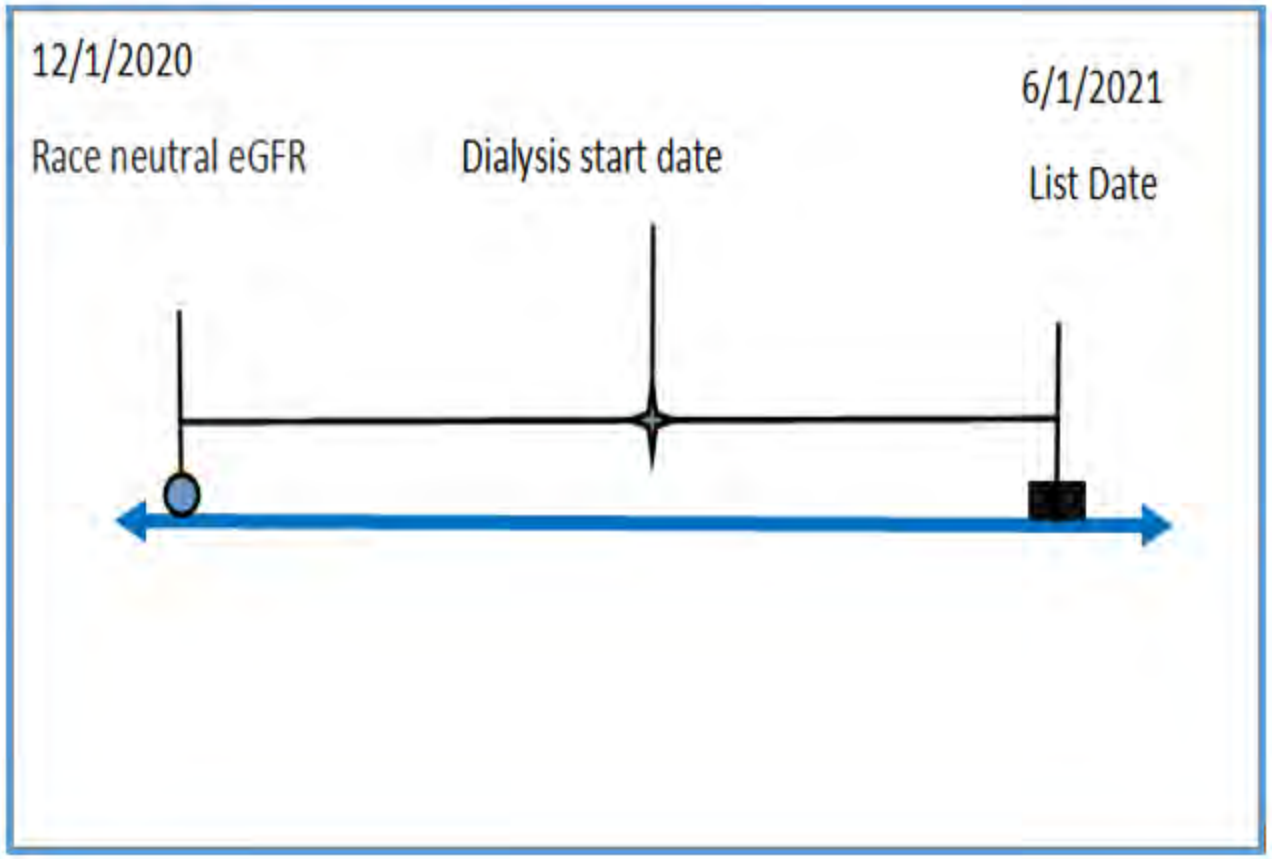
Example 1

- Candidate was listed 6/1/2021 with a qualifying, race inclusive eGFR to accrue wait time
- An earlier eGFR from 12/1/2020 shows the candidate would have qualified earlier if a race neutral calculation had been used
- Candidate qualifies for a Wait Time Modification back to 12/1/2020



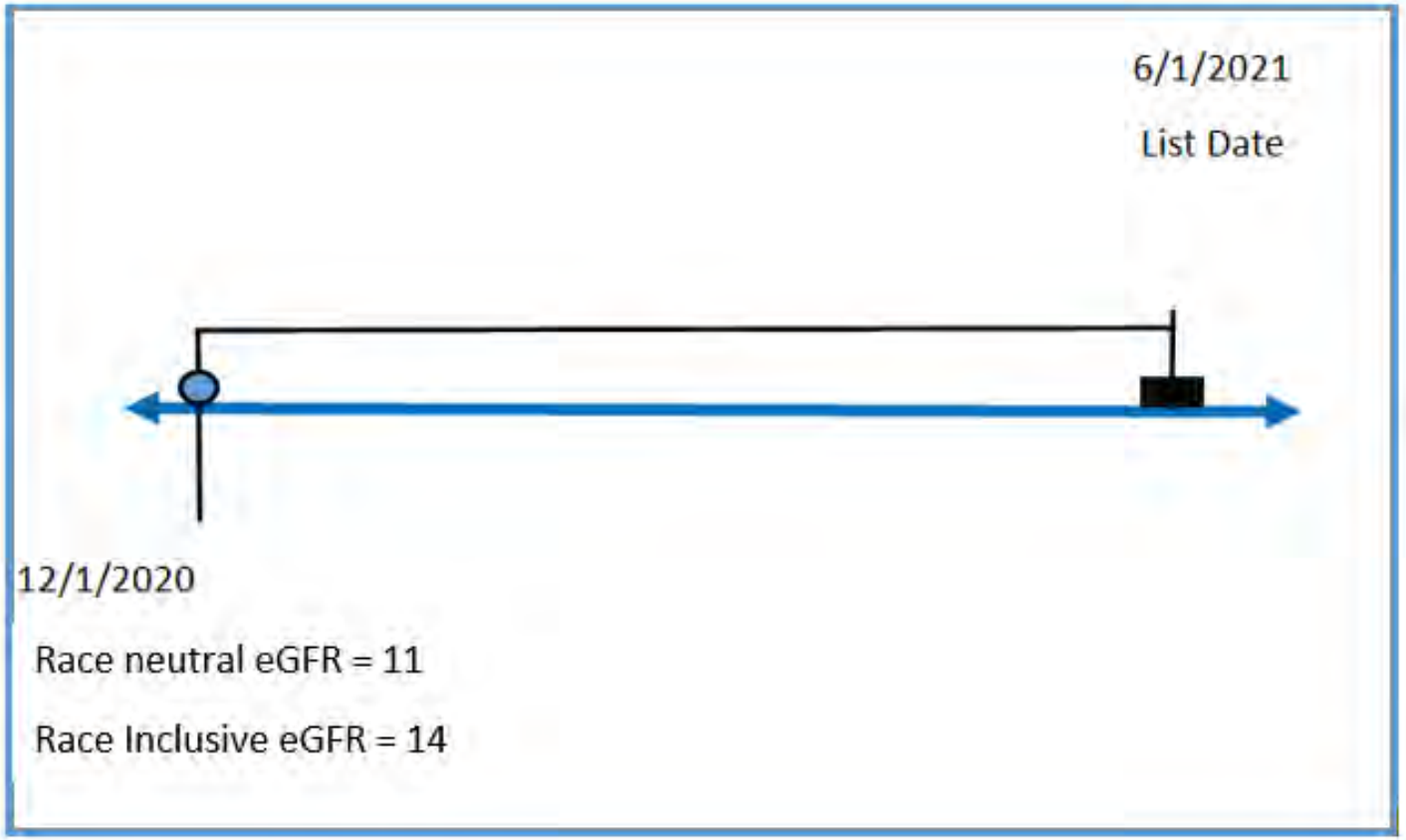
Example 2

- Candidate was listed 6/1/2021 with a qualifying dialysis start date
- An earlier eGFR from 12/1/2020 shows the candidate would have qualified earlier if a race neutral calculation had been used
- Candidate qualifies for a Wait Time Modification back to 12/1/2020



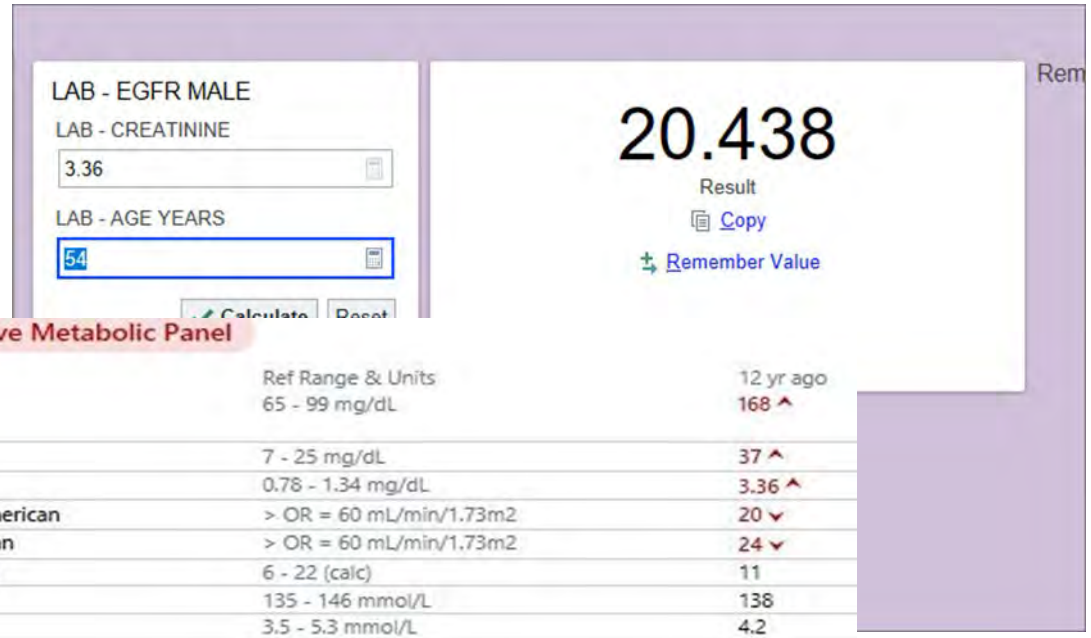
Example 3

- Candidate was listed 6/1/2021 with a qualifying, race inclusive eGFR
- An earlier eGFR from 12/1/2020 shows the candidate was already below 20 ml/min
- This candidate **DOES NOT** qualify for a Wait Time Modification



Devil in the Detail

- This Quest lab eGFR result is rounded to 20
- Results vary based on reporting practices and calculation method
- Wait mod requests denied
  - Rounding in reporting not considered in policy interpre
  - Calculator vs. lab reporting AA and non-AA eGFR



Formula	Result
MDRD 4-Variable Equation	19.2 mL/min/1.73 m^2
CKD-EPI Formula	19.6 mL/min/1.73 m^2
Mayo Quadratic Formula	18.5 mL/min/1.73 m^2

Devil in the Detail

Some remain disadvantaged

- Care gaps
  - Had insurance, but did not tend to labs/follow up care for ESRD
  - Lacked insurance, so no data available **OR**
  - Labs on the wrong day despite regular follow ups

GFR <20 in 2014, pt not referred for transplant until 2017 and on dialysis

Care Everywhere Labs History

LYTES / CHEM 7 BUN,CREATININE,GLUCOSE,GFR

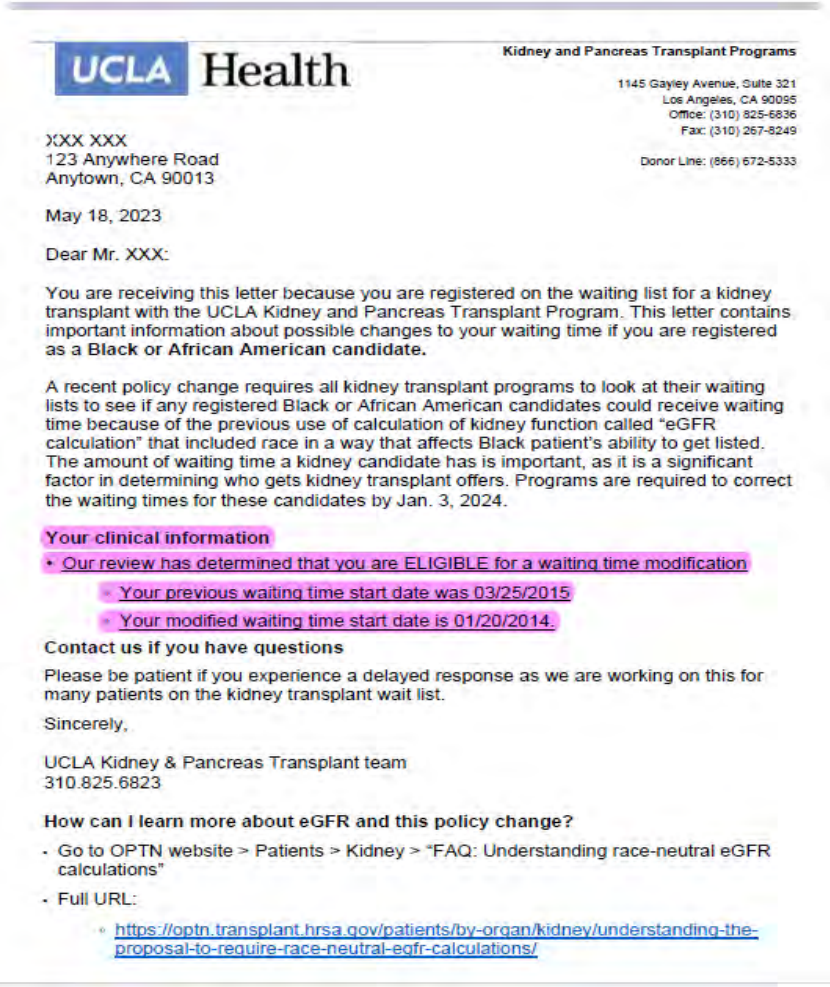
Component	09/03/2014	09/03/2014	09/03/2014	02/12/2014	02/12/2014	02/12/2014
SODIUM	—	—	141	139	—	—
POTASSIUM	—	—	3.6	3.9	—	—
CHLORIDE	—	—	106	102	—	—
CO2	—	—	27	29	—	—
ANION GAP (NA - (CL + C...	—	—	—	—	—	—
BUN	—	42 ^	—	—	31 ^	—
CREATININE	3.00 ^	—	—	—	—	2.40 ^
GLOMERULAR FILTRATION...	19	—	—	—	—	25
GLUCOSE, RANDOM	—	—	—	—	—	—
EGFR, CREATININE-BASED...	—	—	—	—	—	—

UCLA Timeline and Progress

Letter #1 sent 4/2023

- ~210 African American/Black waitlisted patients to review
- 201 complete/near complete as of 8/8/2023
- 107 qualify for wait time modification
    - Days added **17 – 3883** (> 10 years)
  - Average number of days added **524** (< 1.5 years)
- Staffing resources
  - 5 RN Coordinators + 3 admin for waitlisted patients (1600+)
  - 4 RN Coordinators + 6 admin for patients in evaluation (>400)
    - >150 referrals/month
- Patient engagement/questions low
  - Very manageable

Second and Final Notifications



UCLA Health

Kidney and Pancreas Transplant Programs

1145 Gayley Avenue, Suite 321
Los Angeles, CA 90095
Office: (310) 825-6836
Fax: (310) 267-8249

Donor Line: (866) 672-5333

XXX XXX
123 Anywhere Road
Anytown, CA 90013

May 18, 2023

Dear Mr. XXX:

You are receiving this letter because you are registered on the waiting list for a kidney transplant with the UCLA Kidney and Pancreas Transplant Program. This letter contains important information about possible changes to your waiting time if you are registered as a **Black or African American candidate.**

A recent policy change requires all kidney transplant programs to look at their waiting lists to see if any registered Black or African American candidates could receive waiting time because of the previous use of calculation of kidney function called "eGFR calculation" that included race in a way that affects Black patient's ability to get listed. The amount of waiting time a kidney candidate has is important, as it is a significant factor in determining who gets kidney transplant offers. Programs are required to correct the waiting times for these candidates by Jan. 3, 2024.

Your clinical information

- Our review has determined that you are ELIGIBLE for a waiting time modification
  - Your previous waiting time start date was 03/25/2015
  - Your modified waiting time start date is 01/20/2014.

Contact us if you have questions

Please be patient if you experience a delayed response as we are working on this for many patients on the kidney transplant wait list.

Sincerely,

UCLA Kidney & Pancreas Transplant team
310.825.6823

How can I learn more about eGFR and this policy change?

- Go to OPTN website > Patients > Kidney > "FAQ: Understanding race-neutral eGFR calculations"
- Full URL:
  - https://optn.transplant.hrsa.gov/patients/by-organ/kidney/understanding-the-proposal-to-require-race-neutral-egfr-calculations/

- All AA patients notified of eligibility status real time
  - 199 sent as of 8/15/23
- All other waitlist candidates
  - 2nd notification letter to be sent December, 2023
  - ~1350-1400 letters
- Program attestation to follow

- Our review has determined that you are NOT ELIGIBLE for a waiting time modification
  - No eligible records were located
  - You may submit records for consideration at any time.

Final Notification – Stanford Children's

- Notification two is required to be sent to all registered kidney candidates after your program's waiting list assessment.
- This is an example of the notification sent by our Pediatric Kidney Transplant Program.

Dear Parent or Guardian,

This letter serves as the second of two notifications we are sending to all our registered kidney candidates, to fulfill a policy requirement.

An Organ Procurement and Transplantation Network (OPTN) policy change took effect in early 2023. In this letter we would like to confirm that based on our assessment, the policy changes do not impact any of our patients, nor our waiting list.

All kidney transplant programs were required to look at their waiting lists to see if they need to modify the waiting time for any registered Black or African American candidates. Any corrections need to be completed by Jan. 3, 2024.

In the past, race was one of the factors used to calculate the estimated glomerular filtration rate (eGFR). The eGFR is a measure of how well your kidneys are working and is used to place people on the waitlist for a kidney transplant. Transplant programs can no longer use eGFR calculations that include a race factor. With this change and reassessment, Black or African American candidates could receive more waiting time, changing their order on the waiting list.

Our program for pediatric patients has never used race as a factor to calculate the eGFR. All children, no matter what race or ethnicity were, and continue to be, assessed the same way.

This policy change is not affecting any of our patients nor our waitlist. Your waiting time remains the same.

Should you have any questions or concerns, please contact us at (650) [redacted].

Sincerely,

Attestation Provided to the OPTN

- All designated kidney transplant programs must submit an attestation to the OPTN by January 3, 2024, signed by the transplant program director (or their designee), affirming that the program has completed both the following:
  1. Notification to all candidates registered at the transplant program of their eligibility for a waiting time modification according to this policy, and
  2. Submission of eGFR waiting time modifications for all eligible candidates registered at the transplant program.

- The Sample Attestation Documentation is from the UNOS Connect Course KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations.

Sample

Attestation Documentation

In compliance with *OPTN Policy 3.7.D.iv: Reporting Requirements for Kidney Transplant Programs*,

(Program name) attests on (insert date of attestation submission) to the completion of all of the following:

- Notification to all candidates registered at the transplant program of the responsibilities of the program pursuant *to Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations.*
- Notification to all candidates registered at the transplant program of their eligibility for awaiting time modification according to this policy
- Submission of eGFR waiting time modifications for all eligible candidates registered at the transplant program.

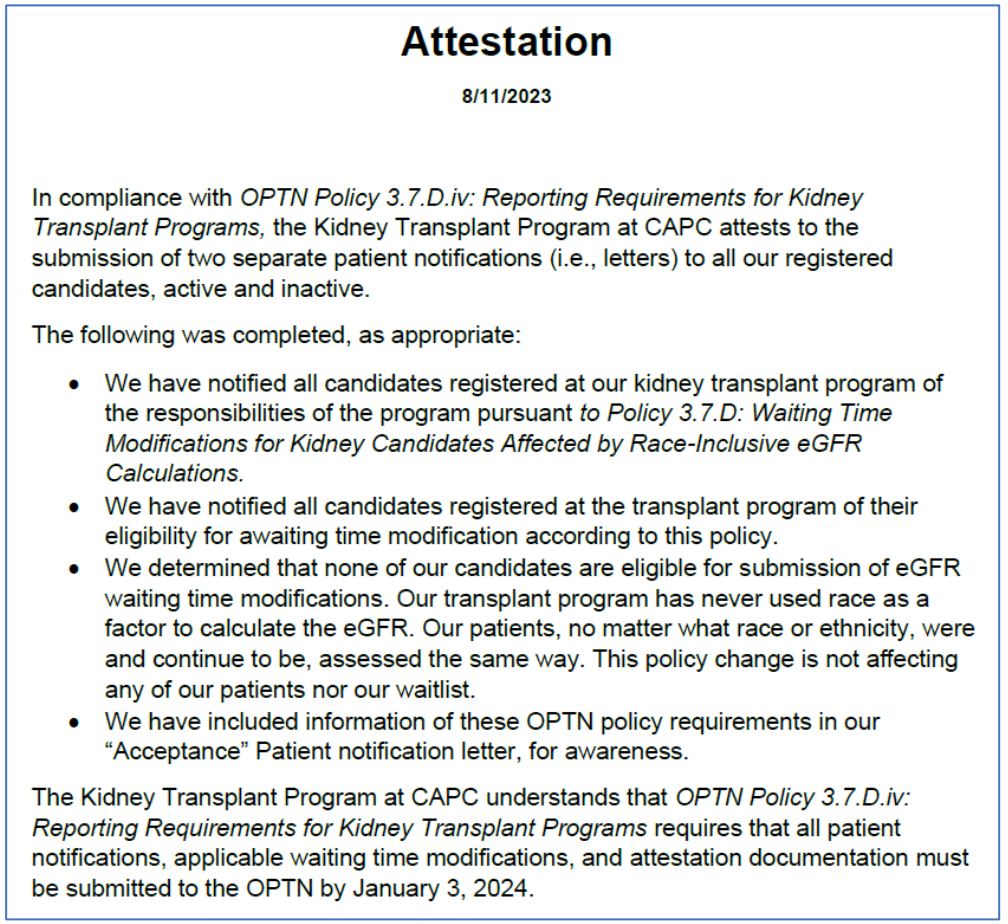
(Program name) understands that *OPTN Policy 3.7.D.iv: Reporting Requirements for Kidney Transplant Programs* requires that all patient notifications, applicable waiting time modifications, and attestation documentation must be submitted to the OPTN by January 3, 2024.

Transplant Program Director Signature (or designee)

Attestation Provided to the OPTN, cont'd

- This example attestation is from the Pediatric Kidney Transplant Program at Stanford Children's.

- The attestation can be sent by fax (804-697-4372) or email (OCOperations.Coordinator@unos.org).



Attestation

8/11/2023

In compliance with *OPTN Policy 3.7.D.iv: Reporting Requirements for Kidney Transplant Programs,* the Kidney Transplant Program at CAPC attests to the submission of two separate patient notifications (i.e., letters) to all our registered candidates, active and inactive.

The following was completed, as appropriate:

- We have notified all candidates registered at our kidney transplant program of the responsibilities of the program pursuant *to Policy 3.7.D: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations.*
- We have notified all candidates registered at the transplant program of their eligibility for awaiting time modification according to this policy.
- We determined that none of our candidates are eligible for submission of eGFR waiting time modifications. Our transplant program has never used race as a factor to calculate the eGFR. Our patients, no matter what race or ethnicity, were and continue to be, assessed the same way. This policy change is not affecting any of our patients nor our waitlist.
- We have included information of these OPTN policy requirements in our "Acceptance" Patient notification letter, for awareness.

The Kidney Transplant Program at CAPC understands that *OPTN Policy 3.7.D.iv: Reporting Requirements for Kidney Transplant Programs* requires that all patient notifications, applicable waiting time modifications, and attestation documentation must be submitted to the OPTN by January 3, 2024.

Resources Available

- Notice of OPTN Policy Change, July 2022

Establish OPTN Requirement for Race-Neutral Estimated Glomerular Filtration Rate (eGFR) Calculations

- Notice of OPTN Policy Change, January 2023

Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations

- OPTN Toolkit with FAQs for professionals and patients, webinars, etc.

OPTN Toolkit Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations

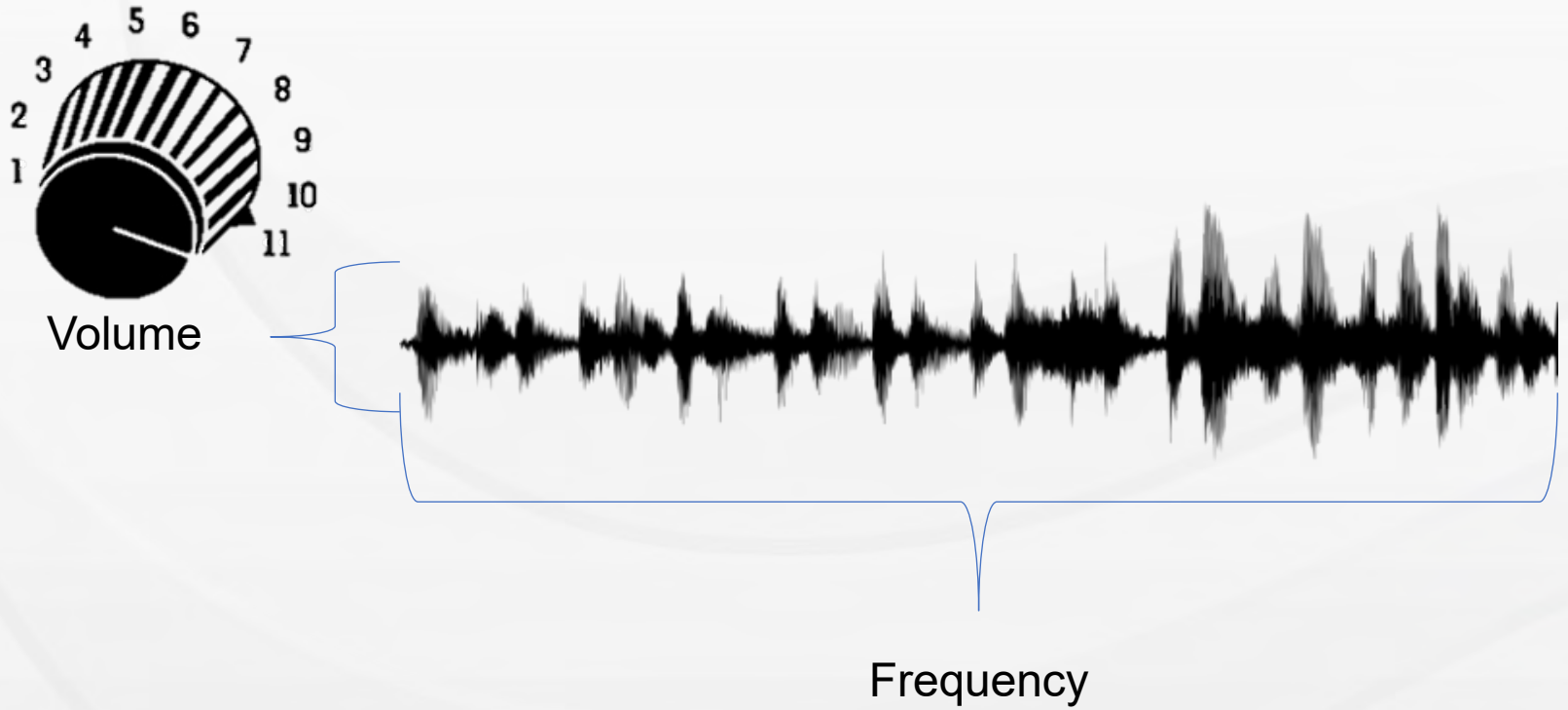
- UNOS Connect Course KID118: Waiting Time Modifications for Kidney Candidates Affected by Race-Inclusive eGFR Calculations. Includes candidate notifications templates and sample attestation for download.

LIFESHARING™

Volume, Frequency and Capacity

Jeffrey Trageser
Executive Director
Lifesharing

Volume and Frequency



LIFESHARING™

On-Call Staffing Models

- OPOs
  - Procurement/Donor Coordinators
  - Recovery and Preservation Staff
  - Family Service Staff
  - Referral Responders
  - Hospital Services
  - AOCs
  - Medical Director
  - Allocation staff
- Transplant
  - Transplant Coordinators
  - Recovery Surgeons
  - Recovery Support Staff
  - Transplant Physicians
  - Call Center Staff
  - Administration
  - Others?

Schedule Math

OPO example:

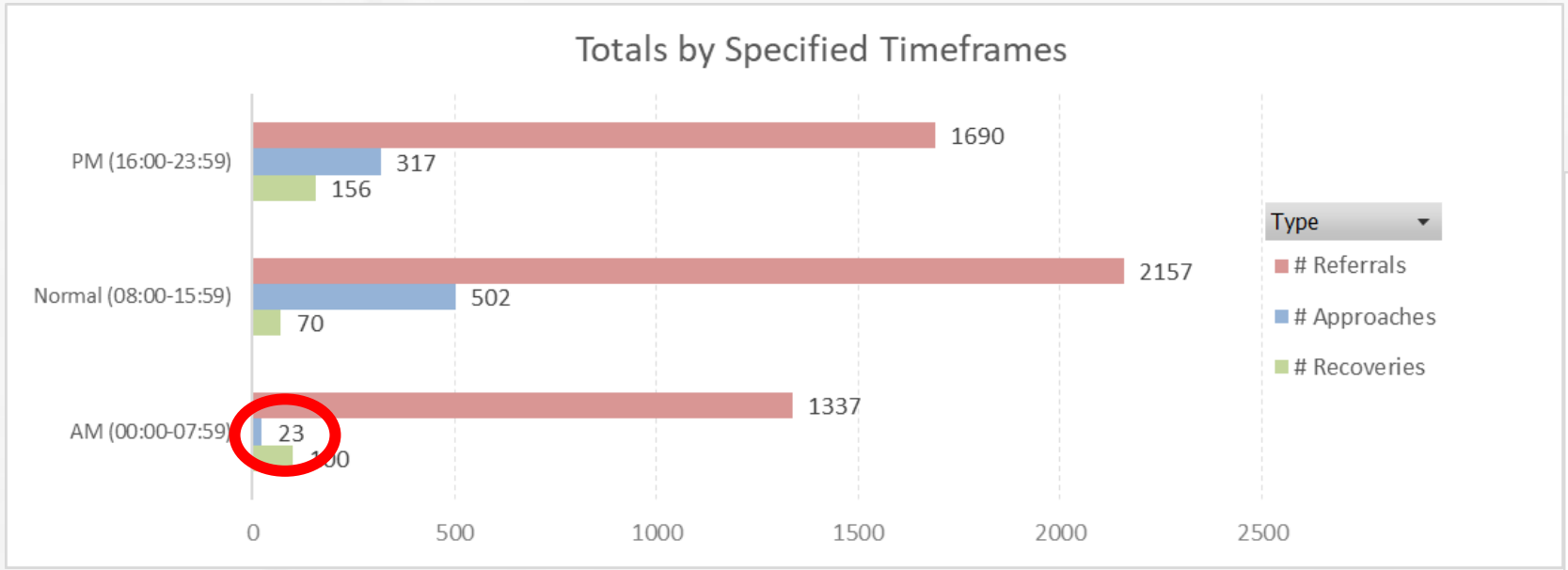
- 1 Donor Coordinator per 10 donors recovered per year
- Average donor volume per year = 210 donors
- 21 Donor Coordinators required (assume 24-hour shifts)
- Split evenly across 7-day week = 3 coordinators/day

Schedule Math

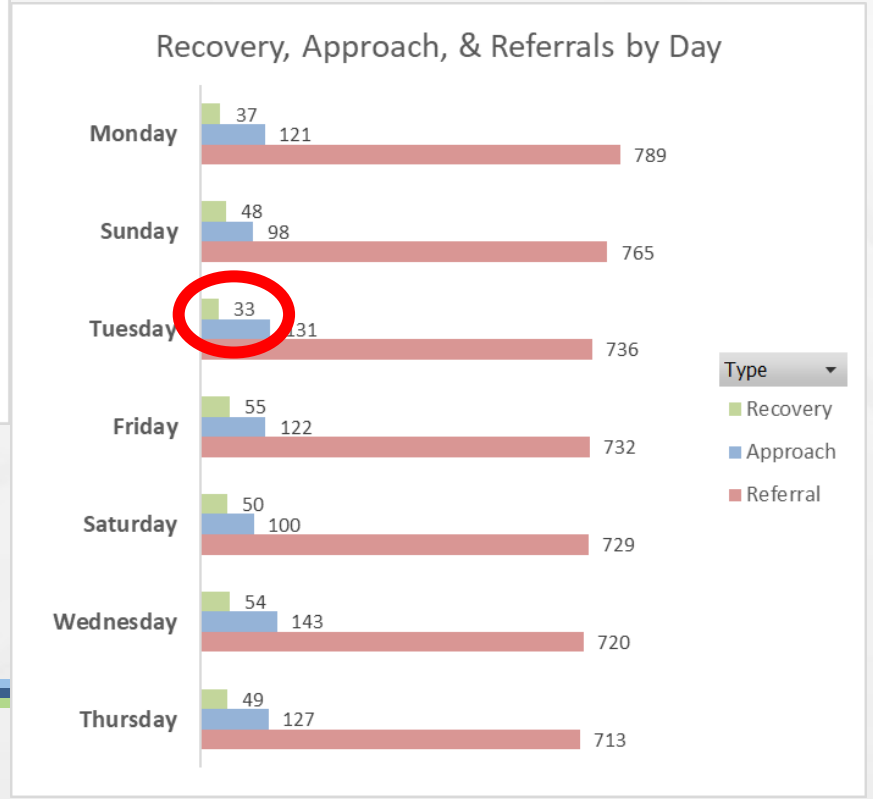
Transplant Center example:

- Targets for deceased donor transplants per month?
  - Per week
- Number of surgeons and staff needed to manage transplant volume?
  - Weekly?
  - Daily?

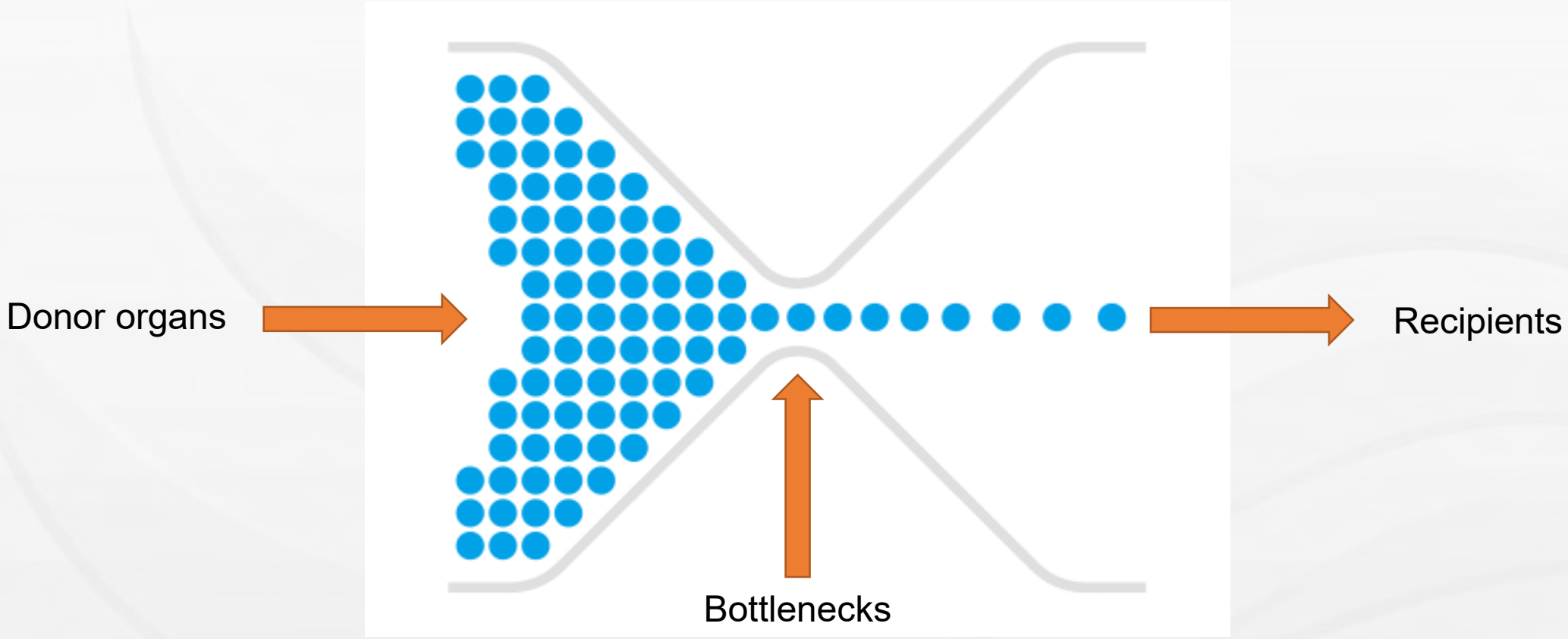
Deceased Donor Frequency



<u>No ability to control or predict:</u>
Brain death
Family decision to WLST



Capacity



LIFESHARING™

Transplant Capacity Factors

- Frequency and volume of organ offers
- Surgeon availability
- Flight availability
- Transplant hospital OR staffing/availability
- Bed-flow/ability to admit recipient
- Recipient readiness
- Financial support from transplant hospital for advanced technologies

OPO Capacity Factors

- Frequency and volume of brain death and EOL decisions
- Staffing
- Donor hospital support for donation
- Family willingness to wait
- Donor stability
- Operating Room availability

Discussion

- Endeavor to understand your colleague on the other end of the phone
- How transparent can we be?
- “If only we had more control over the OR times…”

Thank you

LIFESHARING™

LIFESHARING™

Questions?

jtrageser@health.ucsd.edu

619-386-8281

Jon Saputo, RN, BSN, CCTC
University of California San Diego

REGION 5 COLLABORATIVE

TRANSPLANT CENTER STAFFING MODELS & CHALLENGES WITH INCREASING NUMBER OF ORGAN OFFERS

AUGUST 23, 2023

University of California – San Diego Medical Center

- Multi-organ transplant center
  - Heart, lung, liver, kidney, and bone marrow
  - Center of Excellence, Magnet accredited hospital
  - Living donor program for kidney and liver
  - 200 transplant employees

Transplant Volumes

Program	2023 YTD	2022	2021	2020	2018
Heart	60	89	85	69	56
Lung	41	37	47	30	23
Liver	97	71	82	90	42
Kidney	114	147	150	132	95
Grand Totals	312	344	365	325	216

Offer Volumes

Program	2023 YTD*	2022	2021	2020	2018
Heart	709	1122	991	783	495
Lung	1412	1350	1120	1194	704
Liver	2536	3565	1503	1405	1077
Kidney	1613	2727	2981	2114	1528
Grand Totals*	6671	9312	6677	5848	4055

* January through July 2023
** Totals include heart/lung offers not itemized above

History of Handling Organ Offers

- Traditional method
  - Office coordinators rotate call
  - Coordinators are in the office M-F
  - 1 coordinator on for liver, 1 for kidney, 1 for heart, 1 for lung
  - Backup call as needed
  - 4 primary coordinators paid per day plus 1-2 backups a day
  - Hourly employees (on-call pay plus OT)
  - Call is a side task not a primary job
    - Done in office M-F 8-5
    - At home nights/weekends/holidays

- Dedicated Transplant Recovery Dept
  - Goal: Specialized team of coordinators who handle all aspects of organ call for all programs
  - Additional responsibilities include after-hours patient calls and follow-ups, urgent listings, UNOS updates (MELDs, Statuses), removals, and other specialized projects as needed
  - Fly-outs, preservation, NRP & OCS management, transportation logistics
  - Team is comprised of management, RN Transplant Coordinators, non-RN Organ Allocation Specialists (OAS), and Transplant Recovery Specialists (TRS)

Allocation Team Structure

Allocation Team Manager

- 1 on call manager
- Steps in to help with issues, bed management
- Liaison for physicians, surgeons, OPO, administration
- Develops and implements processes and protocols
- Scheduling, training, etc.

RN-Transplant Coordinator

- 13 RNs (10 FTE, 3 per-diem)
- 1 on at all times (12-hour shifts)
- Covers call for all organs
- Reviews all cases, patient charts
- Afterhours and redline patient calls for all programs
- Transfers, re-MELD's, urgent listings, status updates, patient follow-ups

Organ Allocation Specialist (OAS)

- 4 FTE, 3 per diem
- Non-licensed
- Assist the RN as directed
- Write up offers in our documentation
- Review offers with physicians & surgeons
- Case set-ups
- Special projects as needed

All team members are home based

Management of Allocation Team

Day to Day Manager

- On call as admin 24/7 (backs up Charge RN)
- Liaison for physicians, surgeons, OPO, administration
- Ensure consistency
- Quality control, QA charting, etc.
- Develops workflows, protocols and processes
- Ensure safe staffing levels → determine when to call in extra staff and who to call in
- Transportation guidance
- Avg Calls per Day
  - 30-50 per day most days
  - 100+ on busy days

Day to Day Charge RN

- On call as resource/backup 24/7
- Provides guidance to staff on clinical operations
- Ensures consistency in practice & real-time quality control
- Day-to-day structure of responsibilities, daily staffing
- Avg Calls per day
  - 50-70 per day most days
  - 150+ on busy days

Other

- Structure
- How many special projects going at any given time
- PI Projects
- Data Collection
- Billing
- Schedule
- HR, hiring and recruiting
- Collaboration with all programs and Depts (Quality, Selection, etc)

RN and OAS Responsibilities

OFFER MANAGEMENT

- Review/write up offer
- Present offer to physicians
- Code appropriately in UNOS
- Follow cases to outcome
- Communicate with OPO staff
- Liaison between OPO and transplant team

PATIENT MANAGEMENT

- Review chart for readiness
- Patient notification
- Case setup/patient admission
- Patient calls- Pre & Post
- Lab reviews
- ER referrals
- Re-melds, urgent listings, status updates, consent to eval, etc

OTHER PROJECTS

- Partner with waitlist teams
- Assist living donor team
  - Remove all living donor recipients from UNOS within 24 hours of transplant
  - Facilitate getting vessels from other transplant centers or OPO's as needed
- Eval Reviews
- Calling patients after-hours as needed

TRS Responsibilities

Case Setup

- Arranges transportation for recovery team(s) and on organ-only transports
- Communicates with OPO regarding donor OR needs
- Communicates with MDs for recovery and perfusion needs

Perfusion Services

- Provides perfusion services for heart, lung, liver teams
- NRP & OCS management, Paragonix
- Obtains all supplies for cases as needed, including PRBCs
- Handles communication between recovery team and transplanting surgeon intraoperatively (visual, XC, acceptance, etc)

Other

- Provides education to OPO's and donor hospitals on special cases (NRP, OCS)
- Facilitates donor OR arrangements on rushed cases or cases with unique challenges

Communication with In-House Teams

- Patient calls, Waitlist readiness, Case set-ups
- Waitlist meetings, Selection Committee, Organ offer review, ETCLC participation
- Epic charting and messaging
- Emails

Allocation Team Communication

Charting

- Housed in Microsoft Teams and Epic Phoenix
- Real time documentation of offers, patient calls, follow-ups, case setups, consent to evals, and ABO verifications
- Case set-up forms
- Recipient readiness checklists
- Reference folder with processes and workflows

Report

- Zoom meetings three times daily for report
- Additional meetings as needed throughout the day

Call Team Meetings

- Weekly conference calls
- Preceptor orientations and trainings
- Special Trainings
- Department specific, Selection Committee, and Quality meetings

Challenges

Logistical

- Transition from traditional model to Allocation Team
- Growth of organ offers during transition from traditional model to Allocation Team
- Staffing needs/Allocation team design
- Budgeting constraints
- Scheduling model-24 hour call vs 12 hour call

Clinical

- Training, hiring, and onboarding a brand-new department
- Development of processes and protocols for each program
- Charting, documentation and communication pathways needed to be developed

Cultural

- Change in culture from in-house coordinator to a separate off-site team
- Hospital administration, staff, and physician partnership
- 4 separate organ departments doing call 4 separate ways. Encouraging standardization where possible

Benefits of an Internal Allocation Team

- Own the process
- Offload work from office coordinators
- Can shape/develop as your institute sees fit → what works for one center, may not work for another
  - Specialize to different departments
  - Change as programs change and grow
  - Not everything needs to be a formal process
- 24/7 coverage for after hour projects → feast or famine
- Build relationships with OPO's and patients

The Future is…

UC San Diego Health

THANK YOU!

Organ Offers

&

STAFFING
CHALLENGES

Jennifer Kerney, ACNP
Director of Clinical Operations, Transplant Services

UCSF Health

Context

UCSF Transplant (CAMB & CASF):

- Adult: Heart, Lung, Liver, Kidney, and Pancreas
- Pediatric: Heart, Liver and Kidney
- Very large transplant center (750 tx in CY2022)
- Largest waitlist in the nation for kidney transplant
- Like most transplant centers, we are incurring increased costs associated with transplants (transportation and perfusion) and our organization is facing financial strain post-COVID.
  - Shrinking margins on transplant profits
  - Organization-wide hiring freezes
- Offset the increased costs and shrinking margins → increase volume

Transplants Performed – Growth over Time

2018-2022

	Transplant Volumes					
	2018	2019	2020	2021	2022	
Kidney	368	377	361	389	391	
K/P & Pancreas	14	16	11	14	16	
Liver	160	164	169	161	193	21% increase
Heart	14	24	17	26	47	236% increase
Lung	54	66	80	74	77	43% increase
Kidney (Peds)	12	10	14	12	15	
Liver (Peds)	11	10	7	5	10	
Heart (Peds)	1	3	6	2	1	
total	634	670	665	683	750	18.3% increase

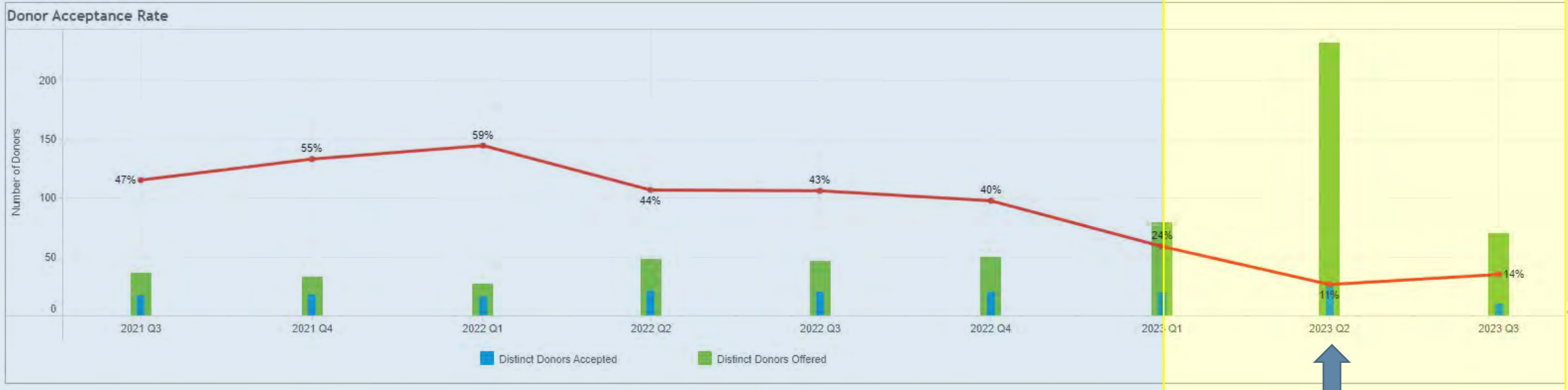
OPTN Center Data optn.transplant.hrsa.gov

UCSF Health

Increase in Organ Offers – Lung Continuous Distribution

Organs that were ultimately accepted and transplanted

Continuous Distribution
March 2023



Prior to Continuous Distribution ~ <50 offers/quarter

Continuous Distribution
232 offers/quarter

UNOS CARE REPORT data as of 8.9.2023

Increase in Organ Offers – Lung Continuous Distribution

All offers, including those never accepted and not transplanted

Continuous Distribution
March 2023

Prior to Continuous Distribution ~ <50 offers/quarter

Continuous Distribution
232 offers/quarter

UNOS CARE REPORT data as of 8.9.2023

Increase in Organ Offers

2021-2022 v 2022–2023

	2021-2022 UNIQUE DONORS				
	Q3 2021	Q4 2021	Q1 2022	Q2 2022	TOTAL
Kidney	118	159	174	161	**612**
K/P & Pancreas	5	9	14	9	**37**
Liver	114	156	165	162	**597**
Heart	29	42	25	30	**126**
Lung	36	33	27	48	**144**

	2021-2022 ACCEPTED OFFERS				
	Q3 2021	Q4 2021	Q1 2022	Q2 2022	TOTAL
Kidney	34	48	56	38	**176**
K/P & Pancreas	0	2	5	3	**10**
Liver	26	37	33	59	**155**
Heart	7	5	6	11	**29**
Lung	17	18	16	21	**72**

	2022-2023 UNIQUE DONORS					
	Q3 2022	Q4 2022	Q1 2023	Q2 2023	TOTAL	
Kidney	192	205	194	188	**779**	**27.3%** ↑
K/P & Pancreas	16	5	7	8	**36**	**2.7%** ↓
Liver	152	178	191	210	**731**	**22.4%** ↑
Heart	40	82	75	83	**280**	**122.2%** ↑
Lung	46	50	79	232	**407**	**182.6%** ↑

	2022-2023 ACCEPTED OFFERS					
	Q3 2022	Q4 2022	Q1 2023	Q2 2023	TOTAL	
Kidney	56	63	70	44	**233**	**32.3%** ↑
K/P & Pancreas	5	3	2	4	**14**	**40.0%** ↑
Liver	33	40	42	45	**160**	**3.2%** ↑
Heart	13	20	21	21	**75**	**158.6%** ↑
Lung	20	20	19	25	**84**	**16.7%** ↑

UCSF Health

UNOS CARE REPORT data as of 8.9.2023

Transplants Performed

2021-2022 v 2022–2023

2021-2022 TRANSPLANTS PERFORMED	2021 Q3	2021 Q4	2022 Q1	2022 Q2	TOTAL
Kidney	94	101	101	95	**391**
K/P & Pancreas	1	2	5	3	**11**
Liver	47	43	44	68	**202**
Heart	9	5	6	11	**31**
Lung	20	18	16	22	**76**

2022-2023 TRANSPLANTS PERFORMED	2022 Q3	2022 Q4	2023 Q1	2023 Q2	TOTAL	
Kidney	102	108	122	82	**414**	**5.8%** ↑
K/P & Pancreas	5	3	2	4	**14**	**27.3%** ↑
Liver	41	60	51	57	**209**	**3.5%** ↑
Heart	13	19	22	21	**75**	**141.9%** ↑
Lung	19	20	19	25	**83**	**9.20%** ↑

UNOS CARE REPORT data as of 8.9.2023

Staffing Resources – On-Call Organ Offers

	ON CALL STAFFING
Kidney	UCSF Transplant Coordinators (67% of the month), Outside Vendor #1 (33% of the month)
K/P & Pancreas	UCSF Transplant Coordinators (67% of the month), Outside Vendor #1 (33% of the month)
Liver	Surgeons mainly, supported by UCSF Transplant Coordinators and Vendor#1 as needed
Heart	Outside Vendor #2 (100%)
Lung	Outside Vendor #2 (100%)

No one takes organ offers for ALL of our organ groups

UCSF Health

Staffing Resources – On-Call Organ Offers

	ON CALL STAFFING
Kidney	UCSF tx coordinators take call as OT (n=5)
K/P & Pancreas	Vendor #1 coordinators dedicated to UCSF (n=5)
Liver	Surgeons mainly, supported by kidney coordinator as needed
Heart	Vendor #2 coordinators dedicated to UCSF (n=3)
Lung	

	VERY BUSY SHIFTS
Kidney	Vendor#1 has a scheduled back-up to support primary Vendor coordinator on busy days
K/P & Pancreas	
Liver	Surgeon may defer logistics calls to Kidney on-call coordinator
Heart	Vendor #2 may pull in their SVR to support primary coordinator on busy days
Lung	

Staffing Resources – Pre- and Post- Transplant RN/APP Teams

LVN/RN/APP Coordinator Staffing	Triage/Evaluation	Waitlist	Living Donor	Inpatient APPs	Post APPs	Post RNs	Pediatric APPs	Pediatric RNs
Kidney	6	9	8	6*	4	5	2	-
Kidney/Panc	1	2	n/a		1	-		-
Liver	7		2	4**	6	1	1	1
Heart	2		n/a		1	3	1	1
Lung	3		n/a	8***	-	5	n/a	n/a

* 6 nights & 7 days/week APP coverage
** 7 days/week daytime APP coverage
*** 24/7 365 APP coverage

UCSF Health

Strategies employed to mitigate organ offer volumes

Filters

- UNOS Kidney Offer Filters
- Local OPOs - internal filters

UCSF Health

Liver Machine Perfusion and DCD Liver Utilization

Jessica Streeter
Clinical Operations Manager
jstreeter@dnwest.org

DONOR NETWORK WEST
Heal a life through organ and tissue donation

Today's Topics

- Machine perfusion at DNW
- Liver utilization pre/post OCS
- Learning points

OCS Machine Perfusion @ DNW

Aug 2021

- DNW screened all LUNG donors for potential TransMedics OCS

March 2022

- DNW screened all LIVER and LUNG donors for potential TransMedics OCS

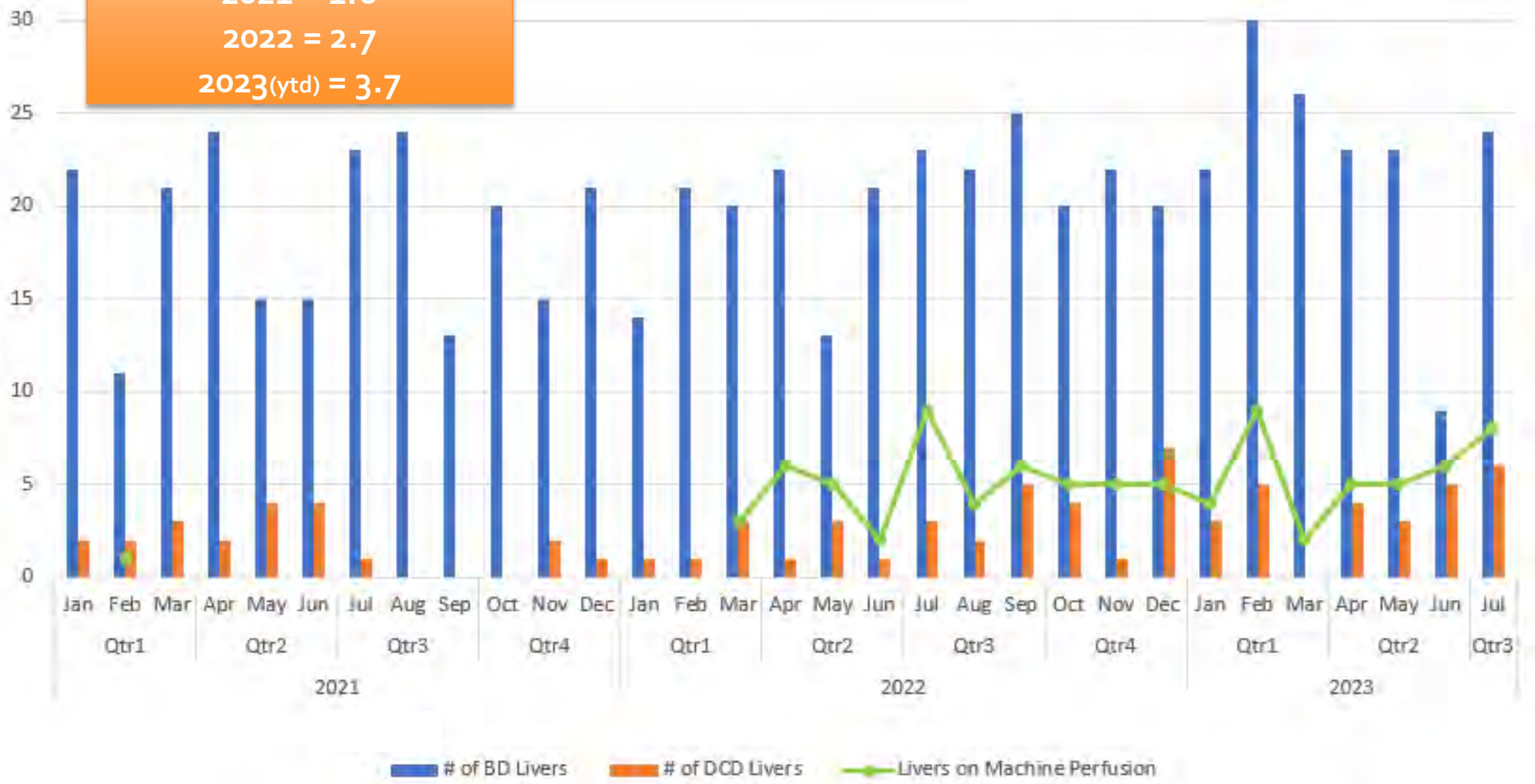
Oct 2022

- OCS for HEART, LUNG, LIVER based on Tx Ctr request

Liver Donors by Month

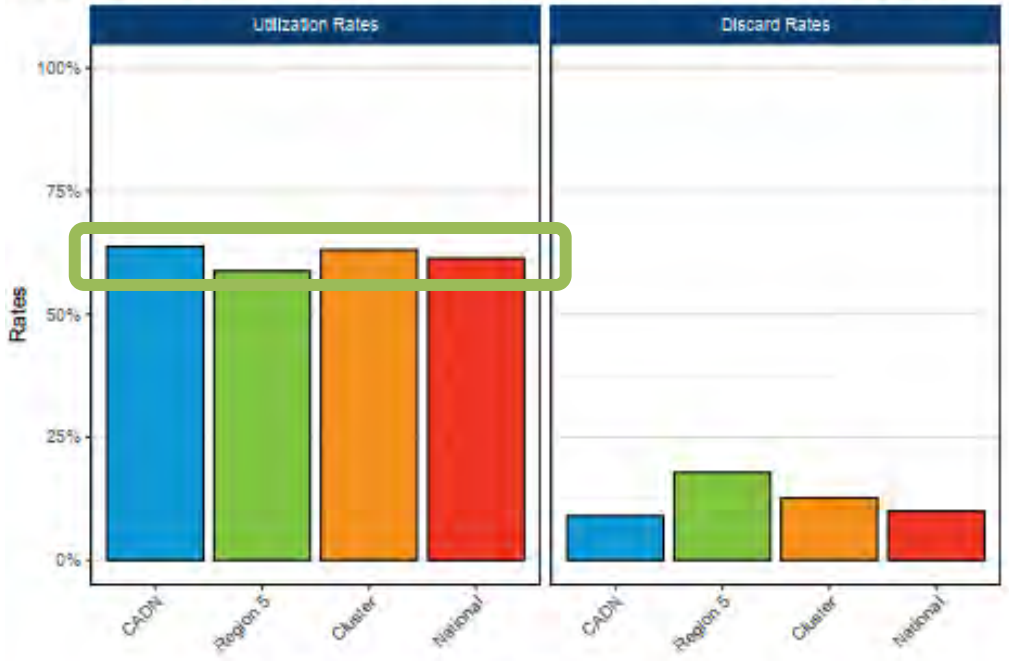
(Jan 2021-Jul 2023)

Avg # DCD livers/month
2021 = 1.6
2022 = 2.7
2023(ytd) = 3.7



Liver Performance Benchmarking

Figure 7. Liver Utilization and Discard Rates Between May 1, 2021 and April 30, 2022

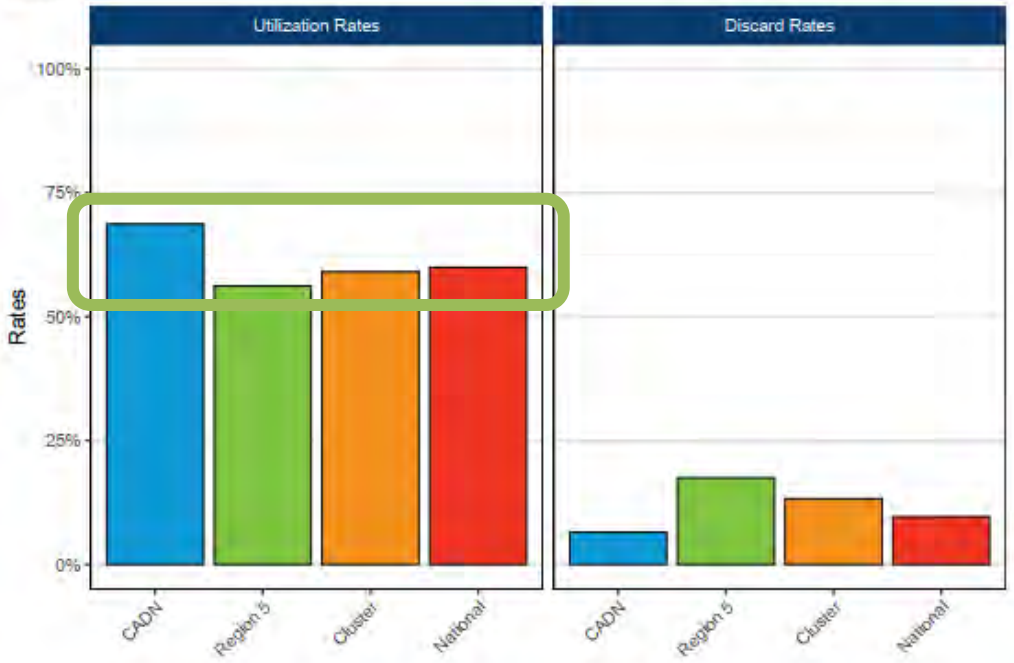


Liver Utilization and Discard Rates (%)

Rate	CADN	Region 5	Cluster	National
Utilization Rates	63.73%	58.80%	63.08%	61.33%
Discard Rates	9.02%	17.84%	12.68%	9.98%

Pre-OCS

Figure 7. Liver Utilization and Discard Rates Between April 1, 2022 and March 31, 2023

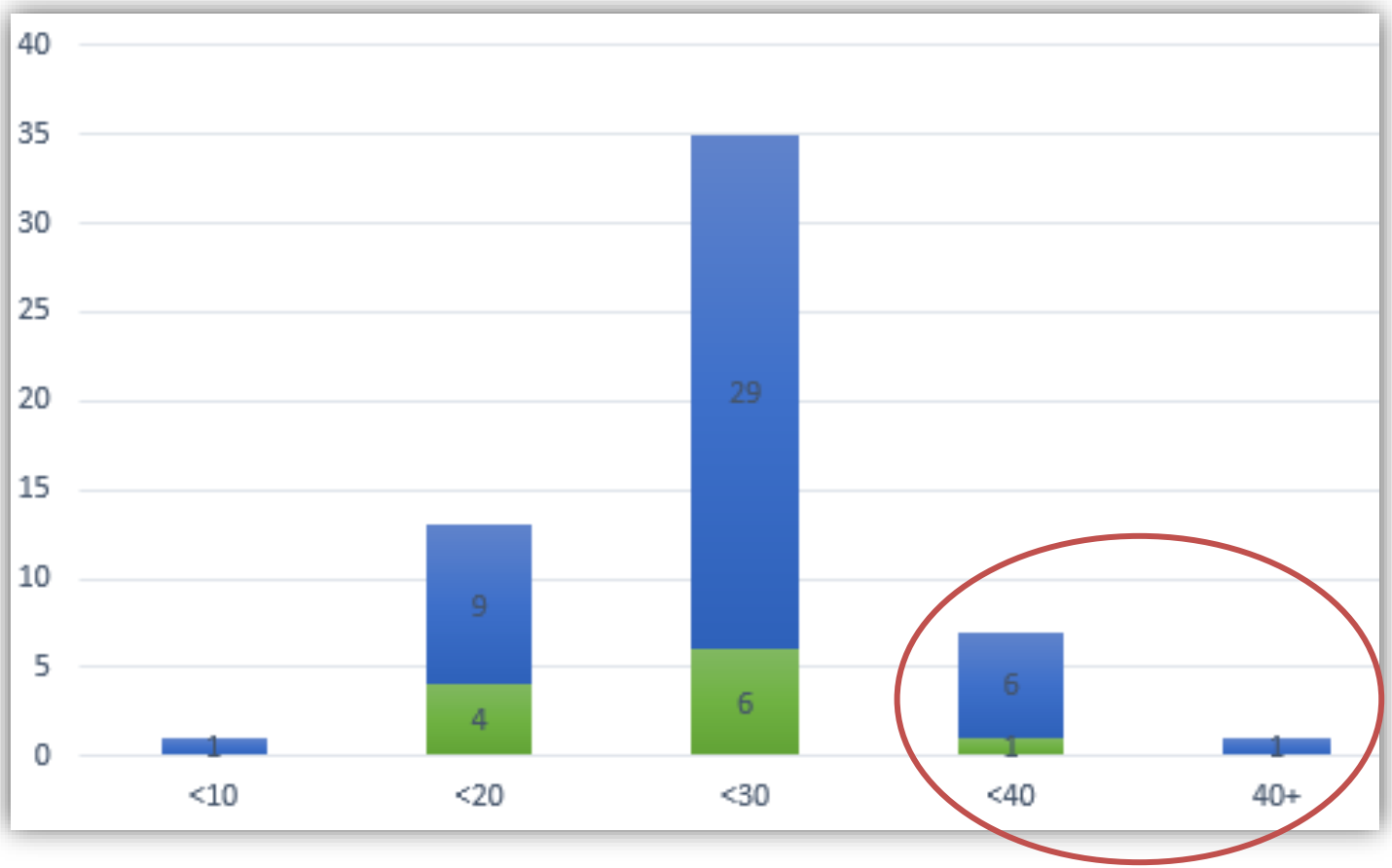


Liver Utilization and Discard Rates (%)

Rate	CADN	Region 5	Cluster	National
Utilization Rates	68.68%	56.19%	59.04%	59.94%
Discard Rates	6.50%	17.46%	13.27%	9.64%

Post-OCS

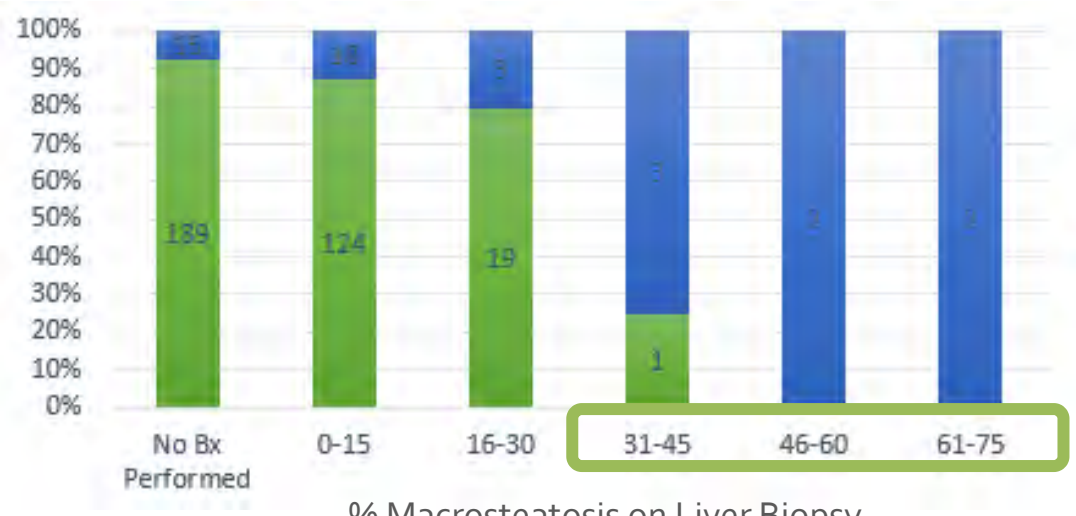
WIT and Machine Perfusion



WIT data from DNW donors March 2022-July 2023

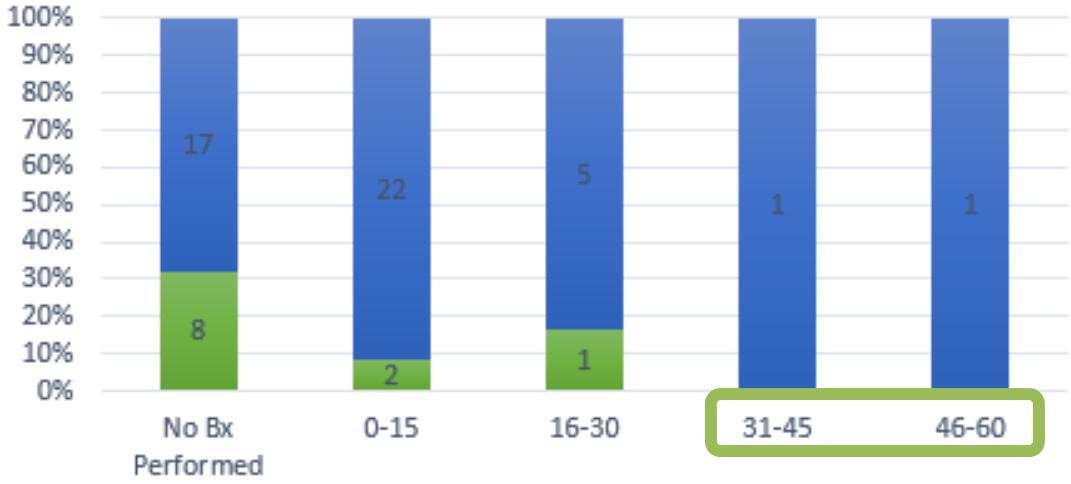
Liver Biopsy and Machine Perfusion

Brain Dead Donors



% Macrosteatosis on Liver Biopsy

DCD Donors



% Macrosteatosis on Liver Biopsy

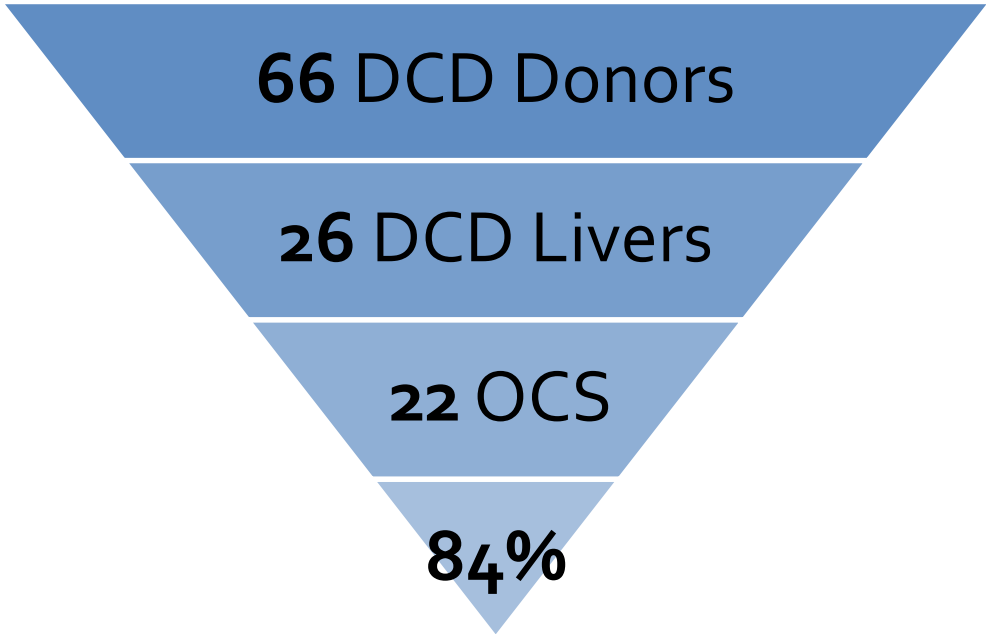
Biopsy data from DNW donors March 2022-July 2023

DNW Liver Utilization

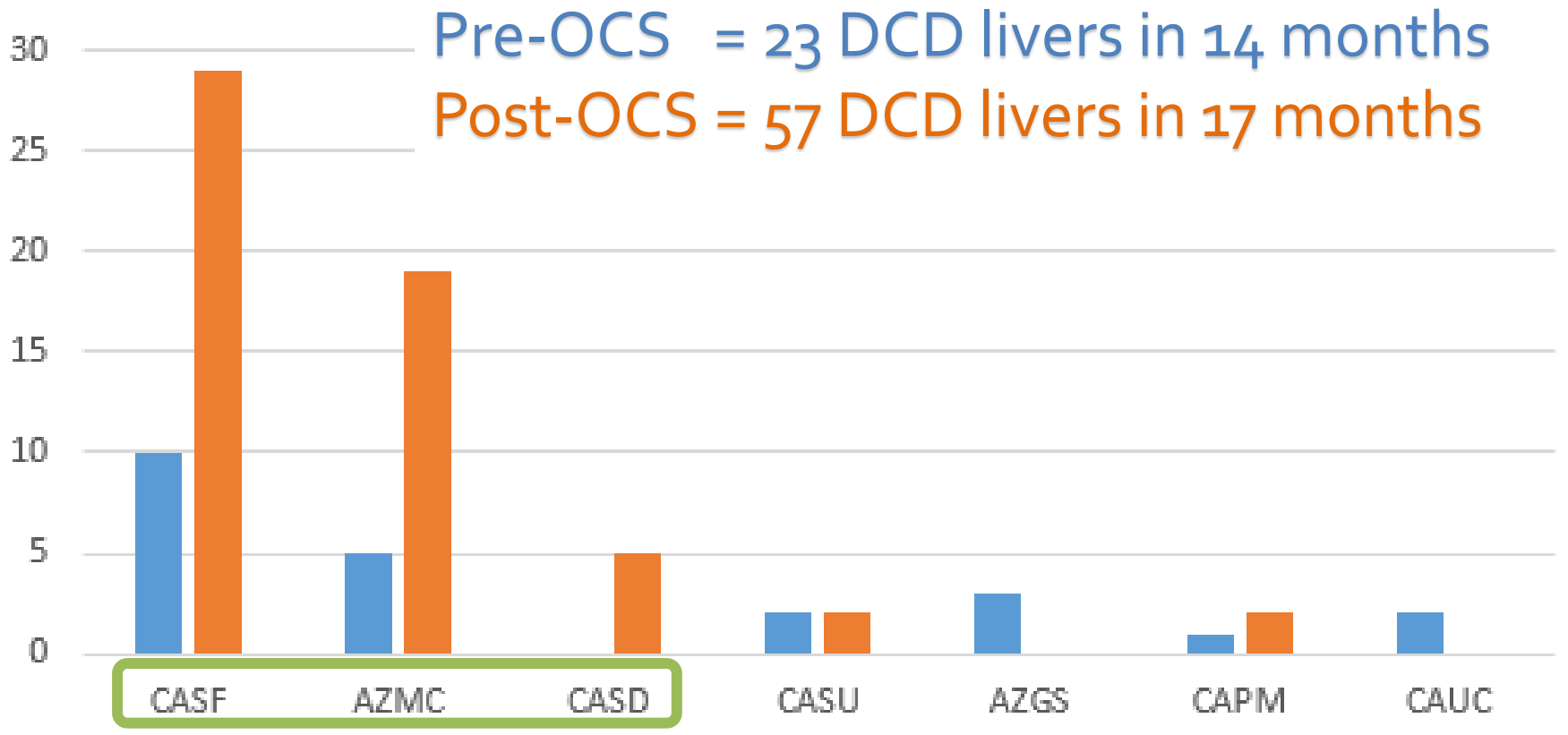
2023 Jan-Jul

Liver	%	#	SPLY	Var	Var %
Transplanted	67.8%	187	150	37	24.7%
Discarded	2.5%	7	8	-1	-12.5%
Aborted	5.8%	16	10	6	60.0%
Not Placed	15.6%	43	28	15	53.6%
Ruled Out	8.3%	23	33	-10	-30.3%
Total	100.0%	276	229	47	20.5%

Local	Non-Local	PSYL Local	SPLY Non-Local
112	75	102	48
60%	40%	68%	32%



DCD Liver Allocation Pre/Post OCS

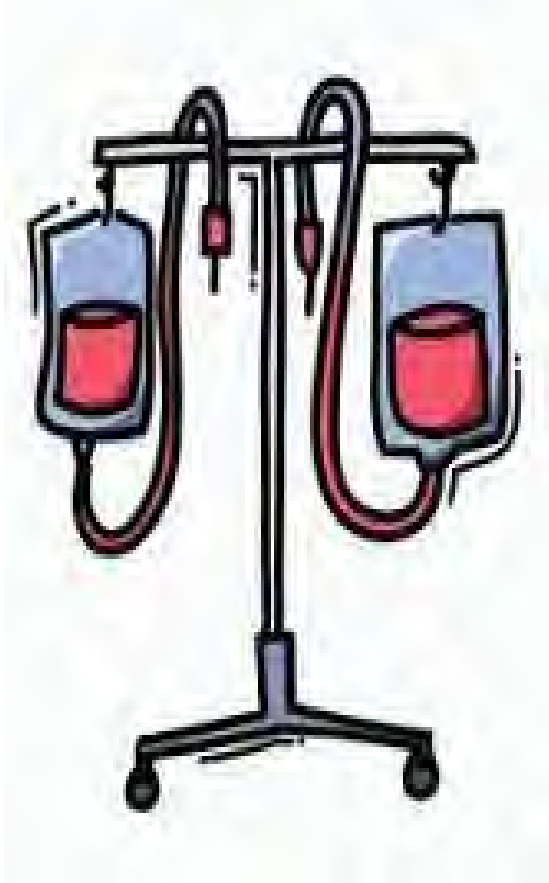


DCD Livers transplanted from DNW donors Jan 2021-July 2023

Challenges and Learning Points

- **Logistics**
  - Scheduling
  - Transportation
  - Kidney/Panc recovery

- **PRBCs**
  - Who provides?
  - Avoid waste



Thank You

DONOR NETWORK WEST

DCD Liver Utilization and Machine Perfusion: Acceptance Practices and Outcomes

Steven Wisel, MD

Assistant Professor, Cedars-Sinai Comprehensive Transplant Center

August 23, 2023

Cedars Sinai

Disclosures

I have no relevant disclosures or financial interests related to the information presented in this talk.

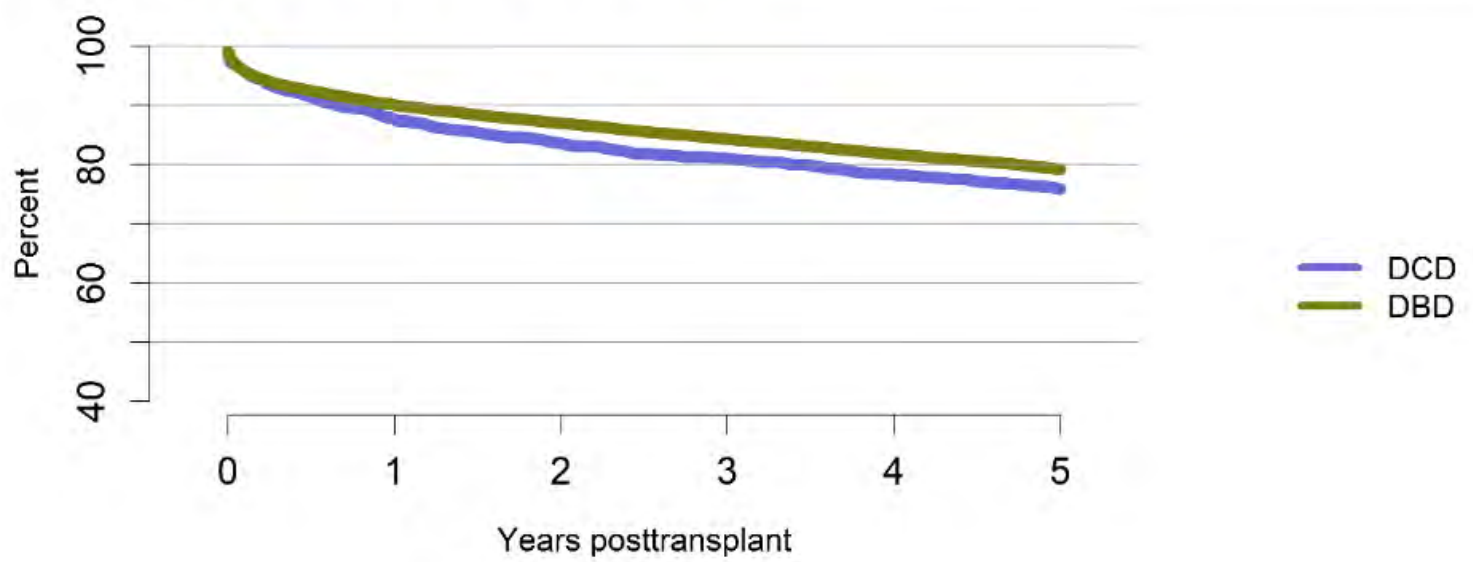
The Cedars-Sinai Experience: Implementing DCD and NMP

- As of 2022, no DCD liver transplant or machine perfusion at Cedars-Sinai
- Rationale for undertaking DCD and machine perfusion simultaneously
- Since March 2023, 9 NMP livers including 3 DCD
- Establishing a program: choosing a machine perfusion strategy, acceptance criteria, procurement logistics, programmatic philosophy
- Financial implications

The Goal is Growth

Utilization of DCD and marginal liver allografts for transplantation represents the largest capacity to increase transplant volume

Figure LI 69: Graft survival among adult deceased donor liver transplant recipients, 2014-2016, by DCD status



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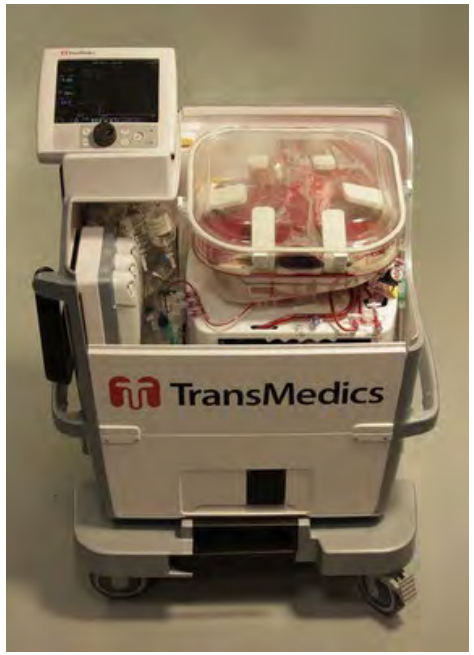
[1]Kwong AJ, Ebel NH, Kim WR, et. al. OPTN/SRTR 2021 Annual Data Report: Liver. Am J Transplant. 2023 Feb; 23(2 Suppl 1): S178-S263. doi: 10.1015/j.ajt.2023.02.006

Challenges of DCD and Marginal Liver Donors

- **Ischemic cholangiopathy**
  - Non-anastomotic structuring of the extra- and intra-hepatic biliary tree
  - Associated with warm (fWIT >30 mins) and cold (CIT >12h) ischemia
  - 10% of DCD liver transplants, with 50% (5% overall) requiring re-txp
- **Reperfusion syndrome**
  - Combination of cold fluid, potassium-rich electrolytes, and accumulated inflammatory cytokines leading to clinical instability upon completion of liver sew-in

Hypothermic (HMP) versus Normothermic (NMP) Machine Perfusion

OrganOx Metra Normothermicic perfusion



TransMedics Normothermic perfusion

LifePort Liver Transporter Hypothermic perfusion

Liver Assist Normothermic and Hypothermic perfusion

Hypothermic (HMP) versus Normothermic (NMP) Machine Perfusion

Normothermic Machine Perfusion (NMP)

- Livers are perfused at normal body temperatures (34-37C) with **blood**
- Livers are **metabolically active** allowing **viability testing**
- Mitigates reperfusion injury – allows for washout of cytokines and inflammatory markers

Hypothermic Machine Perfusion (HMP) / Hypothermic Oxygenated Machine Perfusion (HOPE)

- Perfusion at 8-12C with **perfusate alone** or **blood-based solution**
- Hypothermic temperatures reduce metabolic activity, allowing delivered oxygen to reset the electron transport chain with little metabolic demand
- Improves mitochondrial health
- Reduces reperfusion injury

ORIGINAL ARTICLE

Hypothermic Machine Perfusion in Liver Transplantation — A Randomized Trial

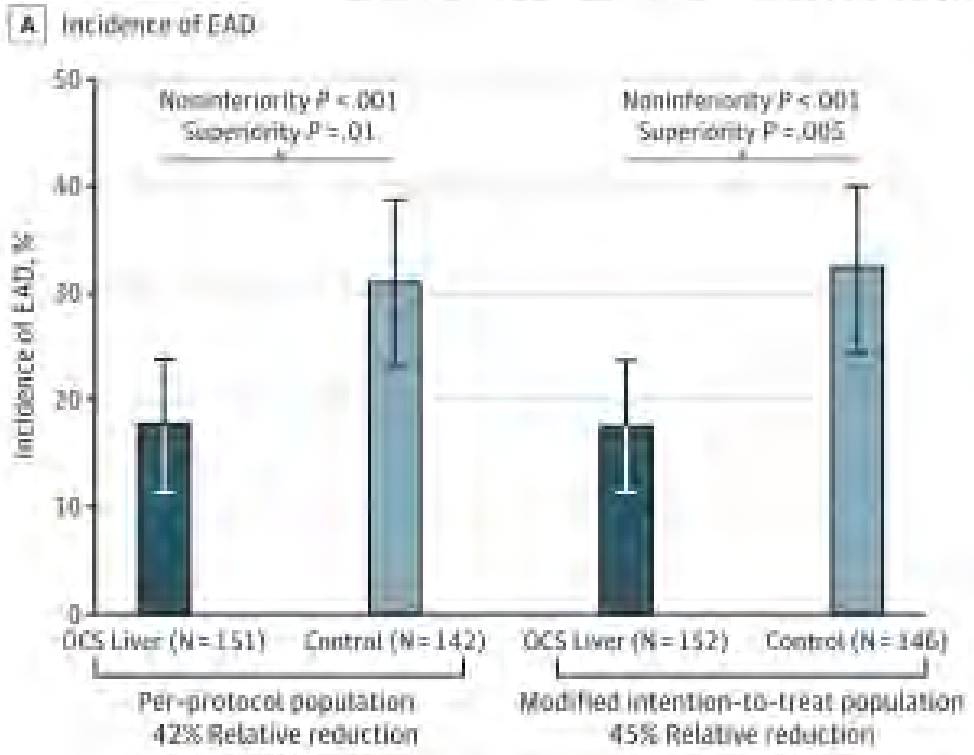
Rianne van Rijn, M.D., Ph.D., Ivo J. Schurink, B.Sc., Yvonne de Vries, M.D., Ph.D., Aad P. van den Berg, M.D., Ph.D., Miriam Cortes Cerisuelo, M.D., Ph.D., Sarwa Darwish Murad, M.D., Ph.D., Joris I. Erdmann, M.D, Ph.D., Nicholas Gilbo, M.D., Ph.D., Robbert J. de Haas, M.D., Ph.D., Nigel Heaton, M.D., Ph.D., Bart van Hoek, M.D., Ph.D., Volkert A.L. Huurman, M.D., Ph.D., et al., for the DHOPE-DCD Trial Investigators*

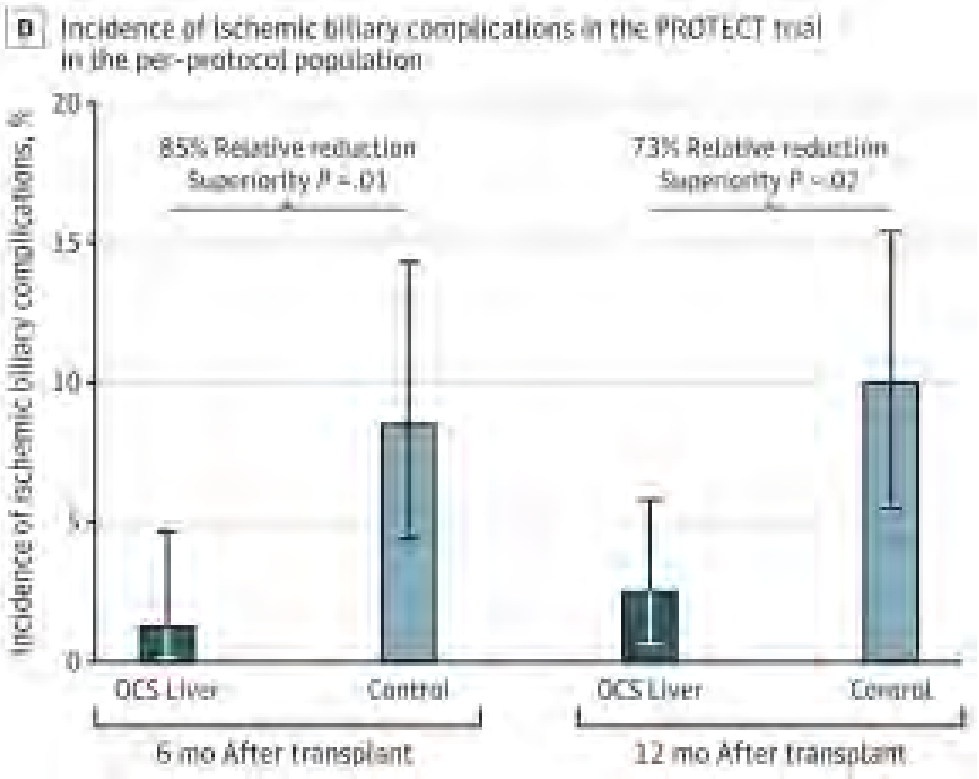
Outcome	Machine Perfusion (N=78)	Control (N=78)	Treatment Effect (95% CI)	P Value
Primary end point†				
Nonanastomotic biliary strictures — no. (%)	5 (6)	14 (18)		0.03
Unadjusted risk ratio			0.36 (0.14 to 0.94)	0.03
Adjusted risk ratio			0.35 (0.14 to 0.92)	0.03
Secondary end points				
Postreperfusion syndrome				
>30% decrease in systemic mean arterial pressure — no./total no. (%)	9/72 (12)	19/70 (27)	0.43 (0.20 to 0.91)‡	
>30% decrease in systemic mean arterial pressure or ≥100% increase in norepinephrine dose — no./total no. (%)	20/72 (28)	33/72 (46)	0.59 (0.38 to 0.92)‡	
Serum potassium after reperfusion — mmol/liter§	4.1±0.7	4.4±1.1	−0.4 (−0.1 to −0.6)	

JAMA Surgery | Original Investigation

Impact of Portable Normothermic Blood-Based Machine Perfusion on Outcomes of Liver Transplant
The OCS Liver PROTECT Randomized Clinical Trial

James F. Markmann, MD, PhD; Marwan S. Abouljoud, MD, PhD; R. Mark Ghobrial, MD, PhD; Chandra S. Bhati, MD; Shawn J. Pelletier, MD; Amy D. Lu, MD; Shane Ottmann, MD; Tarunjeet Klair, MD; Corey Eymard, MD; Garrett R. Roll, MD; Joseph Magliocca, MD; Timothy L. Pruett, MD; Jorge Reyes, MD; Sylvester M. Black, MD; Christopher L. Marsh, MD; Gabriel Schnickel, MD; Milan Kinkhabwala, MD; Sander S. Florman, MD; Shaheed Merani, MD; Anthony J. Demetris, MD; Shoko Kimura, MD, PhD; Michael Rizzari, MD; Ashish Saharia, MD; Marlon Levy, MD; Avinash Agarwal, MD; Francisco G. Cigarroa, MD; James D. Eason, MD; Shareef Syed, MD; W. Kenneth Washburn, MD; Justin Parekh, MD; Jang Moon, MD; Alexander Maskin, MD; Heidi Yeh, MD; Parsia A. Vagefi, MD; Malcolm P. MacConmara, MD





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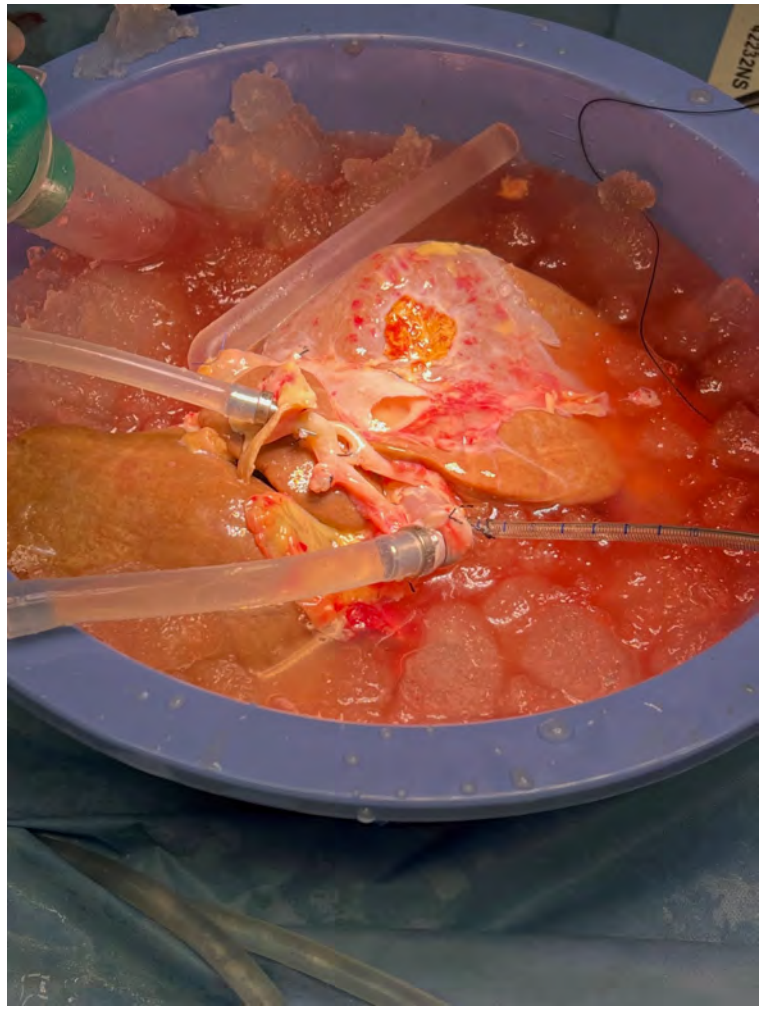
Logistics – Choosing your technology

- **Selection of machine perfusion strategy – NMP versus HMP**
  - NMP resources must be transported to procurement
  - HMP allows “back to base” strategy
  - Availability of in-house resources, capital investment in machine perfusion device, outsourcing of organ monitoring and maintenance

Logistics – Transmedics Surgeon Training



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Logistics

- **Selection of machine perfusion strategy – NMP versus HMP**
- **Peri-transplant coordination – minimum 3-4 hours lead time is essential!**
  - Perfusionist/technologist
  - Pump, disposables, Rx/additives
  - Blood (4-6 units PRBC)
  - Donor surgeon
- **Donor/recipient-specific indication to use machine perfusion**

When to use?

- DCD donors
- Marginal donors (steatosis, elevated LFTs, donor age)
- Assessment of liver quality
- Redo liver transplant
- Predicted long cold ischemia time (long-distance transport, prior abdominal surgery, expedited OR, delay in patient arrival to hospital)

When not to use?

UCSF University of California San Francisco

UCSF Clinical Trials

OCS Liver Perfusion (OLP) Post-Approval Registry

PI: Garrett R. Roll, MD, FACS

a study on Liver Transplant

DETAILS

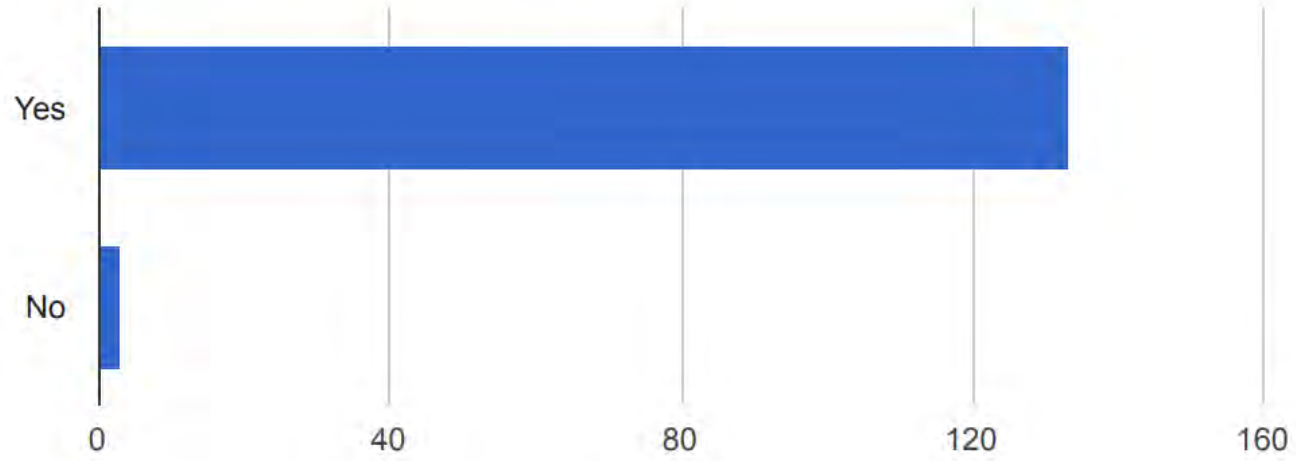
OLP Registry is a multi-center, observational post-approval registry of adult primary liver transplant recipients who are transplanted with an OCS Liver-perfused DBD or DCD donor liver according to the approved indication and that match the eligibility criteria below.

Who performed the procurement?

Counts/frequency: Recipient center's normothermic perfusion trained team (59, 43.4%), National normothermic perfusion team (76, 55.9%), Other (1, 0.7%)

Was the perfused liver transplanted?

Counts/frequency: Yes (133, 97.8%), No (3, 2.2%)



Cost Implications

- **Maximal reward for all parties when total transplant volume increases: more patients transplanted increases overall revenue**
- **Cost of machine perfusion is added to organ acquisition fees as part of Medicare Cost Report**
- **Costs associated with “dry runs” where no transplant takes place are a programmatic expense**
- **Pricing model informs clinical decision to employ machine perfusion**

Cedars-Sinai Comprehensive Transplant Center

Surgeons:
- Todd Brennan, MD
- Irene Kim, MD
- Kambiz Kosari, MD
- Nicholas Nissen, MD
- Justin Steggerda, MD
- Tsuyoshi Todo, MD
- Georgios Voidonikolas, MD

Hepatologists:
- Alex Kuo, MD
- Walid Ayoub, MD
- JuDong Yang, MD
- Hirsh Trivedi, MD
- Aarshi Vipani, MD

Cedars-Sinai Residents and Fellows

Inpatient Team:
- Leslie Hartman, PA
- Yoonah Lee, PA

Anesthesia:
- Jen Cutler, MD
- Darren Filsinger, MD
- Avner Gerberoff, MD
- Wesley Glick, MD
- Hooman Golfeiz, MD
- Robert Kariger, MD
- Kevin Maghami, MD
- Ahmed Shalabi, MD
- Darab Zarrabi, MD

Nursing Team:
- Carmen Saunders, NP
- Vesna Grubic, NP
- Loren Carino, NP

CTC Leadership

Questions?

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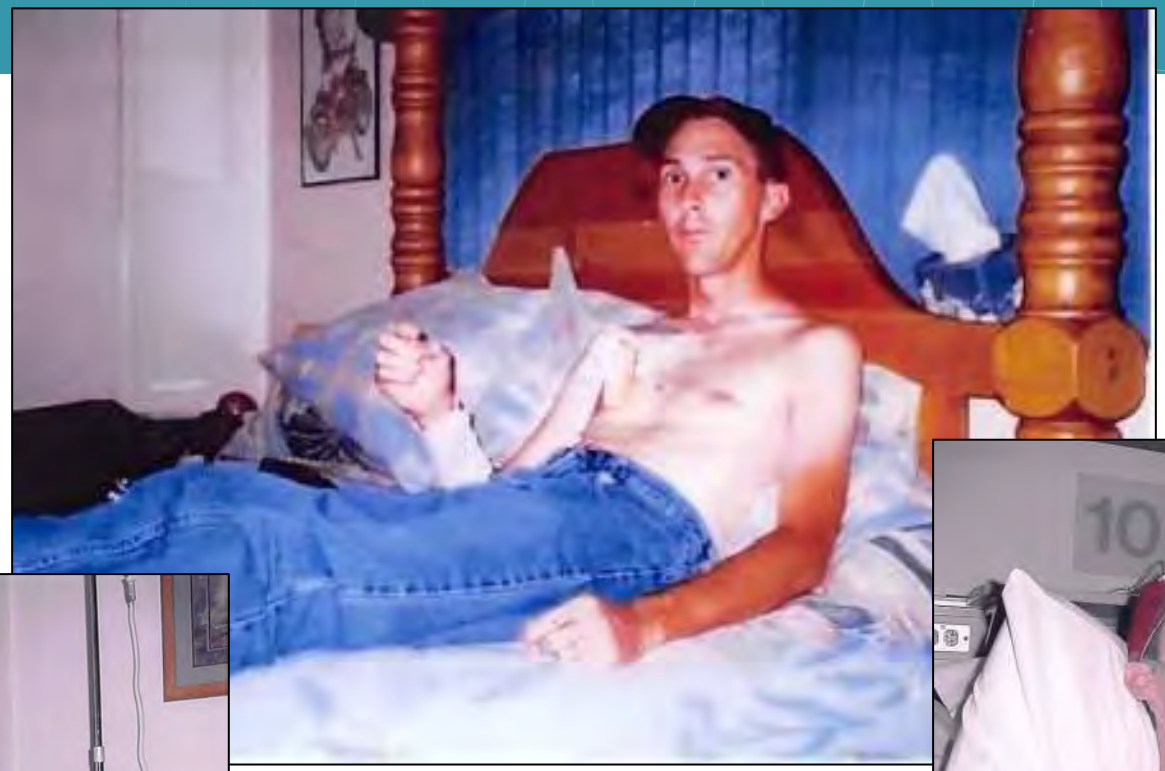
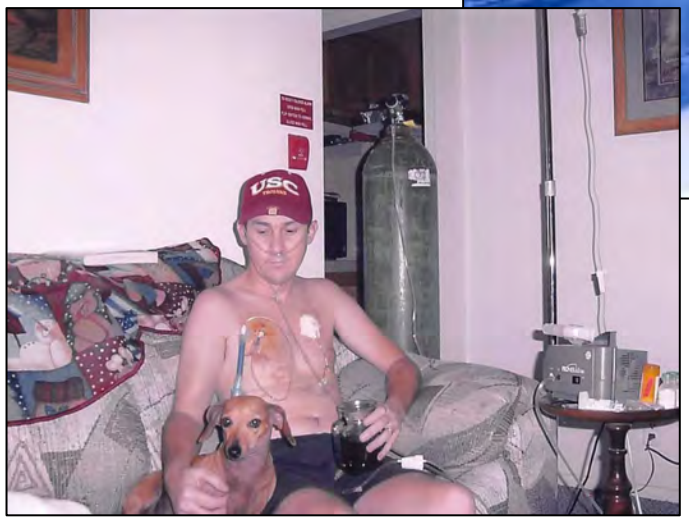
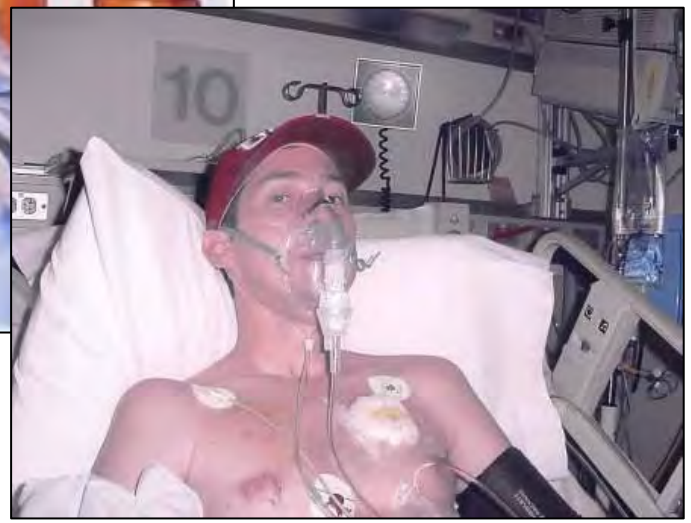
Michael Adams

Lifesharing Volunteer

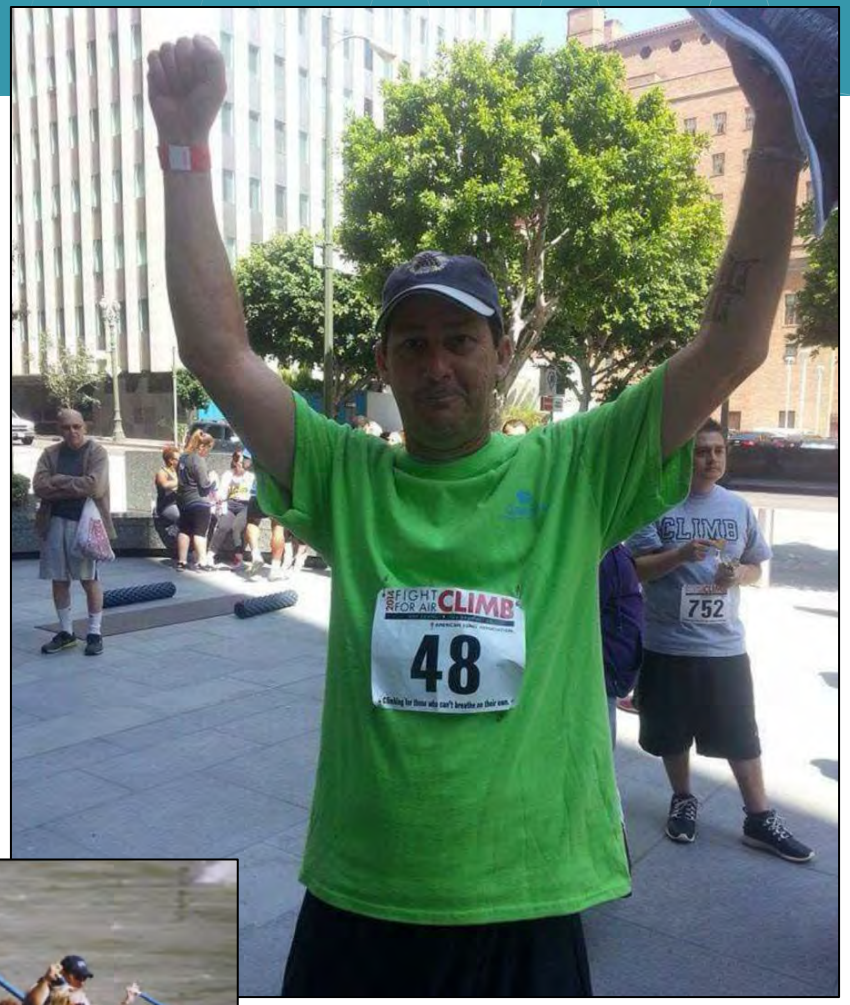
Life with Cystic Fibrosis







My Personal Experience....



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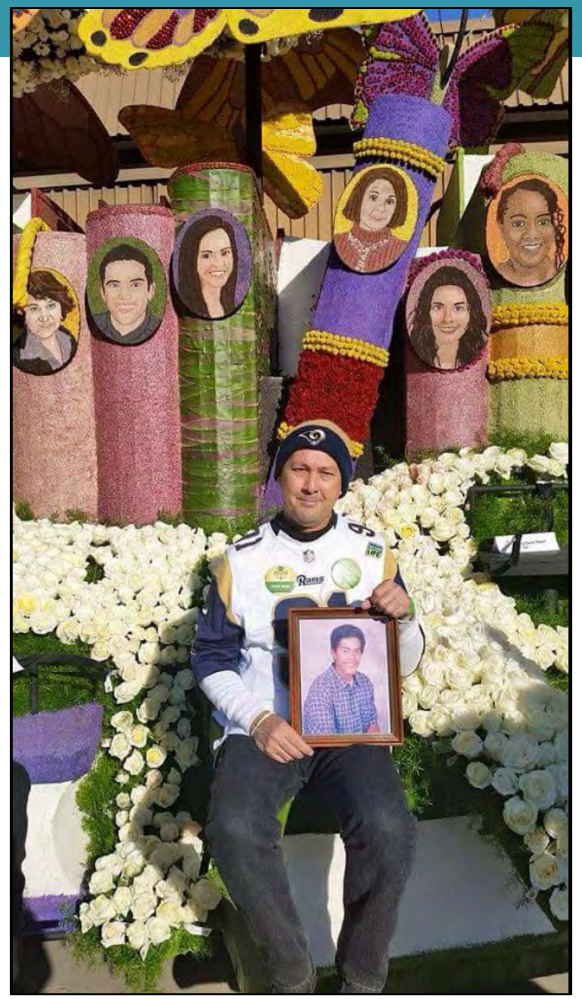
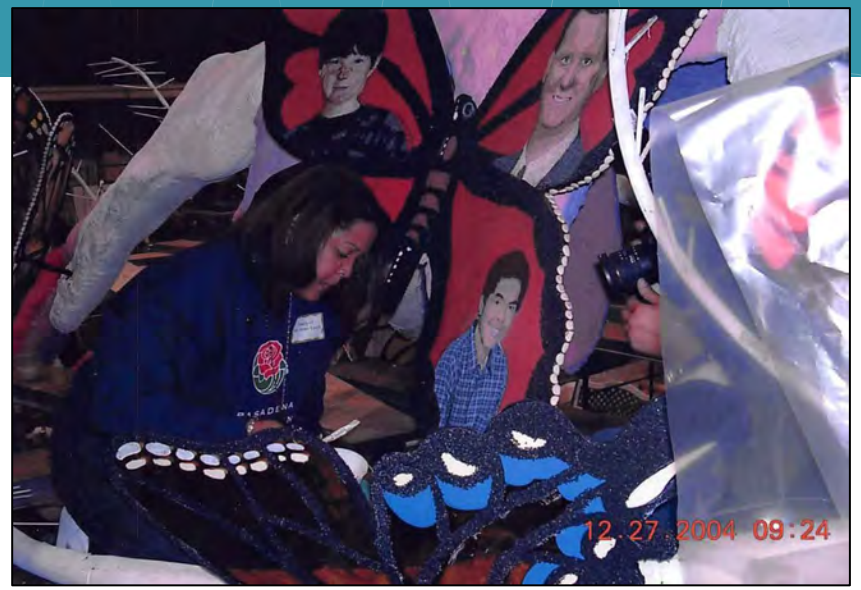
TORY HOWE

Donor Hero

Life after transplant





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- Considered for mini-oral presentation, poster presentation and award

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- Considered for poster presentation and award only

Visit https://unos.org/about/tmf/abstracts/ for more information.

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