

S U M M E R 2 0 2 2

# UNOS Region 5 Educational Collaborative

The Mirage, Las Vegas, NV • August 24, 2022 • 8:00 am–5:30 pm

*Reception to follow – 5:30 pm–6:30 pm*



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# UNOS Region 5 Collaborative

## UCI Irvine COVID-19 Updates



Uttam G. Reddy, MD

Medical Director

UC Irvine Kidney-Pancreas Transplant Program

August 24<sup>th</sup>, 2022

# COVID-19 Updates

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- Vaccination Policy
- Monoclonal Ab use
- COVID+ donors
- Paxlovid Cautionary Tale

# Is Vaccination Mandatory at Your Center?

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- At UCI, vaccination is NOT mandatory for transplant
  - Highly recommended and encouraged amongst our waitlisted and pre transplant patients
  - High percentage of lower socioeconomic patients

# Vaccine Refusal

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- Rising rates of vaccine refusal has challenged transplant centers
  - Do transplant centers deny organ transplant on the basis of vaccine refusal?
    - YES? Based on scarce resource, stewardship and beneficence
    - NO? Justice and respect for persons. Avoid health care disparities or medical coercion



# Argument against Forced Vaccination

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- Not against vaccines, just against denying candidates on the basis of it
- Crosses a moral boundary
- Concerns regarding justice, autonomy, freedom of choice
- Initial differences in transplant outcomes between vaccinated and unvaccinated recipients did not include treatments such as mAb, Evusheld, etc
  - Vaccinated patients are also still dying

# Opposing Vaccine Mandates in Transplant

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- From the individual transplant patient, even if unvaccinated, transplant clearly remains in the patients best interest.
- Immediate, certain and potentially severe harm in denying an organ transplant worse than the downstream possibility of complications due to a vaccine preventable illness.
- What about patients who have medical contraindication?



# Transplant Disparities and Vaccination

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- Vaccine refusal differs by racial, ethnic and socioeconomic, education or religious groups.
- Vaccine hesitancy exists in white and well educated
- Vaccine hesitancy is more common among African Americans
  - Past instances against AA as source of ongoing fear and mistrust of medical system <sup>1</sup>
  - Denial of transplantation can exacerbate trans-generational traumas and worsen already documented inequities in transplantation.

<sup>1</sup> Quinn S, et al. PLoS Curr 2016

# Worsening Disparities

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- Risk of magnifying existing disparities in transplantation by disproportionately affecting people of color, immigrants, and non English language speakers, patients with less education, or minority groups <sup>1</sup>
- We have been able to convince the majority of our unvaccinated patients to get vaccinated after transplant. Building trust with each clinical encounter.

<sup>1</sup> Gilkey MB, et al. Hum Vaccin Immunother, 2017

# Monoclonal Ab Use - >10 days symptoms

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- REGEN-COV Casirivimab + Imdevimab
  - Bamlanivimab (Delta)
  - Sotrivimab (Omicron)
  - Bebtelovimab (BA.2 subvariant)
- 
- Close to 100 doses of mAb given to Transplant Patients at UCI. Zero deaths.



# Improved Mortality in COVID-19 Kidney Transplant Recipients Treated with Bamlanivimab

Anum Hamiduzzaman, MD, Uttam Reddy, MD  
Division of Nephrology Hypertension and Kidney Transplantation  
University of California, Irvine

UCI Health

## Background

Transplant recipients are particularly vulnerable to catastrophic sequelae of COVID-19. In an early multi-center study from 2020 that followed 482 solid organ transplant (SOT) recipients with COVID-19, the authors reported a large percentage of hospitalizations (78%), mechanical ventilation (31%), and death (20.5%) during a 28 day window. Despite mortality reduction following the vaccine, COVID remains a high mortality risk in this patient population. Bamlanivimab is a recombinant neutralizing human IgG1 monoclonal antibody (mAb) directed against the spike protein of SARS-Cov-2.

## Purpose

We sought to identify interventions which could mitigate the mortality risk of COVID-19 by evaluating patient outcomes when early disease diagnosis was paired with bamlanivimab therapy.

## Methods

In a single center cohort of 147 kidney transplant recipients who tested positive for COVID during a 12 month period from March 2020 to March 2021, 41 eligible patients received IV bamlanivimab therapy. Eligible patients had symptoms <7 days and did not require supplemental oxygen at the time of bamlanivimab therapy. Eligible patients were identified by the on-call transplant team who arranged for both expedient COVID testing and bamlanivimab infusions. Patients in the exclusion group include patients diagnosed with COVID before bamlanivimab was available. None of the patients in our cohort received the COVID vaccine as this predated widespread vaccination efforts.

## Results

Of 41 patients who received IV bamlanivimab therapy, zero deaths were observed and only four hospitalizations. Two patients required ventilatory support but were eventually successfully extubated. In contrast, of the 106 patients who did not receive bamlanivimab the mortality rate was 15 deaths (14%).

In the total cohort of 147 kidney transplant patients, 68 patients required hospitalization (47%) though the bamlanivimab cohort accounted for less than 3% of total hospitalizations. Of the total 68 hospitalized patients, 21 patients were intubated (14%) and all 15 deaths occurred in patients deemed ineligible for bamlanivimab.

## Conclusion

With new variants of the SARS-Cov-2 virus continuously being detected, it is evident that COVID-19 will continue to pose a risk to transplant recipients. Since treatment options are still limited it is even more crucial to identify strategies that can mitigate morbidity and mortality in this high risk population. Vigilant testing and early detection of COVID-19 within 7 days of symptom onset allowed for timely intervention with mAb bamlanivimab therapy that significantly reduced disease severity and mortality risk amongst kidney transplant recipients.

## Future Implications

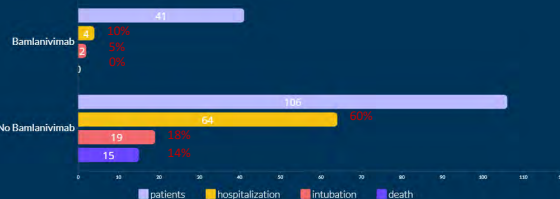
- ✓ Further mutations to the SARS-Cov-2 genome have affected the spike protein which bamlanivimab targets to prevent virus entry into host cells.
- ✓ However, multiple different monoclonal antibodies are also now available.
- ✓ Use of mAb is still an effective treatment strategy.
- ✓ Availability of COVID home testing has facilitated early detection and intervention in transplant patients who are found to be COVID-19 positive.
- ✓ Early detection remains crucial in minimizing the impact of COVID-19 in transplant recipients.

## Citations

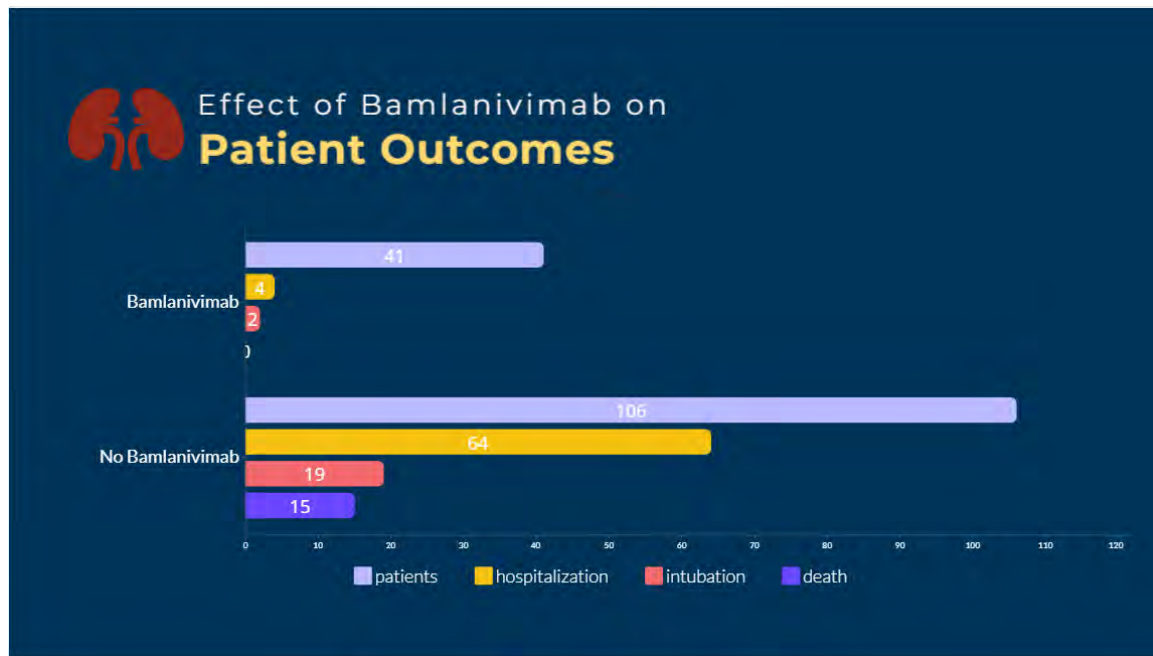
Kates, Olivia S et al. "Coronavirus Disease 2019 in Solid Organ Transplant: A Multicenter Cohort Study." *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America* vol. 73,11 (2021): e4090-e4099. doi:10.1093/cid/ciaa1097  
The authors have no disclosures



## Effect of Bamlanivimab on Patient Outcomes



# Bamlanivimab Improved Outcomes



# Bebtelovimab

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- Since May 2022, 41 patients had COVID.
  - 32/41 got Bebtelovimab
    - Zero hospitalizations, zero deaths
  - 9/41 did not get Bebtelovimab
    - 2 deaths (Vaccinated, but not boosted)

# COVID+ Decreased Donors

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- To date, our program has transplanted 6 COVID positive donors (2 on Monday 8/22/22)
  - Other causes of death (non-COVID)
  - COVID seemed to be incidental
  - High Cycle times (over 25)
  - Offered to COVID vaccinated patients only
  - All doing well. No transmission or random events

# Paxlovid Use in Transplant Patient

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70 year old Chinese male with ESRD due to IgA s/p preemptive DDRT in China in April 2019 in China. Vaccinated x 2, boosted x 1.

Came to the UCI ER on August 11<sup>th</sup>, 2022. ER discharged patient on oral Paxlovid

Patient re-admitted on August 15<sup>th</sup>, 2022 with abdominal pain, nausea, vomiting, diarrhea.



# Paxlovid – Cautionary Tale

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- Labs showed AKI and Prograf level that remained >60 for 3 days. On day 4, Prograf level came back at 55.
- Tacrolimus level held with plan to repeat lab in a few days. By day 7 of having held FK, level came back within therapeutic range.



# Intermountain Transplant Services

COVID Vaccine Requirement

*Amy W. Herbert, RN, BSN, CCTC  
Nurse Manager Kidney/Pancreas Transplant*

# Disclosures

Relevant Financial Relationships:

- Salaried, full-time employee of Intermountain Healthcare.



# Intermountain Transplant Services Leadership



**Dr. Diane Alonso, MD, FACS**  
Program and Surgical Director  
Abdominal Transplant Services



**Dr. Donald Morris, MD**  
Medical Director  
Kidney/Pancreas Transplant



**Dr. Richard Gilroy, MD**  
Medical Director Liver  
Transplant and Hepatology





**Intermountain Kidney/Pancreas Transplant Team**



# Intermountain Liver Transplant Team

# Vaccine Requirements Prior to November 1, 2021

- Hepatitis A series
- Hepatitis B series
- MMR
- PCV 13/ PPSV 23 –or–
  - PPV 20
- Influenza (annually)
- Shingrix
- tDap





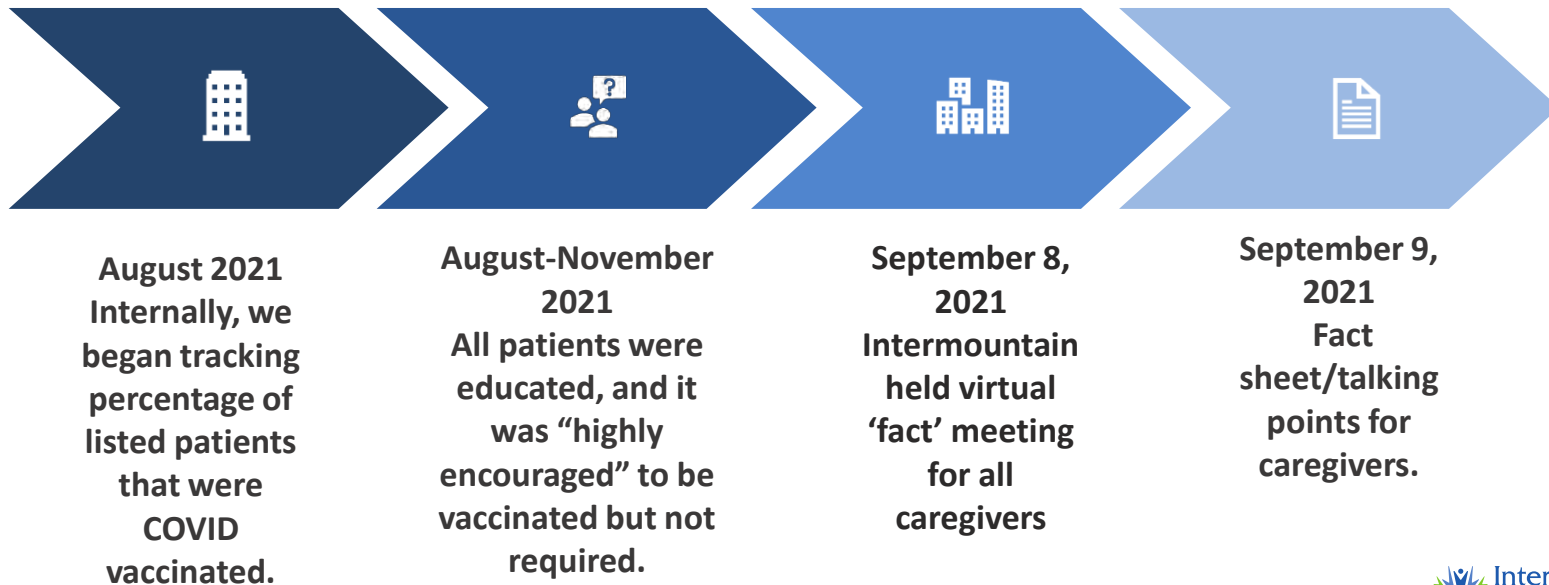
# Proactive Approach





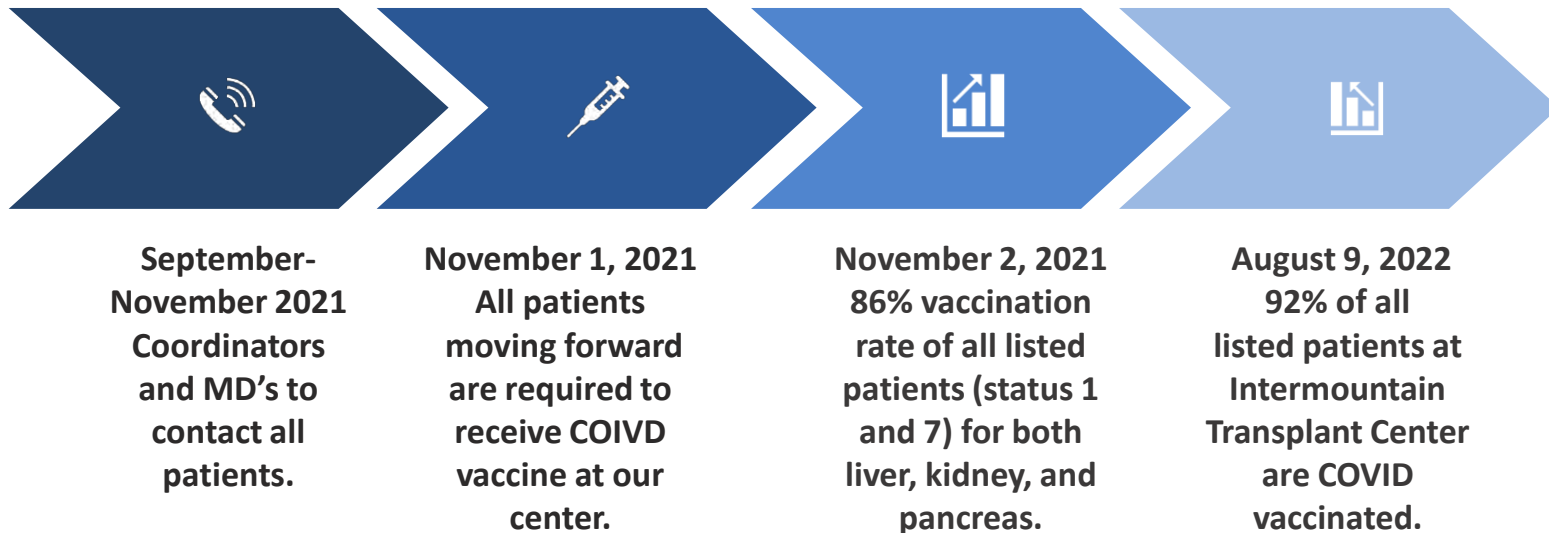
# Intermountain Transplant Services

## Timeline of Vaccine Information and Requirement



# Intermountain Transplant Services Process

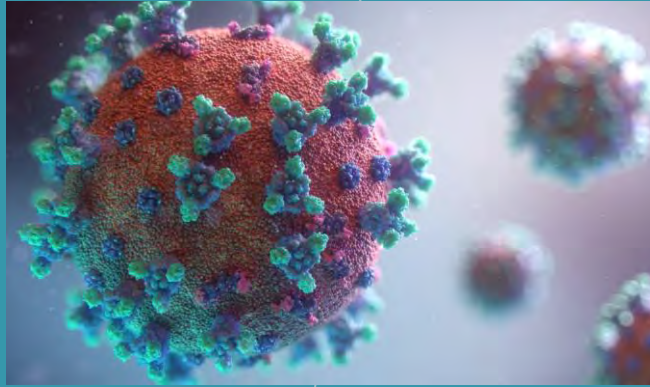
## Timeline of Vaccine Information and Requirement



# QUESTIONS?



# Considerations for Organ Procurement During an Evolving Pandemic



**Angela Velleca, MHDS, BSN, RN, CCTC**

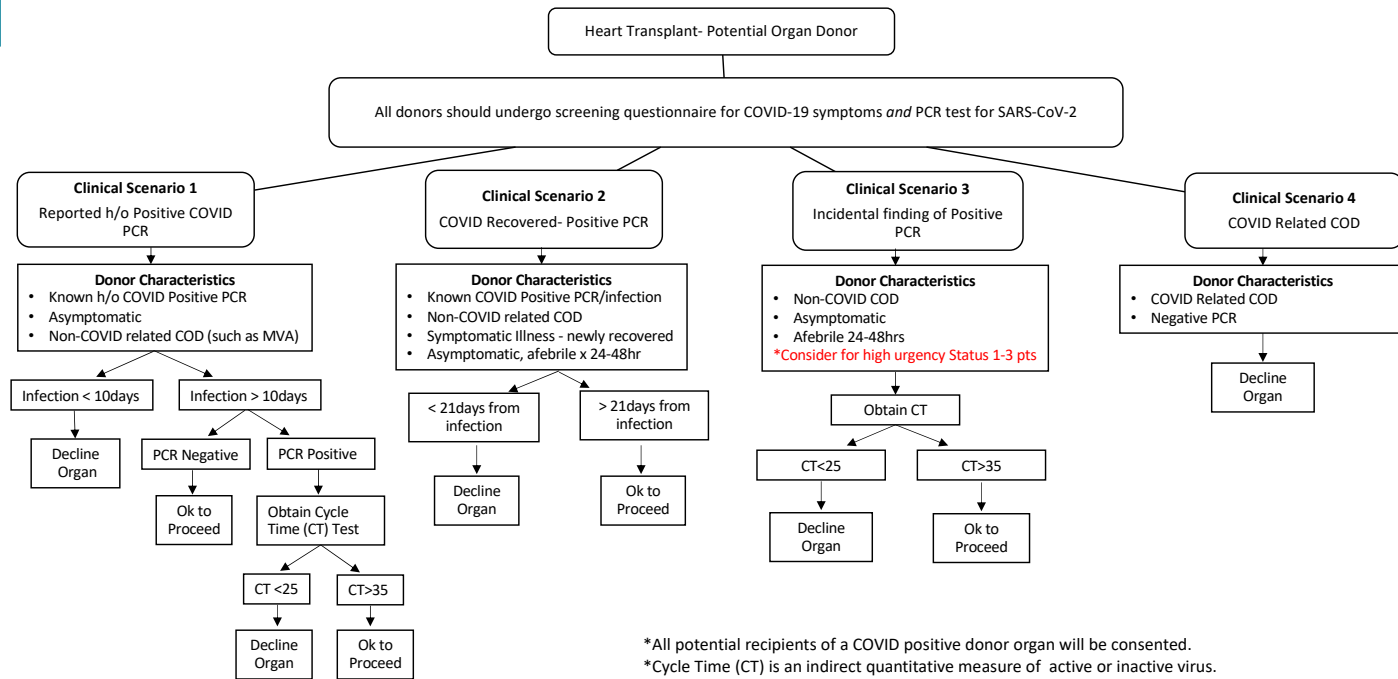
Clinical Operations Manager, Heart and Lung Transplant

Cedars-Sinai | Comprehensive Transplant Center | SMIDT Heart Institute

# Disclosures

*I have no relevant financial relationships to disclose*

# COVID-19 Donor Screening Pathway



\*All potential recipients of a COVID positive donor organ will be consented.

\*Cycle Time (CT) is an indirect quantitative measure of active or inactive virus.

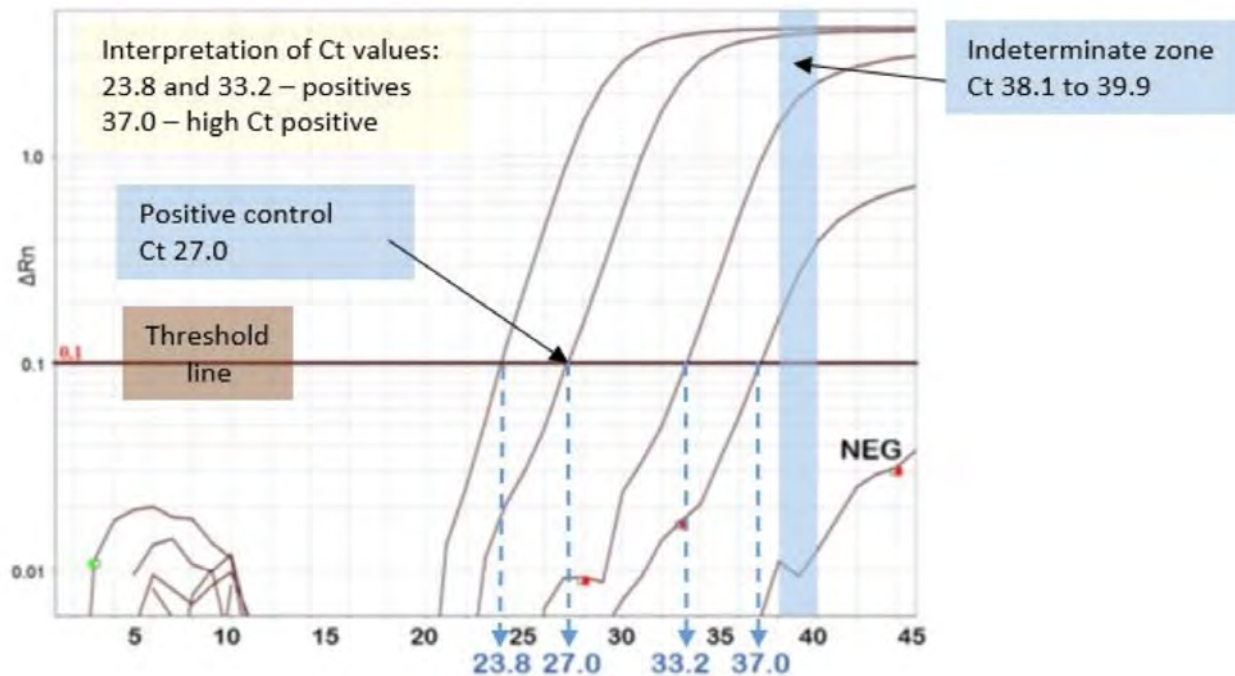
\*CT assay range for this algorithm provided by One Legacy-OPO (Keck lab) is 15-39 (high to low titer).

\*COVID PCR by nasopharyngeal swab only, rapid test not definitive due to potential for false results.

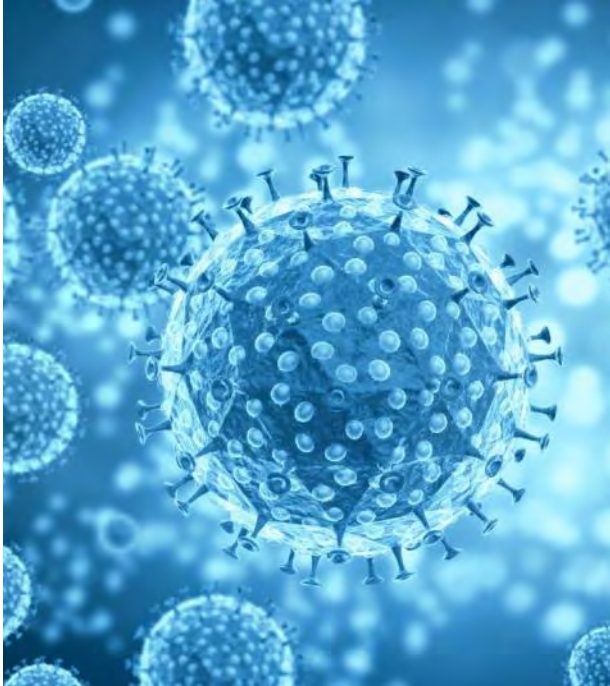
\*Serum antibody testing may be helpful in certain situations, but IgM result should be reviewed with caution and involvement of transplant ID specialist will likely be needed for interpretation.

\*CT in the intermediate range of 25-35 would need clinical interpretation by transplant ID specialist.

# Understanding Cycle Threshold (Ct)



# Donor Evaluation



## Donor tests COVID PCR positive

- Cycle threshold
- Donor/Recipient vaccination status
- Symptom presentation
- CXR results
- Lung- BAL required
- COVID PCR testing from admission and throughout hospital course
- Transplant Infectious Disease collaboration



# Informed Consent for Organ from Donor Positive For SARS COV-2



## COMPREHENSIVE TRANSPLANT CENTER ORGAN FROM DONOR POSITIVE FOR SARS COV-2 (COVID-19) INFORMED CONSENT OR DECLINATION

PATIENT ID:

### To be completed by patient:

I (please print your name), \_\_\_\_\_, have been advised by my doctor (please print your doctor's name), \_\_\_\_\_, MD, of the option to choose to receive the following organ or organs from a donor who has tested positive for the virus SARS CoV-2 associated with COVID-19 disease,

☐ Heart

☐ Lung

☐ Liver

☐ Kidney

I understand this means that the donor may have an active COVID-19 infection or may have a history of having an active COVID-19 infection.

I also understand that while there have been no reports of recipients getting a COVID-19 infection from blood transmission associated with a donor organ, there also has been very limited research on the use of organs from donors with COVID-19.

I further understand that guidelines have been developed by experts based on best available evidence to limit the risk of using organs from donors that may have been or known to have been exposed to COVID-19, and my transplant physicians are following these guidelines.

Finally, I understand that by opting to allow organs from donors who have or may have had an active COVID-19 infection in addition to donors who have no history of COVID-19 infection, I will be offered the first available organ(s).

### My doctor has informed me that the potential or known risks of opting in include:

- Becoming infected with COVID-19 from the transplanted organ(s).
- There are currently no available medications to treat COVID-19 infection except for certain medications to potential reduce the duration of illness.
- COVID-19 infection may result in complications including but not limited to acute respiratory failure, acute injury to the liver, heart and/or kidneys; septic shock; and blood clotting disorders. All such complications could impact survival rate and/or quality of life after organ transplantation.
- There are potentially unknown risks, including that long-term outcomes of transplants from donors with COVID-19 is not understood or known.

TAB 11 (CONSENTS)

(DISTRIBUTION: White = Medical Record Copy; Yellow = Patient Copy)

1011 (0321) Page 1 of 3

# In Summary

- Screening pathway effective in evaluating COVID-19 donors.
- Able to successfully utilize scarce organs for critically ill candidates.
- 8 heart and 8 lung transplants performed utilizing COVID PCR positive donors
- Kidney and liver transplant programs





**THANK YOU**

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UC San Diego Health

# NRP : Transplant Center & OPO Collaboration

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Brandon Jackson, CTP



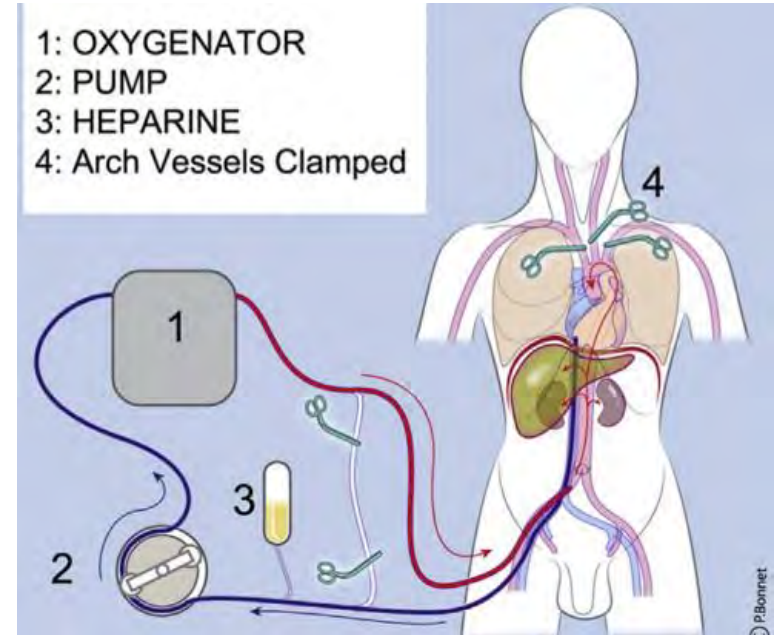
## Disclosures

I have no actual potential conflict of interest in relation to this program/presentation.

# Normothermic Regional Perfusion

Restore flow of **oxygenated blood** following cardiac arrest

Reverse warm ischemic injury of thoraco-abdominal organs after circulatory death



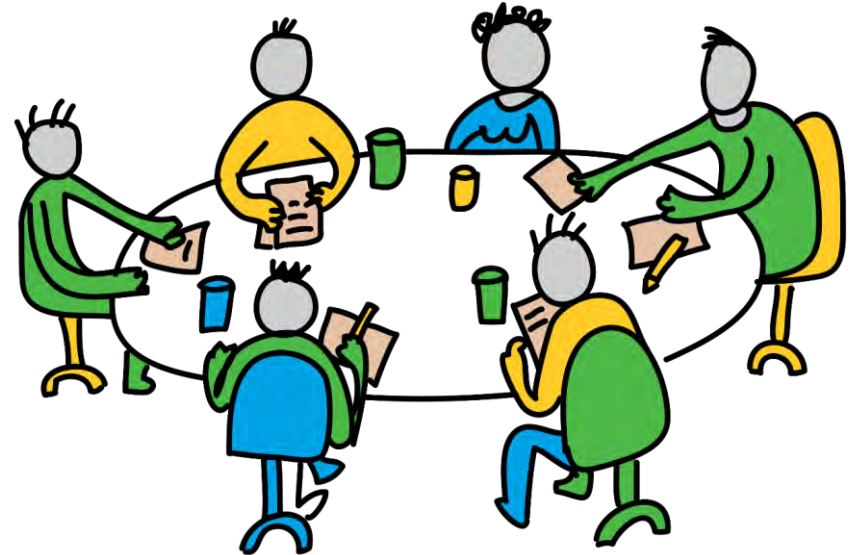
# Pre-OR Preparedness

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# Early OPO/Transplant Center Collaboration

- **Pre-recovery communication is crucial in supporting the success of NRP !!!**
- Discuss needs of transplant center
  - Anesthesia
  - Blood
  - Medications
  - Special Equipment
- Discuss OPO policy on withdrawal
  - Location
  - Stand off Period
  - Vital Sign Update
  - Withdrawal Time ( arriving ready to w/d)





# Transplant Center Collaboration

- Prior to OR have transplant programs discuss NRP (i.e.- abdominal team)
- Discussion should include
  - Cannulation
  - Abdominal Team on Standby for incision
  - WIT thresholds
  - Liver Needs ( liver enzymes, time on pump, lactates, etc)
- **Surgeon to Surgeon discussion !!!**



## Hospital Partner Readiness/Education

- Early communication to hospital OR on NRP needs
  - Large OR Room
- Typical NRP Cases will increase OR hours
  - Withdrawal Time + 4-5 hours in OR
- Detailed Discussion with ICU Team
  - Understanding NRP process
- Anesthesia Request
  - If anesthesia is needed ( reintubation, a-line, bronch)
- Education/Communication
  - Standardized messaging to OR staff



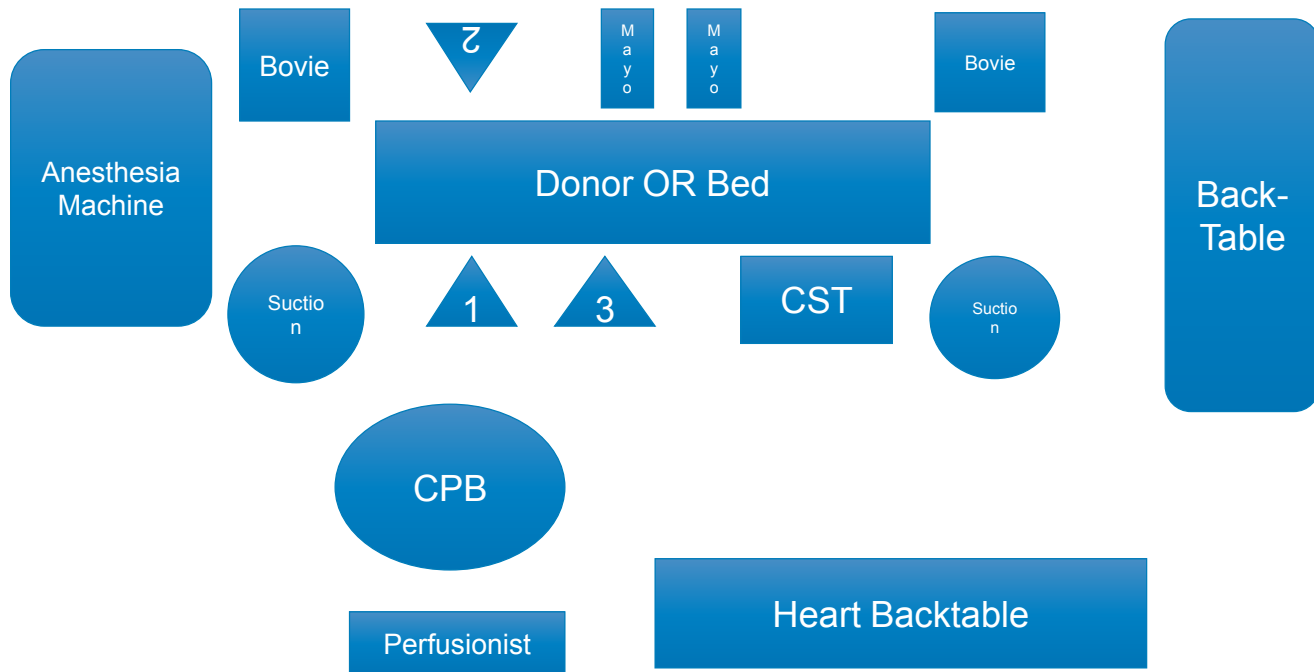
# Communication

Normothermic Regional Perfusion is a worldwide established surgical technique used by transplant centers to increase organ potential and utilization. It involves using machine perfusion to evaluate and assess organs deeming them suitable for transplant.

# Operating Room Readiness

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# NRP OR Recovery Setup



# OR Communication

- **HUDDLE, HUDDLE, HUDDLE !!!!!**
- Proper Introductions
  - Increase number of transplant personnel
- Define Roles
  - Transfer of Donor
  - Time Out
  - Positioning of patient
  - Announcing Incision
- Prepare for Rapid Incision
  - Allow NRP team space to move quick and efficient
  - Noise to a minimum until initiation of CPB
  - Once on CPB, we can slow down and move like a DBD donor.



# NRP Surgical Technique

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# NRP Steps

Chest Emergently open

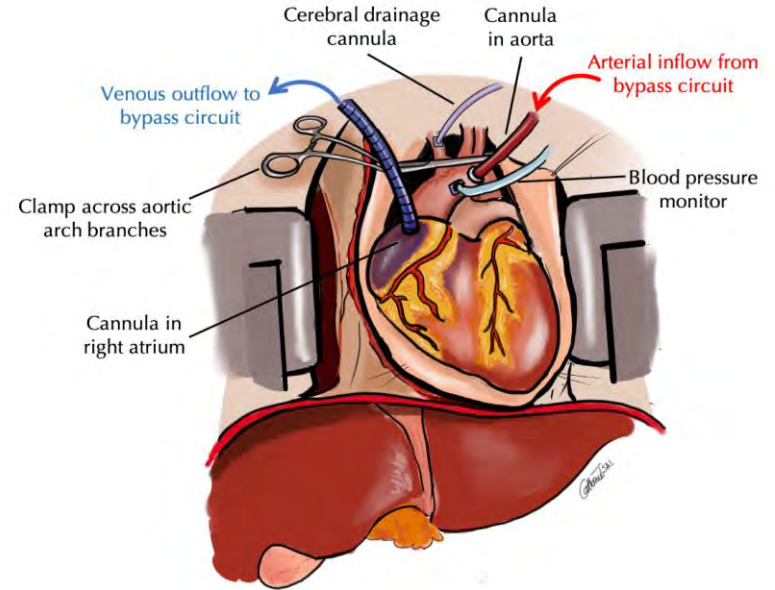
Head vessels exposed and clamped

Venous cannula placed in right atrium, blood drained into pump

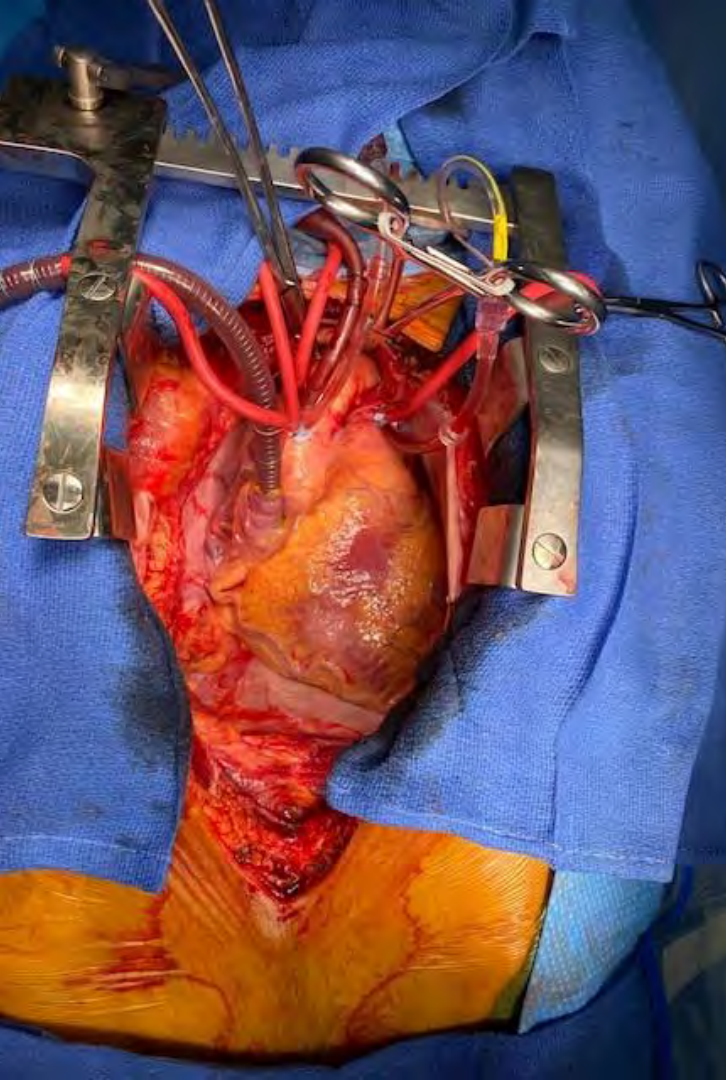
Aortic Cannula placed in aorta

Cardio-pulmonary Bypass initiated

Average time from incision to CPB, 4 min







## Head Vessels

- All 3 head vessels (brachiocephalic, left common carotid, and left subclavian) are cleanly dissected and identified.
- Vascular clamp is placed over all three head vessels prior to any cannulation of CBP.
- Clamping all 3 head vessels occludes flow to the brain
- Aortic Root Cannula placed in the innominate artery to stop all potential collateral flow from the vertebral .
- Result in loss of upper limb blood pressure monitoring

# OR Documentation

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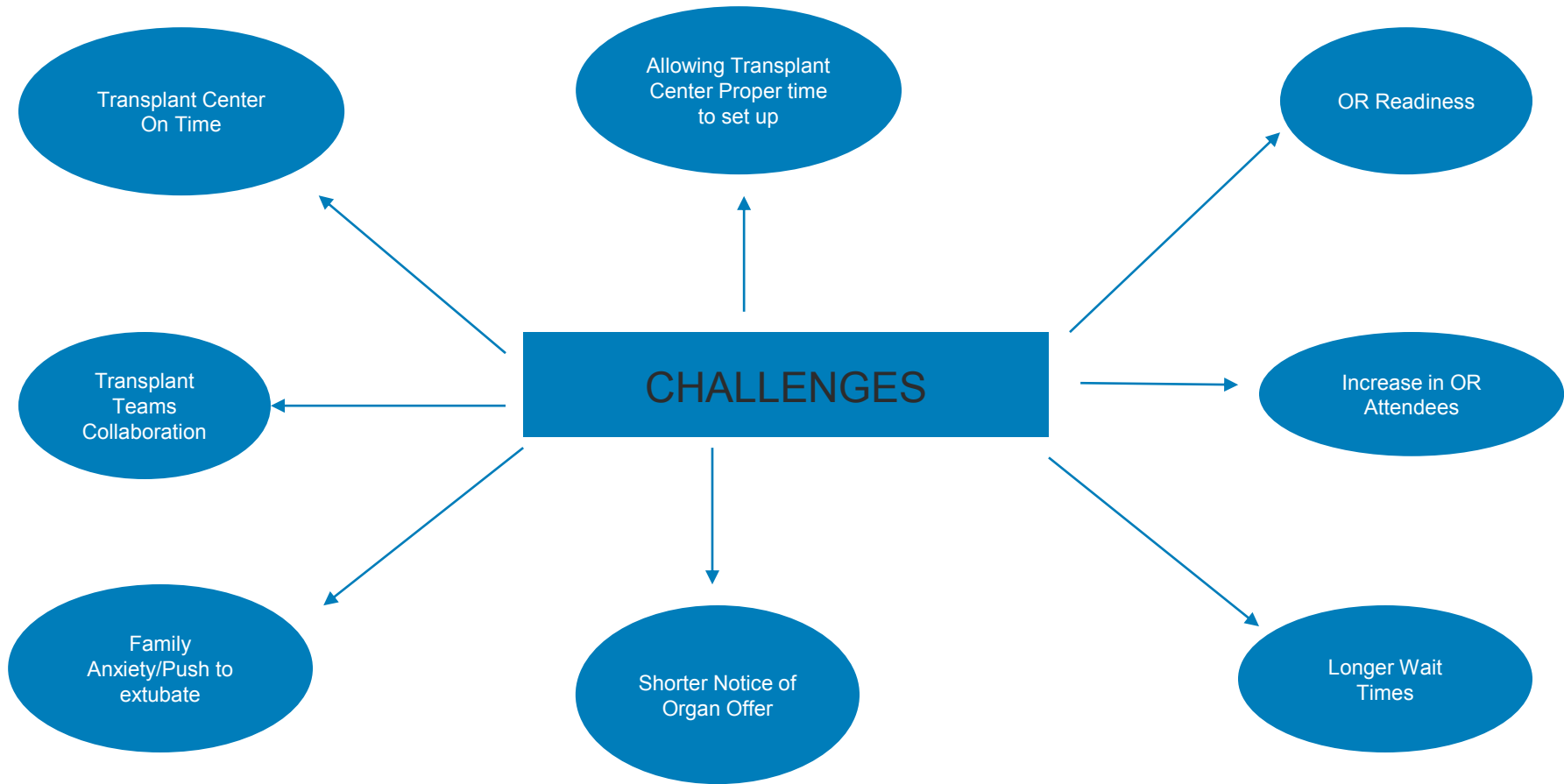
# Times and Documentation

- Warm Ischemic Time
  - Varies by program/Opo
  - Defined as agonal phase to initiation of CPB
- Clamp Time
  - Initiation of Cold flush
  - NOT off CPB
- Bypass Record
  - Should be kept by NRP team
  - Flow Parameters
  - Pressures
  - Lab Values
  - Uploaded to UNET

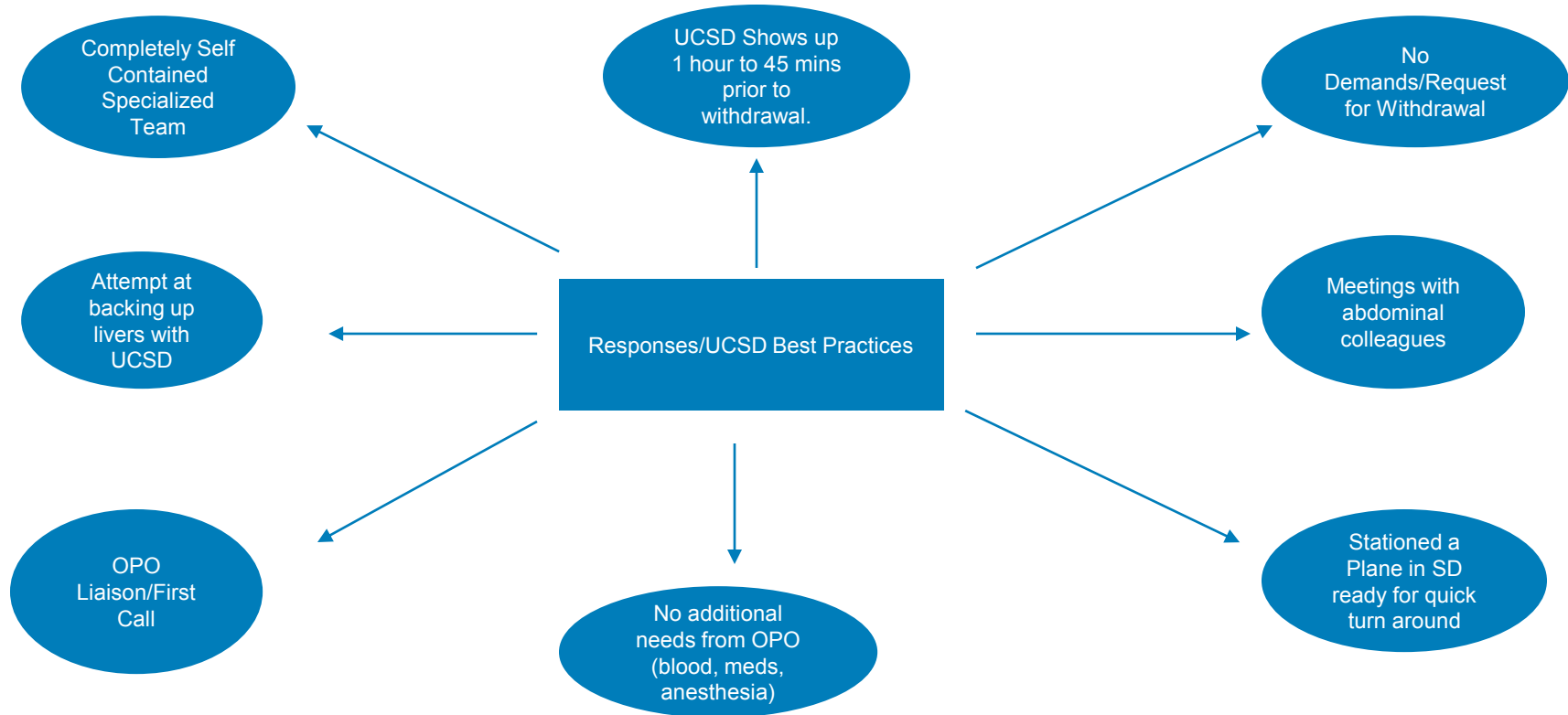


# NRP Challenges and UCSD Best Practices

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# UCSD Response to Challenges



# SUCCESS of NRP Program

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# UC San Diego Health DCD Heart History



NRP DCD  
Heart Activation

May 2021



NRP 2021  
Statistics

25 NRP DCD  
Hearts  
Transplanted



NRP 2022  
Statistics

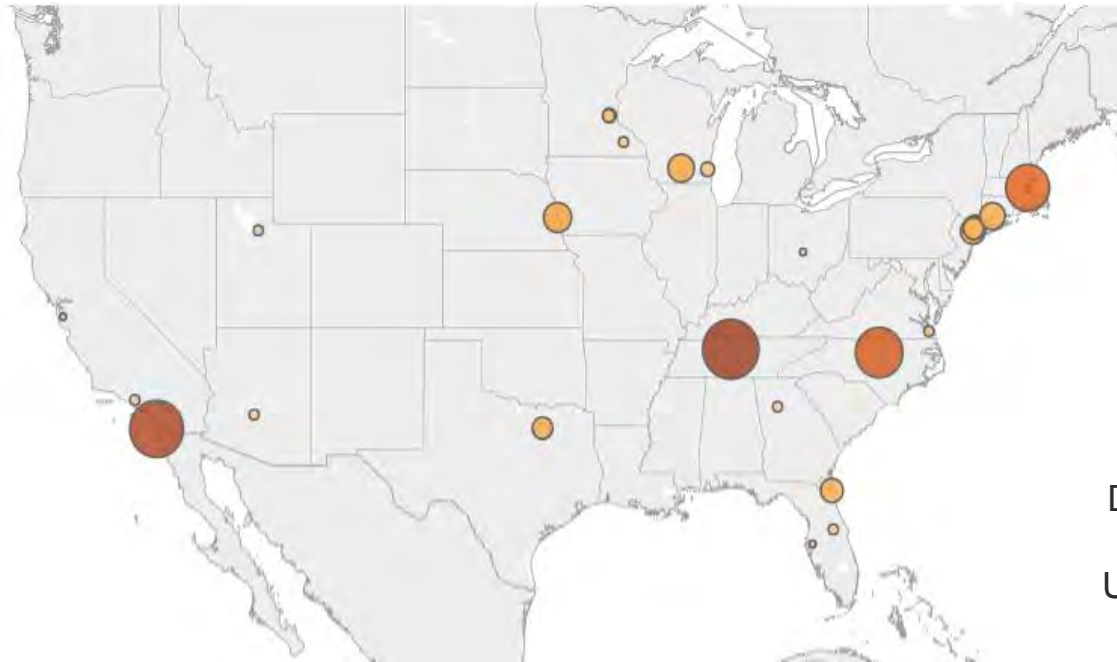
YTD 28 NRP  
DCD hearts  
transplanted



**40-50 % DCD Volume**



## Current DCD Heart Centers



DCD transplant from  
1/2/21-present  
UNOS Data Services

## UCSD Abdominal NRP Team

- Collaboration and education for UCSD abdominal surgeons and CPB cannulation
- Abdominal only NRP completed by cardiac team in conjunction with training
- Plans for independent abdominal only NRP program
- Increased WIT threshold for DCD livers
- Offering our local OPO NRP recovery DCD resources



# Teamwork

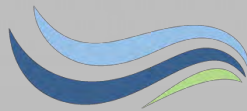


# Thank You !!

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Brandon Jackson, CTP

UC San Diego Health Center for Transplantation



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LIFESHARING™

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# Stacking the Odds in Our Favor:

Navigating the Implementation of NRP

*One OPO's Journey*

Jaclyn Russe RN, BSN, CCRN

Kiersten Smith RN, BSN

# Lifesharing

## New Frontiers

- First NRP Case in May 2021
- Abdominal only in September 2021
- Lots of bumps in the proverbial road
- Facilitated increased communication with our transplant partner
- Started with heavy HD involvement to prepare hospitals for what was coming





# Navigating the Implementation of NRP

## Overview

- Mitigating Barriers
- Managing Relationships
- Communication/Sharing Information
- Forms & Consent
- New Template
- OR Procedure
- Logistics



# Potential Barriers to Advancing NRP

- Ethical questions
  - 2021 ACP Statement of Concern
    - Defining Death
    - Clamping of cerebral arteries
    - Transparency with donor families
- Logistics
  - Equipment, available team, transportation, timing, etc.
- Donor hospital misconceptions
  - Rumors or spread of inaccurate information

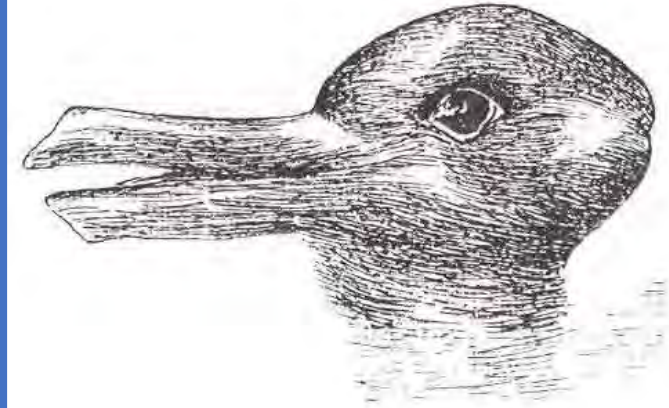




# Navigating the Implementation of NRP

## Interpersonal Management

- ***We are not there to force anyone!***
- Integrating NRP and other initiatives into routine in-services
- HD committed to onsite, real time Q&A with unit staff in early cases
- Every hospital and OPO is unique
- Questions were abundant, don't let them derail you!
- Perception is reality



# Navigating the Implementation of NRP

## Interpersonal Management

- Managing Relationships
  - We are there to help facilitate communication between surgeons and transplant centers
  - Teamwork CASD teams have been more than willing to initiate those calls
  - Leveraging NRP/OCS teams for hospital huddles prior to extubation



# Navigating the Implementation of NRP

## Interpersonal Management

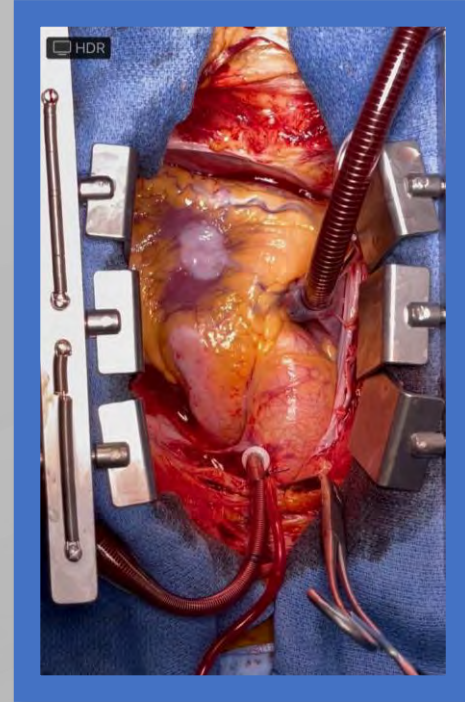
### Communication/Sharing Information

#### Avoid:

- “Restarting”
- “Reanimating”
- “Resuscitating”

#### Use:

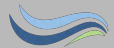
- “Reperfusion”
- “This does not occur until after cardiac death”
- “Provides a select reperfusion to allow for a more thorough organ assessment for transplantation”

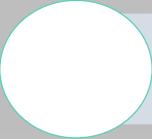




## NRP Key Talking Points

- NRP (Normothermic Regional Perfusion) is a method of preserving organs from deceased organ donors that can give transplant recipients a better chance of survival.
- NRP is used in DCD cases where the patient's family has elected to withdraw care and donation has been authorized.
- During NRP, oxygenated blood is pumped to the specific organs being procured. **This happens after the donor has died — but before the organs are removed from the deceased donor's body.**
- During NRP, oxygen is not circulating to the deceased donor's brain.
- NRP can help reverse organ damage that occurs during the dying process. **But it does not and cannot reverse death.**
- **By law, organ donation cannot occur until after a patient has died.** Death must be declared by a medical expert who is not involved in the organ donation or transplantation process.
- Utilizing NRP during recovery does not deviate from the standard DCD protocol. NRP occurs after death is declared and cardiac standstill has been confirmed.





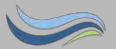
# Navigating the Implementation of NRP


## Process/Protocol Formation and Adaptation

### Forms & Consent

- Consent woven into current DCD notification forms
- Consent now has attestation
- Heparin Consent

*“Organs may need to be placed on machines before being transplanted. These machines help to optimize an organ’s function before transplant and assist transplant doctors with determining if an organ is suitable to safely transplant.”*





# Navigating the Implementation of NRP

## Process/Protocol Formation and Adaptation

### New Template in Donor Highlights:

Definition of WIT- Agonal time to circulation restoration

*Patient extubated:*

*Agonal phase started at:*

*CTOD at:*

*NRP (ECMO) started:*

*Aortic Flush at:*

*WIT (Agonal phase to start of NRP):*

# Navigating the Implementation of NRP & OCS

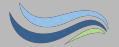
- Challenges
  - Staffing
  - Transportation and logistics of machines
  - Anesthesia
  - Transplant center protocol, labor intensivist, more supplies



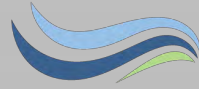


## Other Successes

- Total of 7 DCD cases with 4+ OTPD since implementing NRP in March 2021
  - A total of 35 organs transplanted from those 7 cases
- Improved outcomes in rapid and expedited DCDs
  - Able to allocate after x-clamp if placed on OCS pump
- 9 DCD hearts transplanted since March 2021
  - 8 with NRP, 1 on OCS Pump
  - 70 hearts transplanted in that timeframe, making DCD hearts 13% of our total heart transplanted







LIFESHARING™

**Thank you!**

# OCS Utilization at a Busy Lung Transplant Program

Kate Grief, MBA, MSN, RN, CCTC  
Sr. Director of Transplant Services  
August 24<sup>th</sup>, 2022



**Dignity Health™**  
**Norton Thoracic**  
**Institute**

*Work that uplifts humanity has dignity and importance and should be undertaken with painstaking excellence*

-Martin Luther King Jr.



## St. Joseph's Hospital and Medical Center

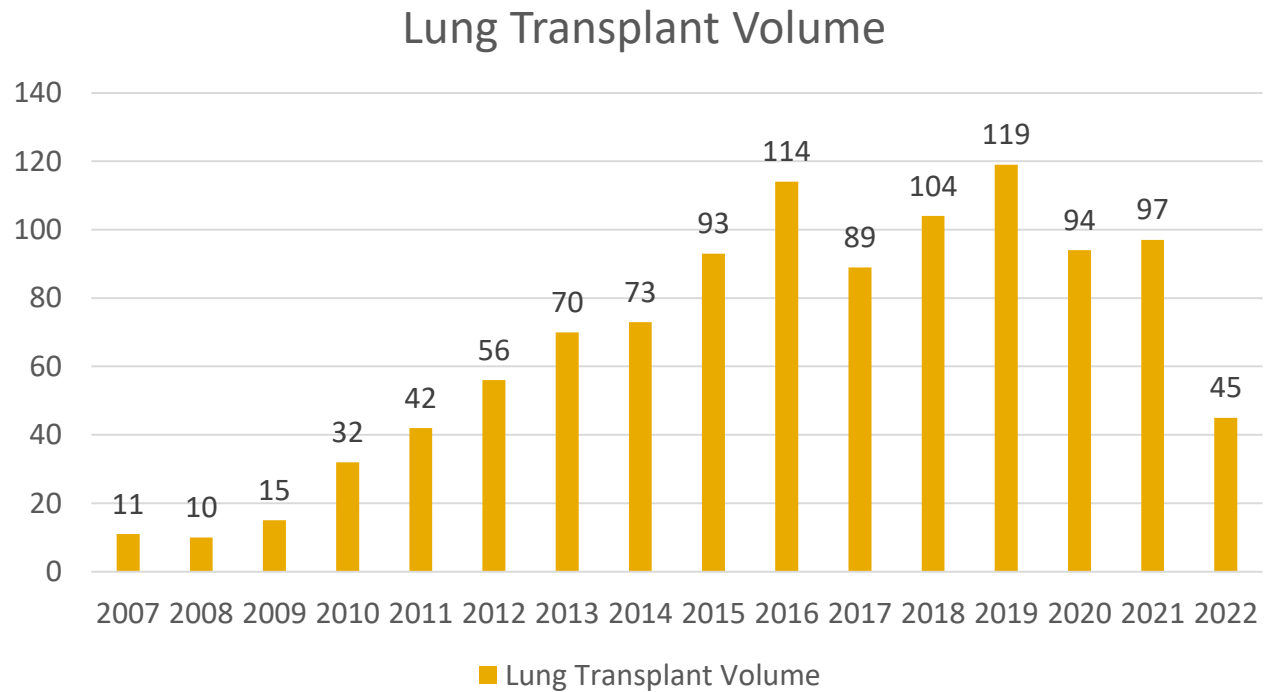
Transplant Program	Volume Since Inception	Centers of Excellence	CMS Approved Transplant Program
Lung	1064	Yes	Yes
Kidney	207	Yes	Yes
Liver	141	Yes	Yes

## NTI Lung Transplant Program Overview

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- Established in 2006
- UNOS approval 2007
  - Transplant ~ 100 lung transplant patients/year
  - Quality outcomes better than national average
  - Lung: Transplant #1065
  - Short waitlist times (<3 weeks)

# Total Lung Transplants Performed at NTI



# Indications for Lung Transplant

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- Chronic, end-stage lung disease
  - High risk of death (>50%) within two years if not transplanted
  - High likelihood (>80%) of surviving at least 90 days after transplantation
  - High likelihood (>80% of 5 year post transplant survival from a medical perspective provided that there is adequate graft function
- All other medical therapies have been exhausted
- Candidates Usually report a poor quality of life

# Indications For Lung Transplant

---

## — Chronic Obstructive Lung Disease

- Emphysema
- A1AT Deficiency

## — Interstitial Lung Diseases

- Idiopathic Pulmonary Fibrosis (IPF)
- Sarcoidosis
- Lymphangioleiomyomatosis (LAM)

## — Infectious Lung Diseases

- Cystic Fibrosis
- Bronchiectasis

## — Pulmonary Vascular Diseases

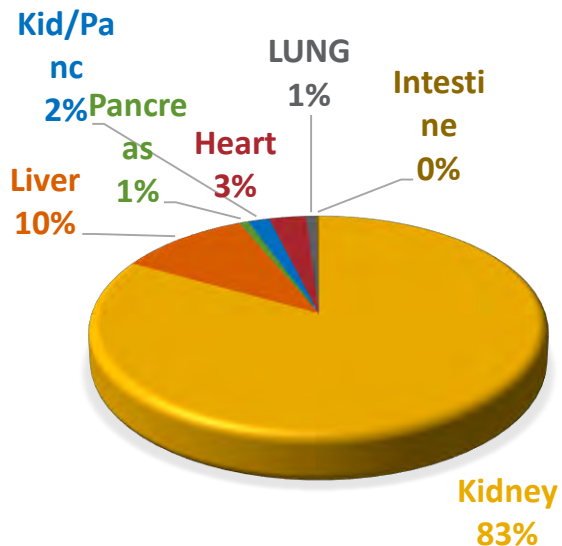
- Primary Pulmonary Hypertension
- Eisenmenger's Syndrome

## — Retransplantation



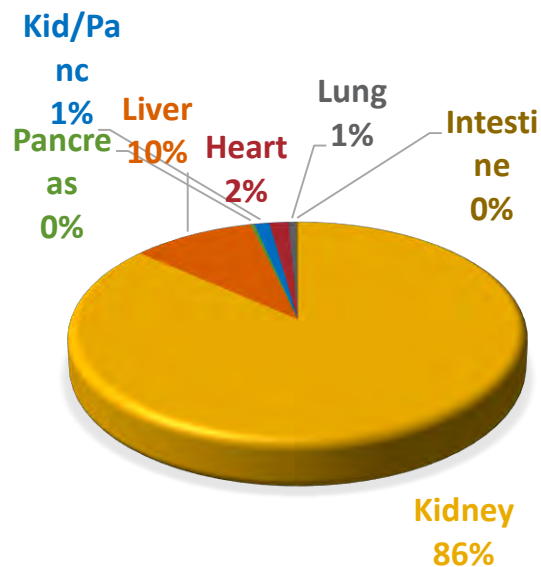
# Current Realities of Lung Transplantation

# Waitlist in USA



Organ	Candidates
Kidney	97,277
Liver	11,281
Pancreas	870
Kidney/Pancreas	1,987
Heart	3,952
<b>LUNG</b>	<b>1,014</b>
Heart/Lung	29
Intestine	201

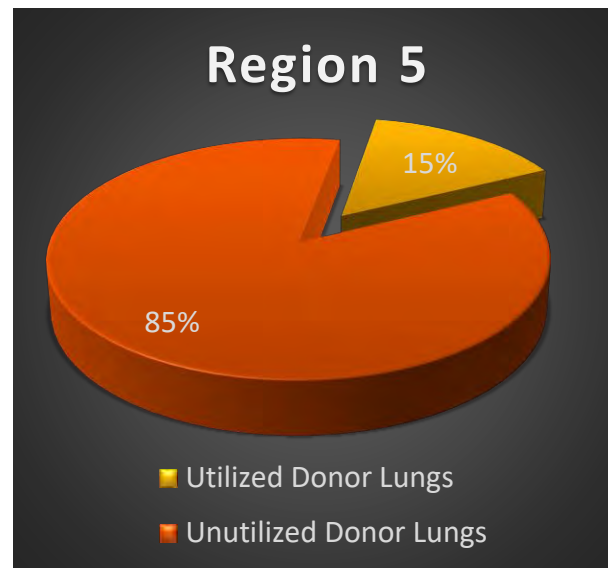
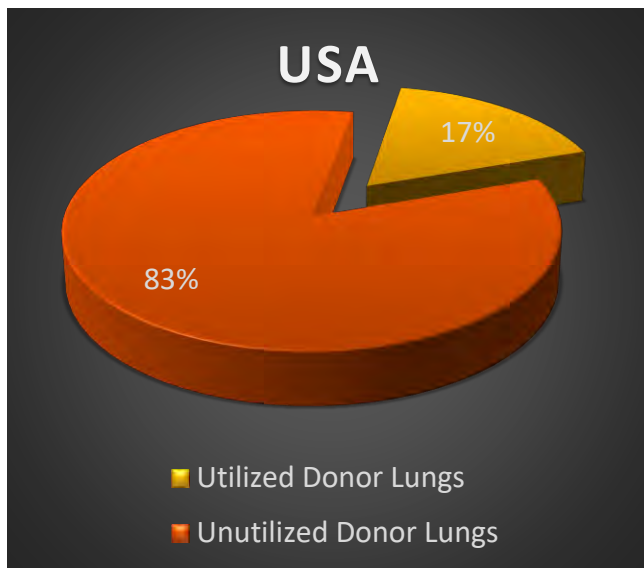
## Waitlist in Region 5



Organ	Candidates
Kidney	21,462
Liver	2,433
Pancreas	74
Kidney/Pancreas	293
Heart	372
LUNG	152
Heart/Lung	6
Intestine	36

# Current Realities of Lung Transplantation

## Lung Shortage



# Transmedics Organ Care System

Expanding the Donor Pool

# Rationale for Ex-Vivo Lung Perfusion

---

## Cold Static Storage

- Slow metabolism
- Decreases need for O<sub>2</sub>/nutrients
- Preservation by slowing organ deterioration for a short period
- Unable to assess/recondition

## Normothermic EVLP

- Tissue physiologically active
- Allows for several hours:
  - Preservation
  - Assessment
  - Reconditioning

## Cold vs. Normothermic

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## Ice Bath

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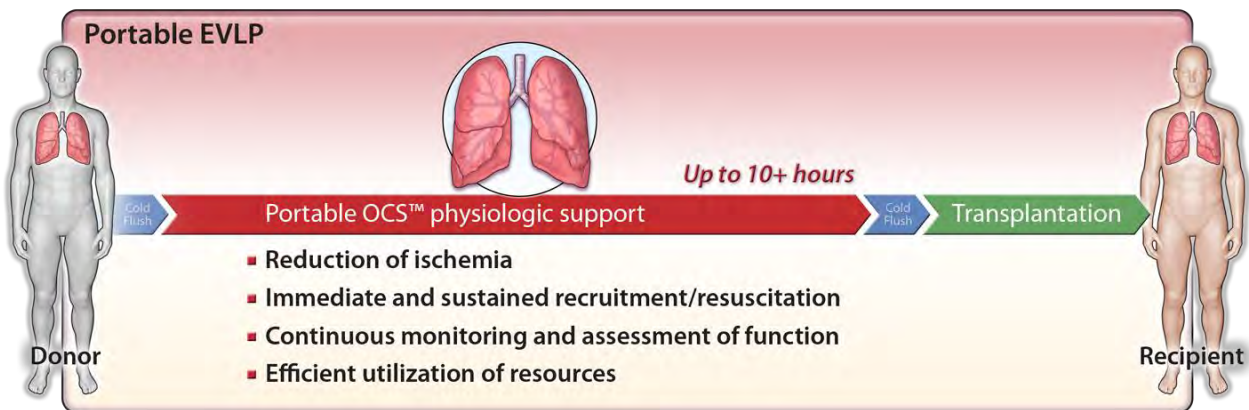


## Warm Bath

---



# How Does Transmedics Organ Care System Work?



## How OCS Works

---

- Cold perfusate flush in donor and retrieval
- Lungs placed on device in the donor OR
- System primed with perfusate/additives
- Perfusate warmed to 32 deg C
- Gradually increase pump speed (1.5-2 L/min) as temp increases to 37 deg C
- Start ventilator when temp gets to 34 deg C

# Implementing an OCS Program

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- Requirements:
  - Specialized surgeon training with Transmedics
  - Specialized OCS operator training with Transmedics
  - Blood Bank Protocol
  - Pharmacy Protocol to release medications
  - Adequate storage space for device and disposables

## Specialized Surgeon Training

---

- Passive antegrade and retrograde flush
- Ensure sufficient trachea to put on device
- Clear redundant tissue from around the left atrial cuff
- Reconstruct PA if heart is taken
- Excluded from OCS if:
  - Moderate to severe pneumothorax, hemothorax, or pulmonary contusions
  - Presence of pneumonia or lung infection

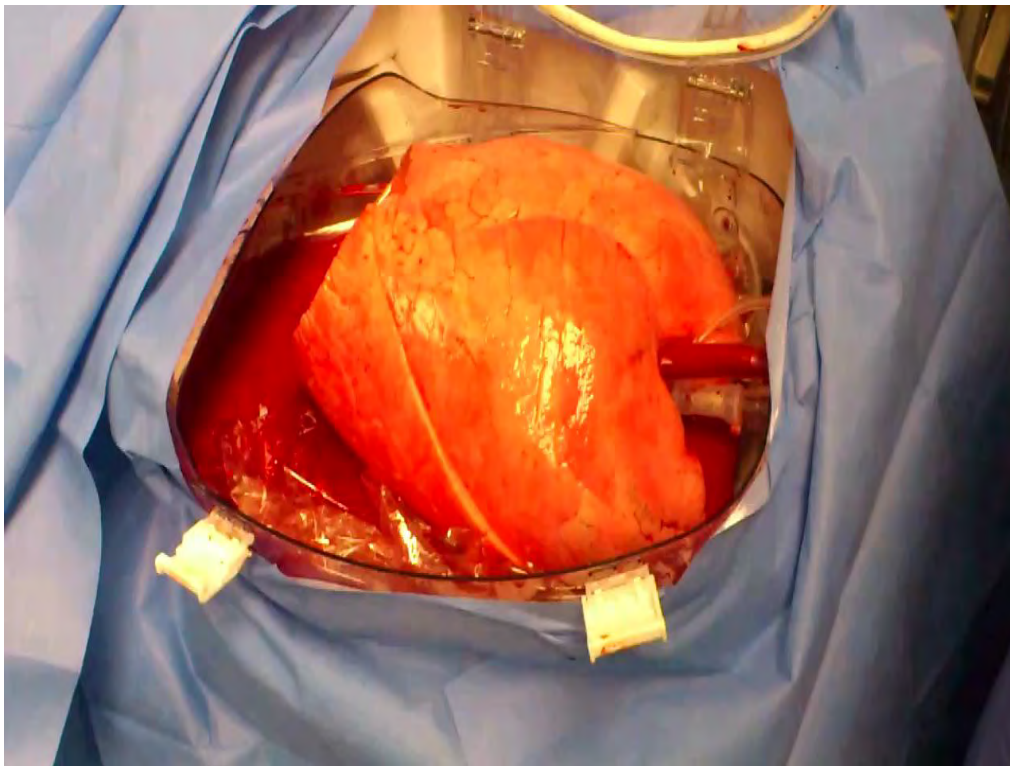
## Specialized Surgeon Training

---



## Healthy Lungs on OCS Device

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# Specialized Operator Training

## Parameter Adjustment and Assessment

### — Hemodynamics

- Flow
- PA pressure
- PVR
- LA pressure
- HCT

### — Ventilation

- Settings (TV, rate, PEEP, FIO<sub>2</sub>)
- Airway pressures
- Compliance
- Oxygenation capacity (S<sub>PA</sub> O<sub>2</sub>, S<sub>LA</sub> O<sub>2</sub>, P/F ratio)

### — Modes/Settings





## Specialized Operator Training

---



# Hospital Processes

---

- Blood Bank Protocol
  - Requires 3 units of ABO compatible or O-Neg PRBC's
  - Ordering and release process for a non-admitted donor
  - Temperature control transportation method
  - Return process for unused blood products
- Pharmacy Protocol
  - Requires multiple drugs
  - Ordering and release process
  - Return process for unused medication
  - Charge process for used medications

## Device Storage



## Equipment Needed for OCS Run

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## Advantages

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- Recovery and placement of marginal lungs
- Multiple transplants feasible
- More complex cases considered
- Staggering cases based on complexity
- Allows for procurement with a crossmatch pending
- Increased mileage to capture lung donors

## Considerations

---

- Purchase of device, disposable kits, and OCS preservation solution/equipment
- Storage of device, disposable kits, and OCS solution/equipment
- Transportation logistics
- Specialized training of staff
- Long procurement runs
- Communication with OPO ( OR space)
- Contracting with insurance companies to cover costs of disposables

## Transmedics National OCS Program

---

- Transmedics partners with OPO's
  - Primary center can choose to use the service
  - If lungs not allocated prior to donation, Transmedics may place on device so allocation can continue
- Local recovery surgeon/team
  - Surgeon to surgeon communication needed
  - No charge to transplant center if lungs declined in the OR
- +/- travel logistics support
- Clear communication between OPO/TX Center/Transmedics

## Different Processes for Coordinating the Implant

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- Standard Procurement
- OCS Procurement
- Transmedics National Recovery
- DCD Procurement
- Local Recovery Surgeon
- NRP



## Conclusion

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- Lung utilization is low nationally and in our region
- Lung perfusion devices offer opportunity to recover lungs that may otherwise be discarded
- Implementing a hospital based OCS program requires specialized training, additional resources and well defined processes
- Using OCS can allow for multiple transplants, staggering transplants, or optimize the timing for complex cases
- Communication is key

Thank You

# Review of OCS™ use in Heart Transplantation



Angela Velleca, MHDS, BSN, RN, CCTC

Clinical Operations Manager, Heart and Lung Transplant

Cedars-Sinai | Comprehensive Transplant Center | SMIDT Heart Institute

# Disclosures

*I have no relevant financial relationships to disclose*

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# OCS™ (Organ Care System)



## OCS™ (Organ Care System)

- “Heart in a box” or “TransMedics®”
- Currently, the only FDA approved technology for Ex-vivo perfusion and preservation of the donor heart
- Ex-vivo resuscitation of donor organs from the insult of brain/circulatory death
- Ex-vivo metabolic and functional assessment

# OCS™ System

## The Organ Care System (OCS™)



**Wireless Monitor**

- Controls and displays heart parameters



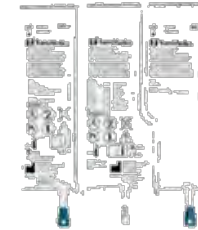
**Organ Care System Console**

- Portable, easy to use, and fits within all modes of transportation



**Heart Perfusion Module**

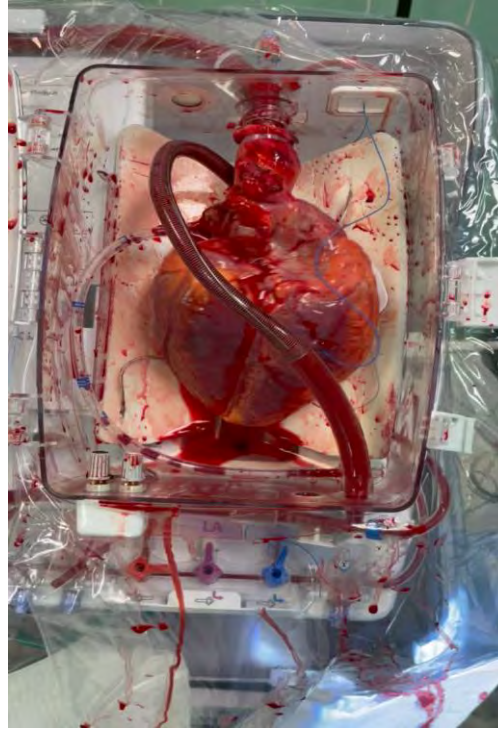
- Provides the sterile blood circuit and protected environment for the donor heart



**Heart Solution Set** <sup>110</sup>

- Infused into blood circulation in order to optimize heart perfusion

# OCS™ “Heart in a Box”



111

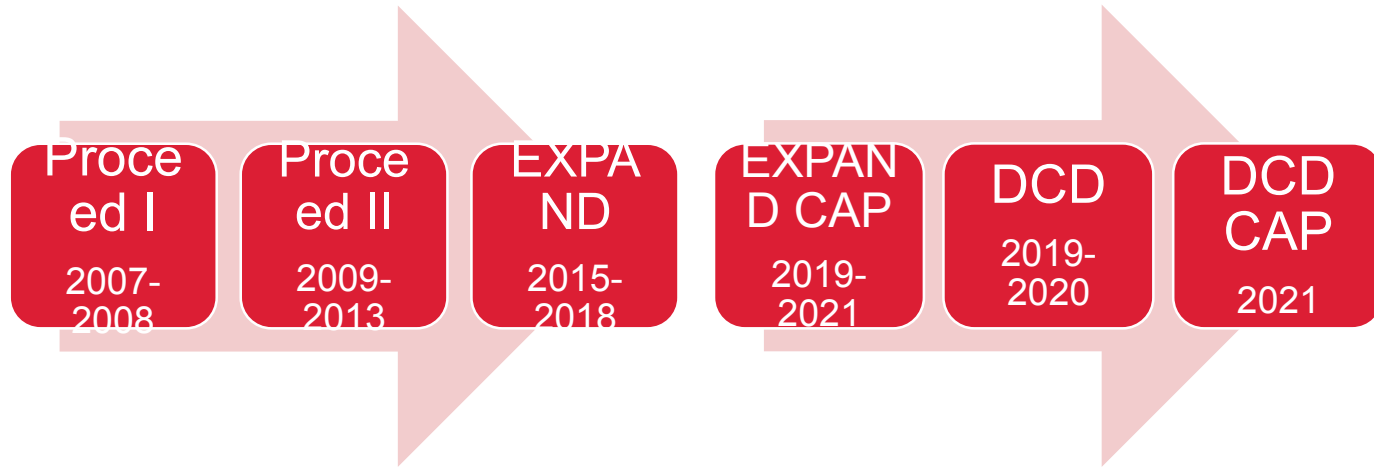
# Benefits of OCS™ (Organ Care System)



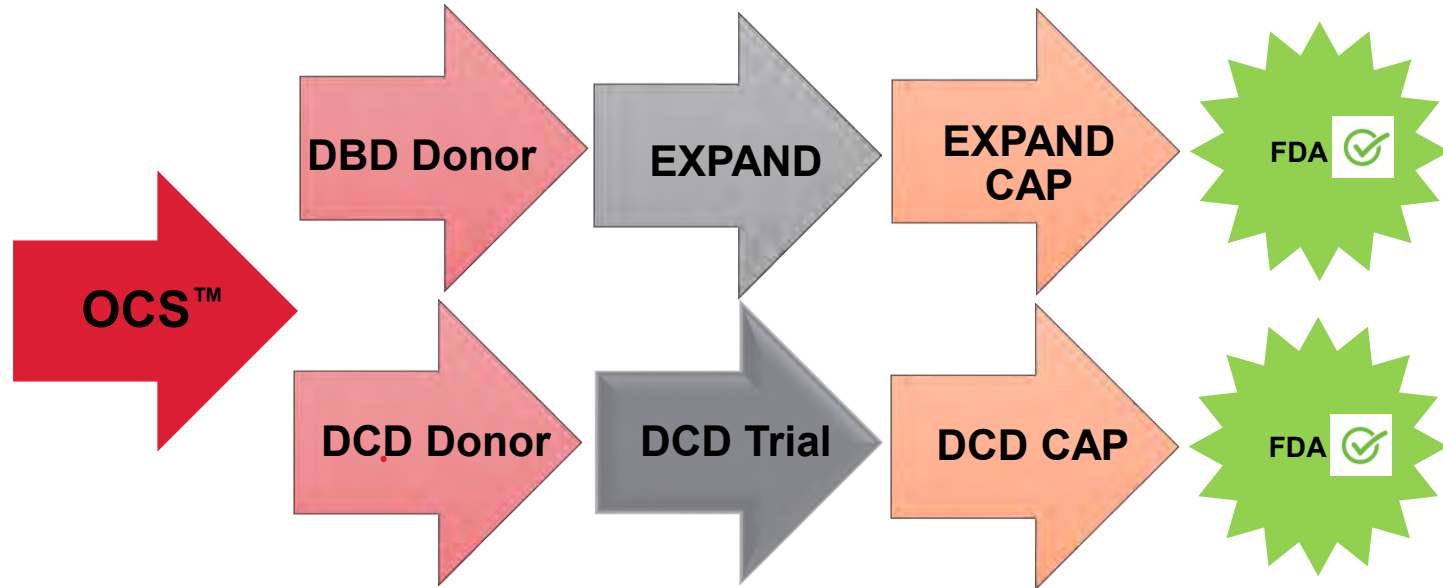
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# OCS™ Research Trials in Heart Transplantation

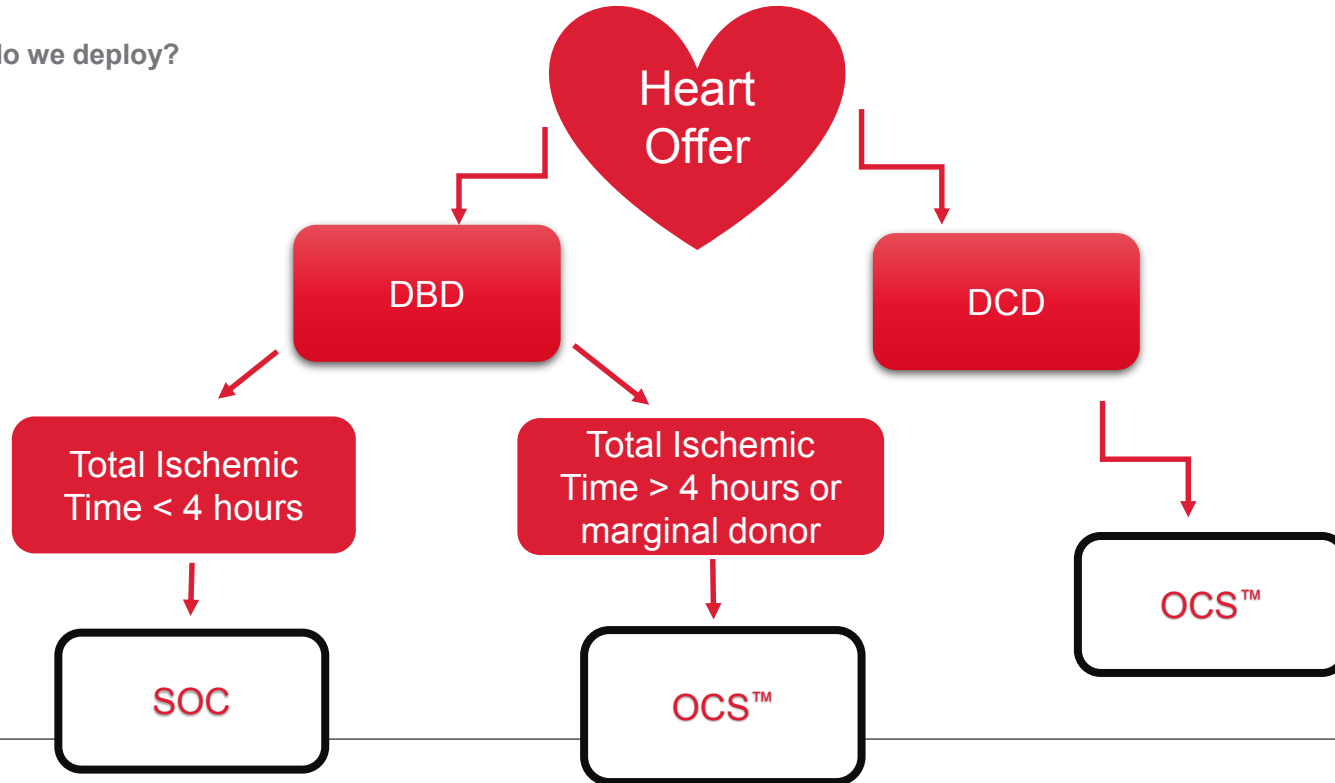


# OCS™ (Organ Care System)



# OCS™ (Organ Care System)

When do we deploy?



# Considerations

## Financial

- **Transportation** - Larger plane and vans, more pilots for longer flights (Hawaii)
- **Staffing** - More team/personnel, increased wages for longer hours, time away from medical center
- **Supplies** - OCS™ module, solution set, gas, supplies, etc. (~\$70,000)

# Considerations

## **Donor Management** – More communication

- Hematocrit > 28% (q6), lactate (q12), reduce pressor dependency prior to OR (if possible), euvolemic

## **Donor OR**

- Neptune suction preferred (DCD), 1-5L blood prior to XClamp, timing of opening OCS™ module and supplies to prevent waste, i-STAT processing time, CSMC pharmacy kits for readily available meds

## **OPO**

- Larger donor OR, early team arrival (~1 hr.) d/t prolonged setup, 2 units of packed RBCs (washed/irradiated) available in the OR, liver team DCD delay d/t donor blood collection for OCS™ circuit

# Lessons Learned

- Donor blood collection failure from right atrium-clotting
  - Now use suction into cell saver reservoir
  - Need 1L of donor blood then supplement with blood units if needed
  - Need 2 units washed/irradiated blood on standby
- Sternal saw battery failure for DCD OCS™ heart cases
  - Backup saw battery on surgeon Mayo stand
- Abdominal team unaware of blood collection delay on DCD
  - Transplant surgeon pre-OR meeting + huddle at donor OR with all staff/teams

# Lessons Learned

- Miscommunication of type of case w/ OPO – “pump case”
  - Need to cite all types of terminology – OCS™, Heart in the Box, TransMedics® machine
- Nearly exceeded pilot duty time to Hawaii
  - Coordinate a departure time w/ aviation team to circumvent FAA restrictions (third pilot)

# Future Directions

- Increased DCD heart procurement using OCS™
- DCD policies aimed to value donation
- Pilot study using NRP (Normothermic Regional Perfusion)

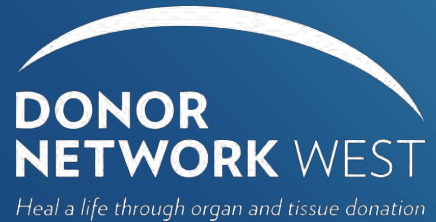


# Thank You



# OCS Liver and OPO Logistics

Valerie Chipman, RN, BSN  
Director of Organ and Allocation Operations



# Objectives

- Review OCS Liver process
- Discuss logistical challenges for OPO's

# Donation Service Area

**45** Counties Serving Northern California & Nevada

**175** Hospitals

**44** Coroners & Medical Examiners

**500+** Funeral Homes

**5** Transplant Centers

**14** Million People

**1987** Year Founded

**120,000** Square miles

# OCS Liver



- DNW has had it in use since 2/2022
- OCS keeps the liver in normal physiological condition (not ischemic).
  - Can tell it's working because it produces bile
- Suitability for OCS:
  - All BD donors
  - DCD donors <55, < 30 min WIT, <15% macrosteatosis
  - TxC request
  - No split livers or livers with moderate or severe traumatic injury or active bleeding

# OCS Liver- why being used?

- Reduction of Early Allograft Dysfunction
  - (27 of 150 [18%] vs 44 of 141 [31%];  $P = .01$ )\*
- Reduction in histopathologic evidence of ischemia- reperfusion injury
  - less moderate to severe lobular inflammation: 9 of 150 [6%] for OCS Liver vs 18 of 141 [13%] for ICS;  $P = .004$ \*
- Higher use of DCD livers
  - 28 of 55 [51%] for the OCS Liver vs 13 of 51 [26%] for ICS;  $P = .007$ \*
- Reduction of incidence of ischemic biliary complications
  - 6 months (1.3% vs 8.5%;  $P = .02$ ) and 12 months (2.6% vs 9.9%;  $P = .02$ ) after transplant\*
- More control over recipient OR timing as well as potential for further distances

\*Markmann JF et al Impact of Portable Normothermic Blood-Based Machine Perfusion on Outcomes of Liver Transplant: The OCS Liver PROTECT Randomized Clinical Trial. JAMA Surg. 2022 Mar 1;157(3):189-198. doi: 10.1001/jamasurg.2021.6781.

# OCS Liver- How we're using it

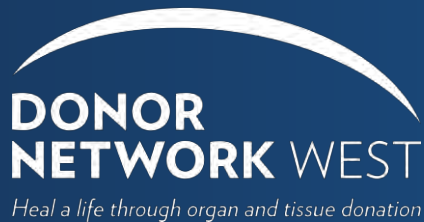
- OPO machine for local donor cases
- Import team partnering with local center's for national program
- Considerations:
  - Must partner with Transmedics to find qualified surgeon
    - Will also provide an OCS clinical expert, transportation and device through the national program if not through our local OPO.
  - Blood products- 5 units of PRBC's
  - Need backup surgeon in the OR for all DCD cases
  - Need second surgeon in the OR for pancreas (and sometimes for kidneys as well)

# OCS Liver

- Pros
  - Increase used of DCD livers
  - Ability to see how organ is performing following procurement
  - Reduction of post-tx complications
  - Greater control of recipient OR and Tx/C work/life balance
- Cons
  - Delay in donor OR's
    - This may not be possible in which Tx/C needs to decide if they will still accept.
  - Increase in costs
  - Logistics is more difficult
  - Extra surgeons needed in OR
    - Especially for DCD who may not pass in time
  - Difficulty in obtaining blood (5 units PRBC's) and chance for wastage if not used
  - Allocation is more difficult with donor cases that have time constraints (family, unstable donors or hospital barriers)



# Questions?



**Valerie Chipman, RN, BSN**

Director of Organ and Allocation Operations

[Vchipman@dnwest.org](mailto:Vchipman@dnwest.org)

*Thank You!*

# Independent Living Donor Advocate (ILDA)

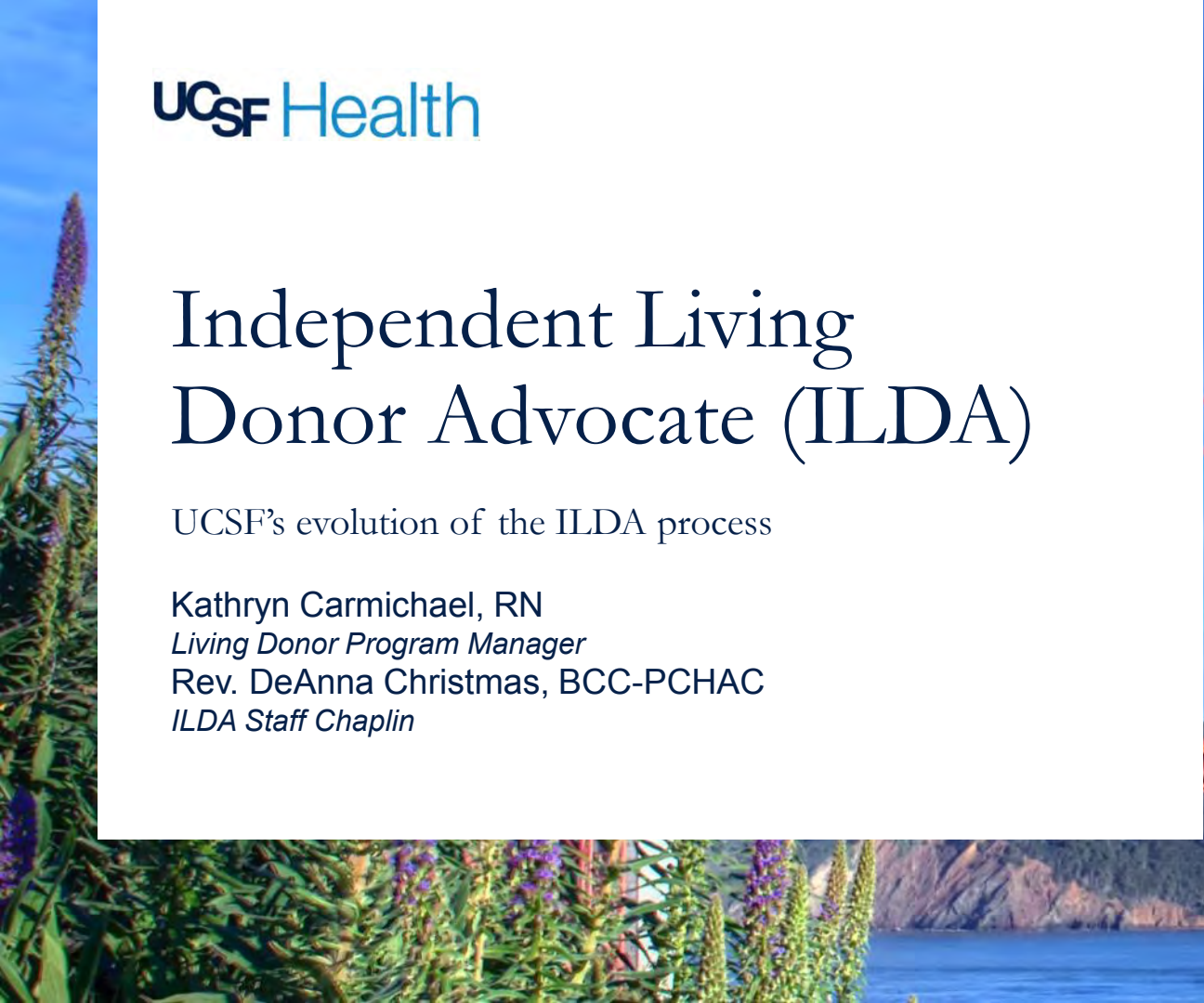
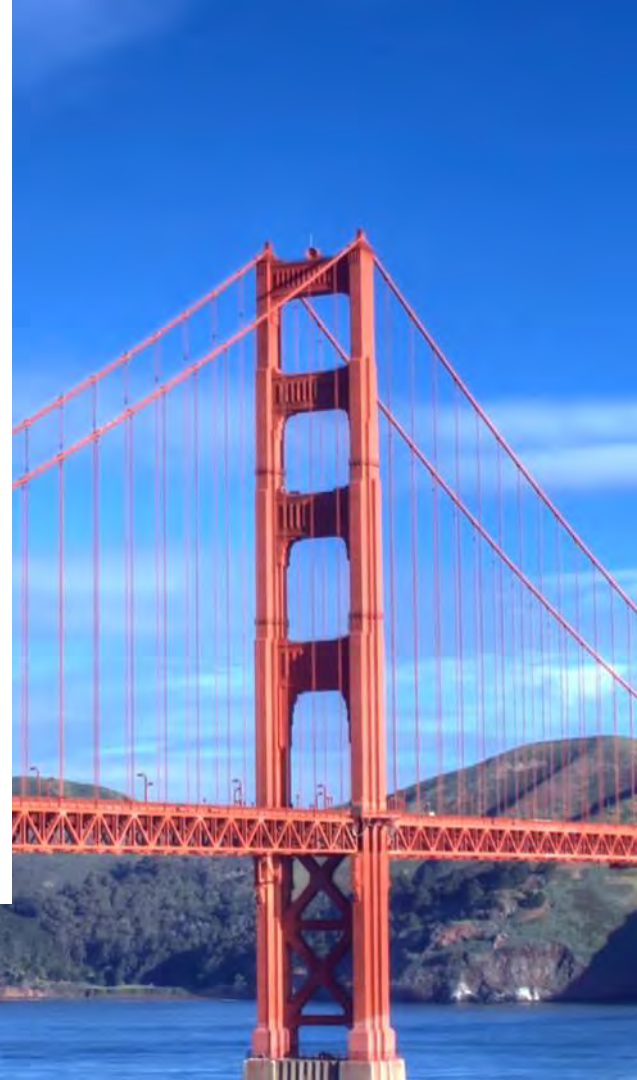
UCSF's evolution of the ILDA process

Kathryn Carmichael, RN

*Living Donor Program Manager*

Rev. DeAnna Christmas, BCC-PCHAC

*ILDA Staff Chaplin*





The living donor recovery hospital must designate and provide each living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

*OPTN Policies*

*Policy 14: Living Donation*

The future is living donation....

FY22	Liver	Kidney
Total dHHQ	1375	2829
Breeze Passed	888	1849
Registered	481	852
<i>Completed Labs</i>	<i>46%</i>	<i>54%</i>
<b>Total Transplants</b>	<b>196</b>	<b>370</b>
LD Complete	28 ( <i>14% of total Tx</i> )	131 ( <i>35% of total Tx</i> )
PE	**	53 ( <i>40% of LD cases</i> )

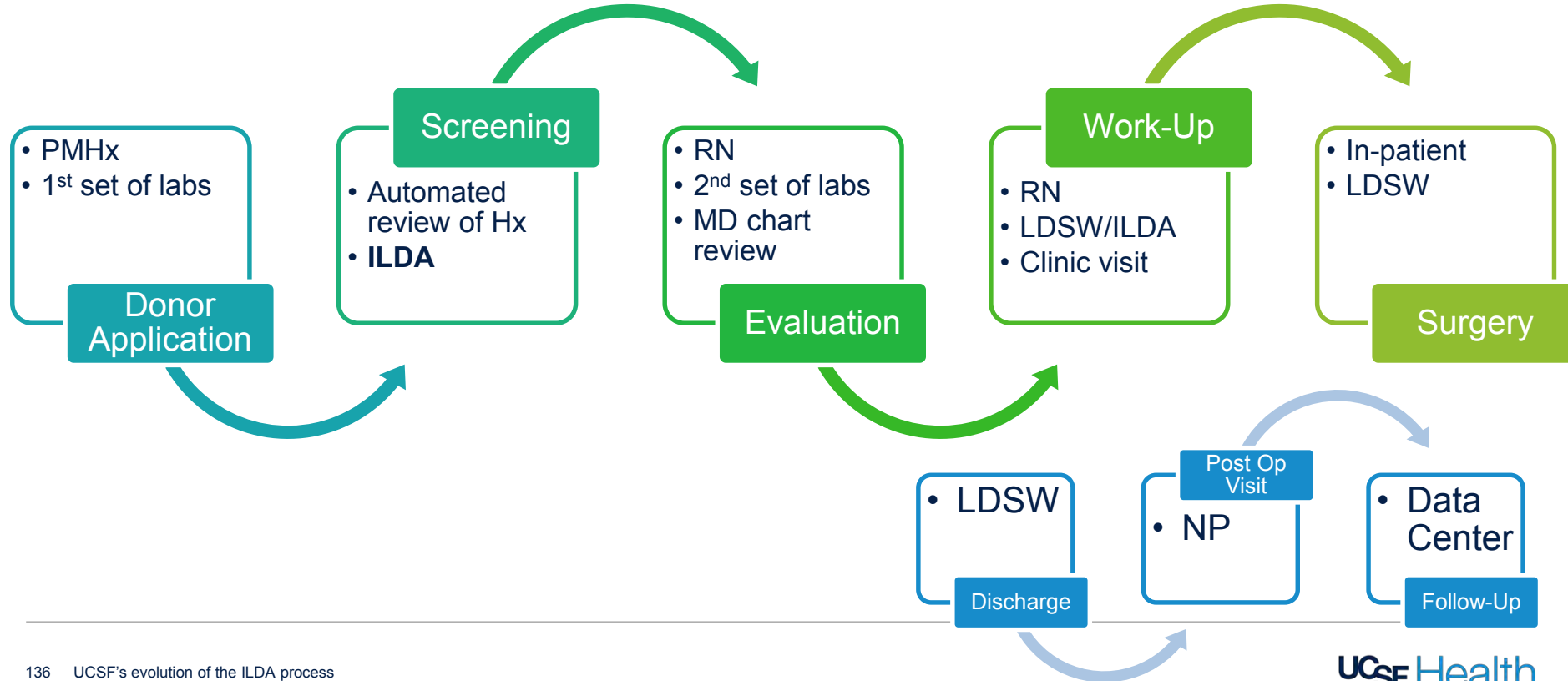


## UCSF Living Donor Team: Our Mission;

*Increase the amount of living donor transplants by elevating the patient experience. Assisting the donor to navigate the process, be an advocate for them, and support them to make well informed decision.*

# Our Current Workflow

## Example: Living Donor – Kidney





# UCSF Living Donor Team

Kidney	
Practice Coordinators	Cristina Maravilla
	Brady Ralston
	Jessica De Leon
	Lourdes Texin
	Magali Vasquez
	Michelle Acosta
Clinical Patient Navigator	Helen Christensen
Nurse Coordinators	John Nguyen
	Elizabeth Ortiga
	Hanna Kim
	Rosy Acevedo
Nurse Coordinator NKR Lead	Kelly DeDominic

Liver	
Practice Coordinator	Mary Ann Arias
	Koki Ylagan
Nurse Coordinator	Finesse Louie
	Caitlin Hohe
Kidney Recipient	
Admin Support	Karen Lew
Nurse Coordinator	Janine Sabatte-Caspillo
	Anthony Swanner
Living Donor	
Independent Living Donor Advocate	DeAnna Christmas
Living Donor Social Worker	Sandy Weinberg
Nurse Practitioner	Ana Marie Torres

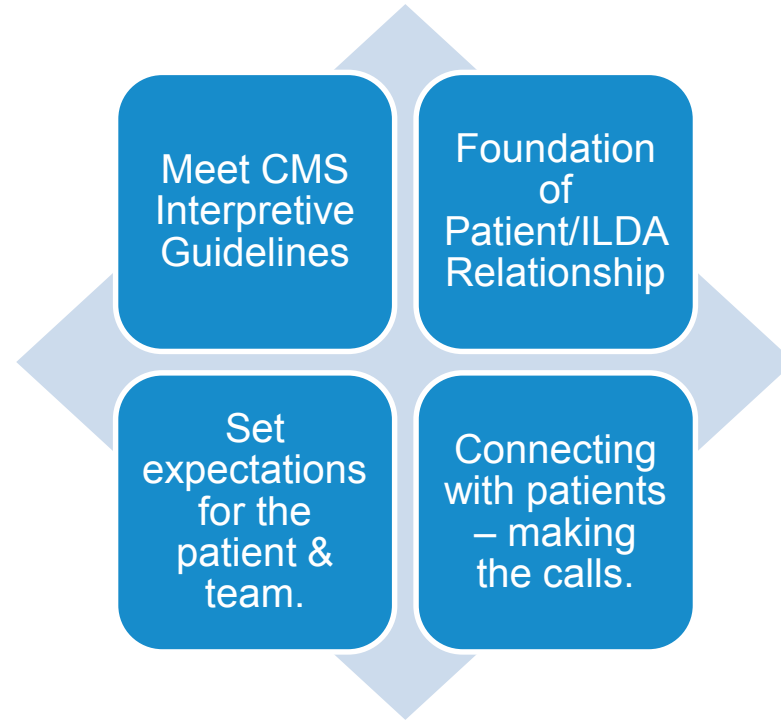
# Independent Living Donor Advocate

# PDSA Cycle 1

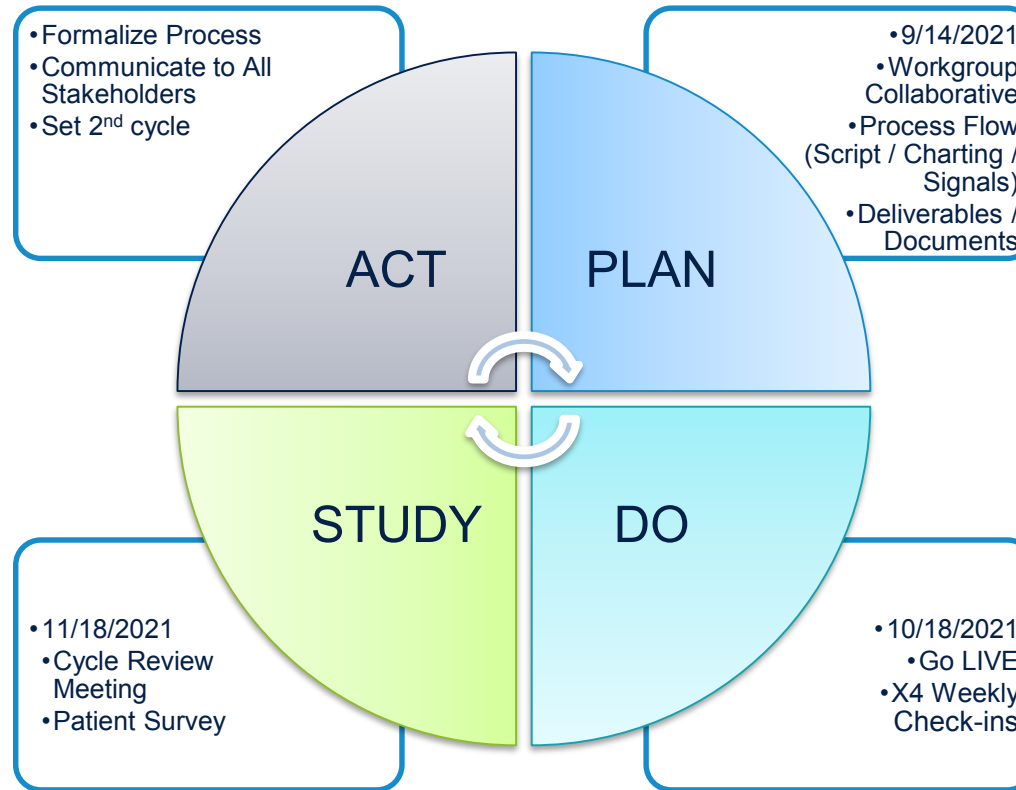
10/18/2021 - 11/12/2021



# Our guiding principles



# PDSA Cycle 1 - 10/18/2021 – 11/12/2021



# Study

## PDSA Cycle 1 Data

PDSA Week	Date Range	ABO received (Liver)	Registered in Titus (Kidney)	1st attempts completed	Liver	Kidney
-1	10/10/2021 - 10/16/2021		7	4	2	2
1	10/17/2021 - 10/23/2021		17	11	2	9
2	10/24/2021 - 10/30/2021		13	12	6	5
3	10/31/2021 - 11/06/2021		20	9	0	9
4	11/07/2021 - 11/13/2021		23	16	2	14

Total = 61 intros completed from cases assigned during PDSA weeks 1-4

8 cases expanded to 2nd attempts

1 case closed - Patient did not respond 2 weeks after 2nd attempt

2 cases have still not reached 2 weeks after 2nd attempt, but have assigned deadlines

# PDSA Cycle 1: patient survey data

42 Patients Surveyed

8 Responses = 19% Response Rate

Question	Yes	Unclear / N/A	No
1. Did you receive a call from the Independent Living Donor Advocate from UCSF?	8	0	0
2. Did they introduce themselves and explain their role clearly?	8	0	0
3. Was the concept of Informed Consent introduced / discussed?	8	0	0
4. Were you provided with an overview of the living organ donation process?	8	0	0
5. If you had any questions were they all answered?	7	1	0
6. Did the Independent Living Donor Advocate explain the next step in the Living Donor process <i>after</i> the Introduction Call?	8	0	0
7. Is there anything else you would like to add? (Optional)	See 3 comments below.		

*"The process was very thorough and complete"*

*"very helpful"*

*"UCSF made this happen very quickly and always were concerned about how soon we needed to get things started so my daughter would not [have] to start dialysis. It was amazing how everything feel into place. Thank You UCSF for giving my daughter a new life. She had never known what feeling normal felt like until she received a new kidney. "*



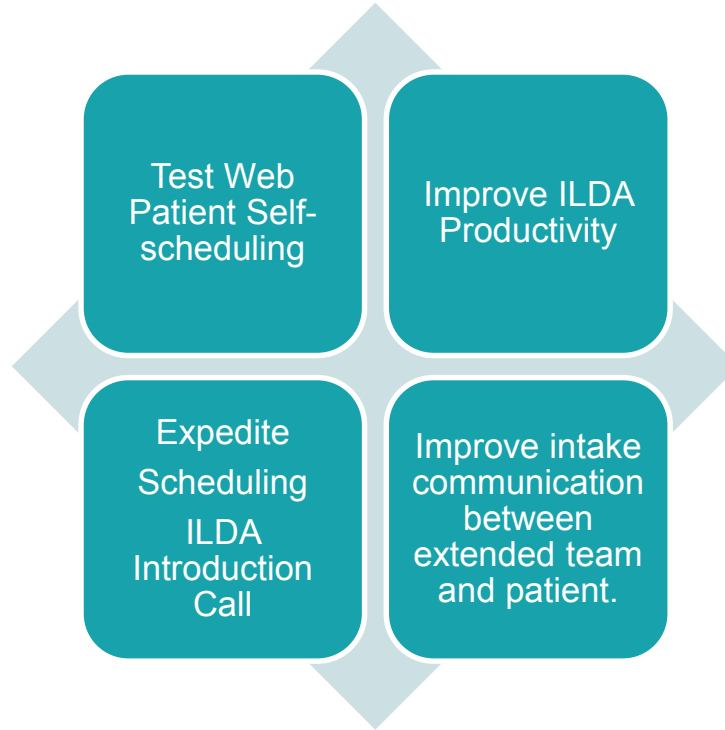
# PDSA Cycle 2

5/2/2022 – 5/27/2022

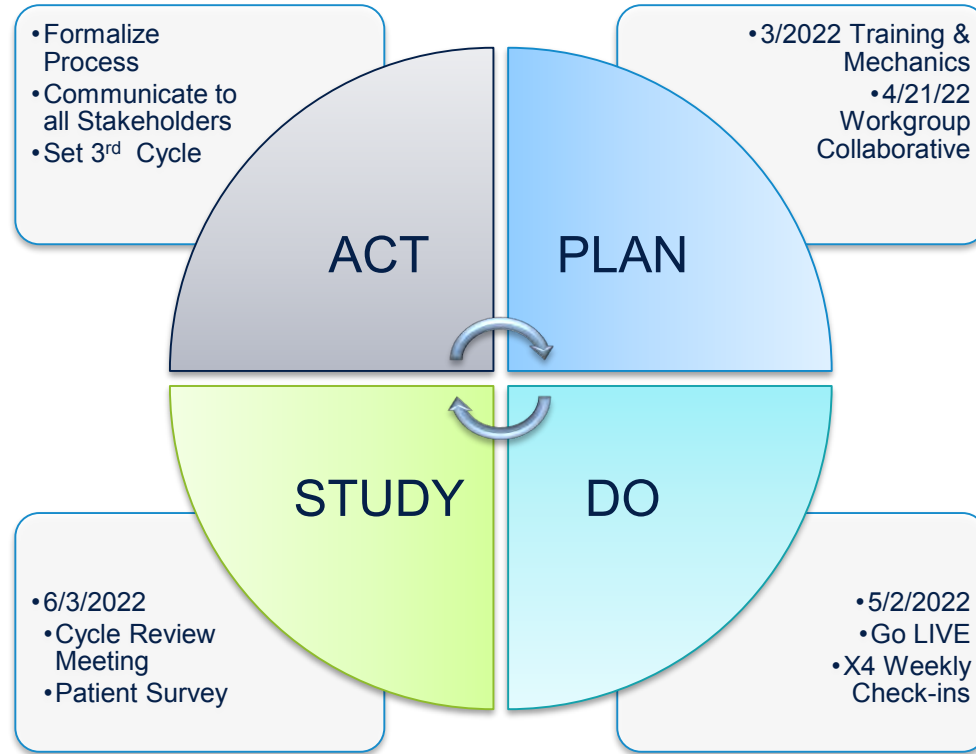




# Our guiding principles.

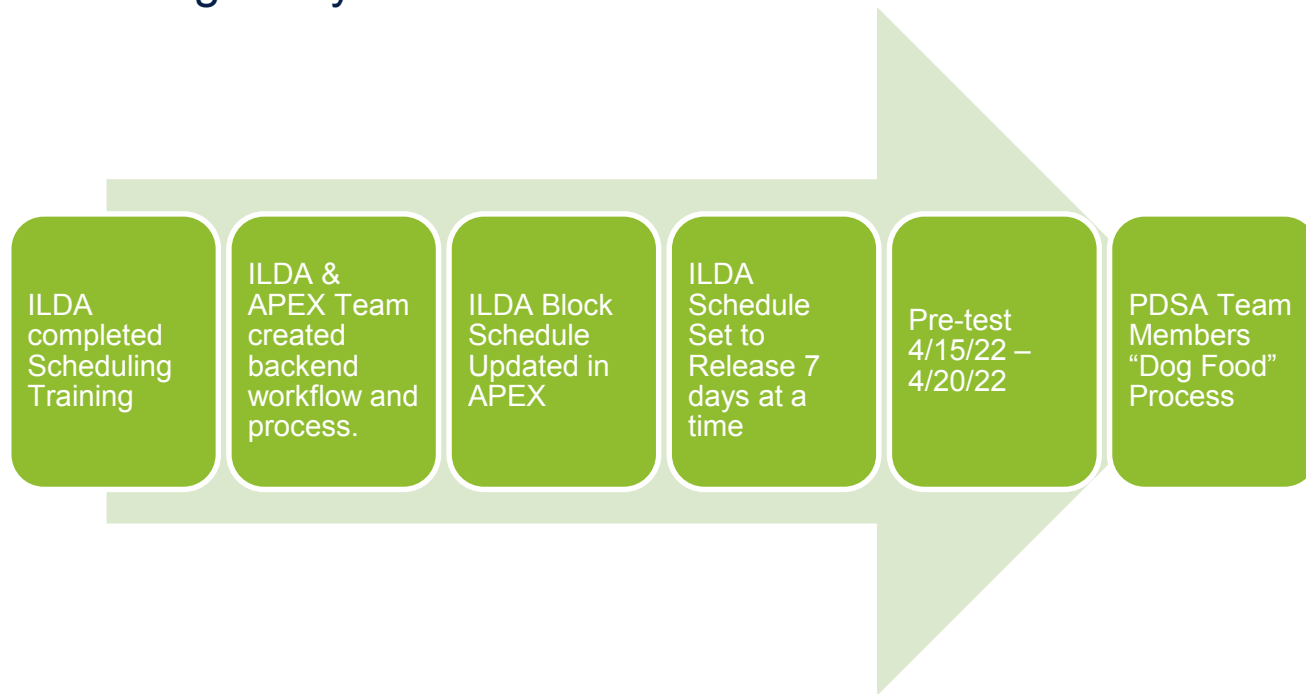


# PDSA Cycle 25/2/2022- 5/27/2022



# Plan

## Getting ready



- Pre-Test;
- 22 Web-scheduling Patient Invites
- (4/15 – 4/20)
  - 3 – waiting response 14%
  - 14 – Patient Scheduled 63%
  - 5 – ILDA Scheduled '1 Click' 23%

# Do

Testing 5/2/2022 - 5/27/2022

## All English Language Kidney & Liver Patients

- Sending e-mail & text
- Documented in APEX
- Patient schedules via URL – or – ILDA schedules with “1 Click”

## Non-English Kidney & Liver Patients

- ILDA Calls with Interpreter and schedules using “1 Click”

## RN / PC / SW ILDA Queries

- APEX vs. spreadsheet

# Study

## PDSA cycle 2 Data & Findings

•Patient Experience / Control	Increased ILDA Productivity – 50% Time Savings	Improved Donor Intake Communication	Decreased patient inquiries about next step.
<ul style="list-style-type: none"><li>•Answers question: “What’s happening?” “What’s next?”</li><li>•Patient selects time of appointment.</li></ul>	<ul style="list-style-type: none"><li>•Block scheduling for appointments and follow-up.</li></ul>	<ul style="list-style-type: none"><li>•ILDA Scheduling Appointment Invitation sent within 24 hours of request from Living Donor Nurse Coordinator.</li></ul>	

### 86 Patients / Average 20 per week

- 33 / 38% ILDA 1 Click Scheduled
- 52 / 61% Patient Self-scheduled
- 1 / 1% Unscheduled

Note: No apparent concerns about need to answer ‘insurance’ questions.

# PDSA cycle 2 patient survey data

84 Patients Surveyed	22 Responses = 26% Response Rate	
<b>Question 1: Did you receive a request from the Independent Living Donor Advocate (ILDA) to schedule an Introduction Phone Call?</b>	Yes: I received both an e-mail and a text message. Yes: I received an e-mail. Yes: I received text message. No: I did not receive a request.	64% (n14) 28% (n6) 8% (n2) 0
<b>Question 2: How did you schedule your Introduction Phone Call with the ILDA?</b>	I scheduled the appointment using UCSF MyChart.. I called the ILDA, and the ILDA scheduled the appointment for me.	50% (n11) 50% (n11)
<b>Question 3: On a scale of 1-5 ( 1 easy - 5 difficult), how easy was it to schedule the ILDA Introduction appointment?</b>	Very Easy Easy Neither Easy Nor Difficult Difficult Very Difficult	77% (n17) 9% (n2) 9% (n2) 5% (n1) 0
<b>Question 4: Is there anything else you would like to add? (optional)</b>	<ul style="list-style-type: none"> <li>• <i>nothing this time</i></li> <li>• <i>no</i></li> <li>• <i>Call and answers were very much appreciated...</i></li> <li>• <i>Yes I'm happy to give my grandmother my kidney!!</i></li> </ul>	

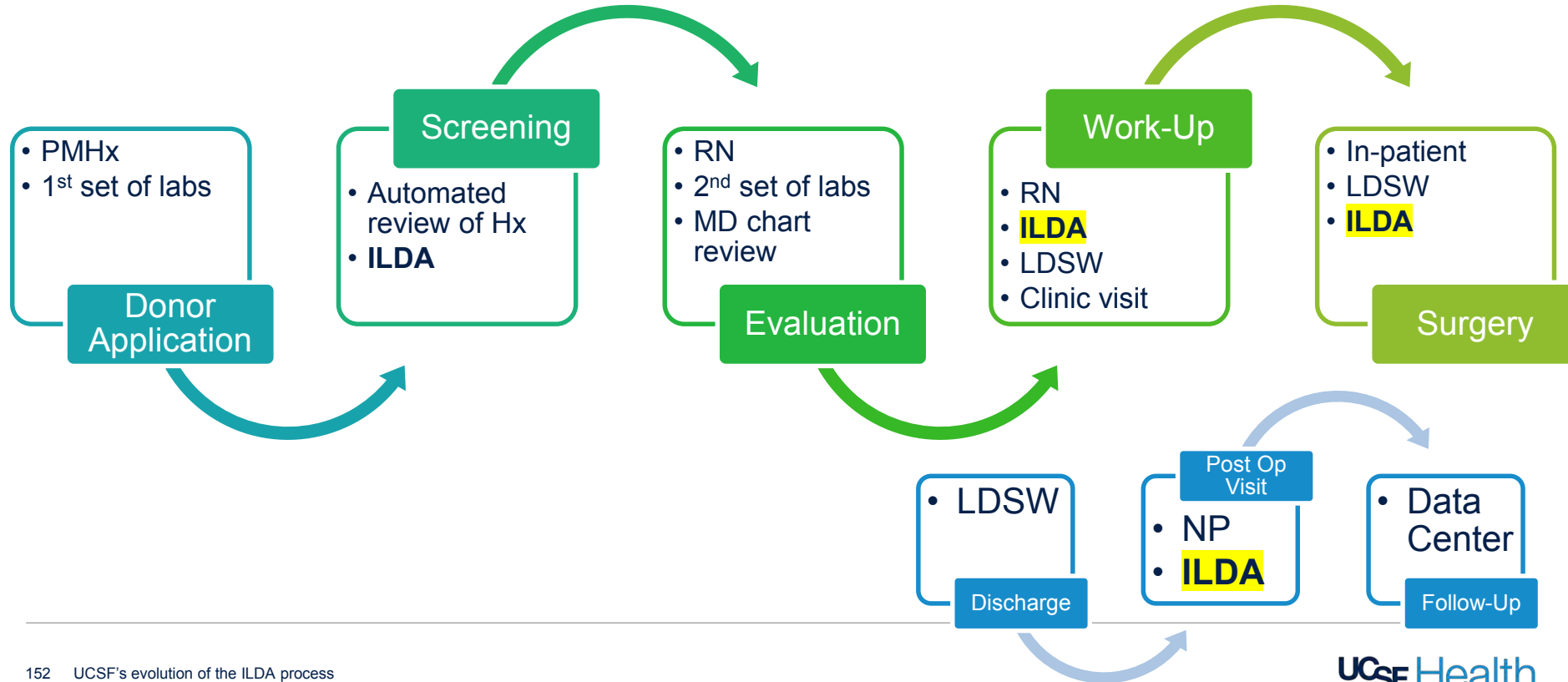


ILDA future state. Developing continuum of care.

Each member of the team is a donor advocate, however by having a dedicated ILDA to support a donor through the whole process we hope that we will retain patients and see red flags earlier.

# Our *Future* Workflow

Example: Living Donor – Kidney









# **CMS Revised OPO Final Rule OPO / Transplant Center and Donor Hospital Impact**

---

## **CMS Potential Organ Donor Definition Change 42 CFR § 486.302**

- Published in Federal Register December 2, 2020
- Implementation August 1, 2022
- First OPO performance measurement threshold period 2023
- First OPO performance measurement period 2024
- First OPO certification/decertification 2026



**CMS Potential  
Organ Donor  
Definition  
Change 42  
CFR § 486.302**

- **What remains:**
  - 75 years or younger
  - Death occurred in an inpatient setting
- New Term: **Donor potential**
  - The number of inpatient deaths within the DSA among patients 75 years and younger with primary causes of death consistent with organ donation.

## CMS Potential Organ Donor Definition Change 42 CFR § 486.302

- **Primary Impact:**  
Removes subjectivity of self reporting donor eligibility

Introduces variation of state by state death certificate data

# CMS Potential Organ Donor Definition Change 42 CFR § 486.302

- **New Terms:**
  - **Donation Rate:**
    - Organ Donors ÷ Donor Potential
  - **Organ Transplantation Rate:**
    - Organs Transplanted ÷ Donor Potential
      - Risk adjusted for age

OPOs impact the  
numerator ...

... with help from  
Transplant centers transplanting organs  
Donor hospitals partnerships  
EMR access  
OR availability  
Timely referrals  
Registry Support  
Donor families saying yes  
Funeral Homes  
Medical Examiners  
Media stories



# CMS Potential Organ Donor Definition Change 42 CFR § 486.302

- **Organ donor:**

- Current:
  - A person who has been declared dead with at least one organ recovered.
- New:
  - A person who has been declared dead with at least one organ transplanted or Pancreas used for research or islet cell transplantation.

- **Organs Transplanted:**

- Current:
  - The number of organs recovered that results in transplant.
- New:
  - The number of organs recovered that results in transplant or Pancreas used for research or islet cell transplantation

RNTs don't count...  
unless the pancreas goes for  
research



# Donor Hospital Impact

Death Record Review Process to be inclusive of review of primary diagnoses via ICD-10-CM codes

Changes to referral criteria to evaluate those with a primary diagnosis consistent with organ donation (or broader)

Increased DCD opportunities leads to increase in hospital resource utilization and unique navigation for donor timing

Increased Involvement of donor families, OPO resources, transplant center resources

## OPO Survey

- **Brain Death donation growth:**
  - Room for improvement, but low growth expectations
- **DCD donation growth**
  - Higher growth expectation
  - OPO variation in pursuit
- **Extended criteria organ transplants:**
  - All OPOs looking at transplant center acceptance practices and basing decisions on extended criteria center tolerance limits
  - Increasing Expedited Placement / Open Offers

# Allocation Policy Changes timeline

June 2013 – Share  
35 **Liver** allocation

November 2017 –  
DSA removed from  
**Lung** Allocation

February 2020 –  
DSA removed from  
**Liver** Allocation

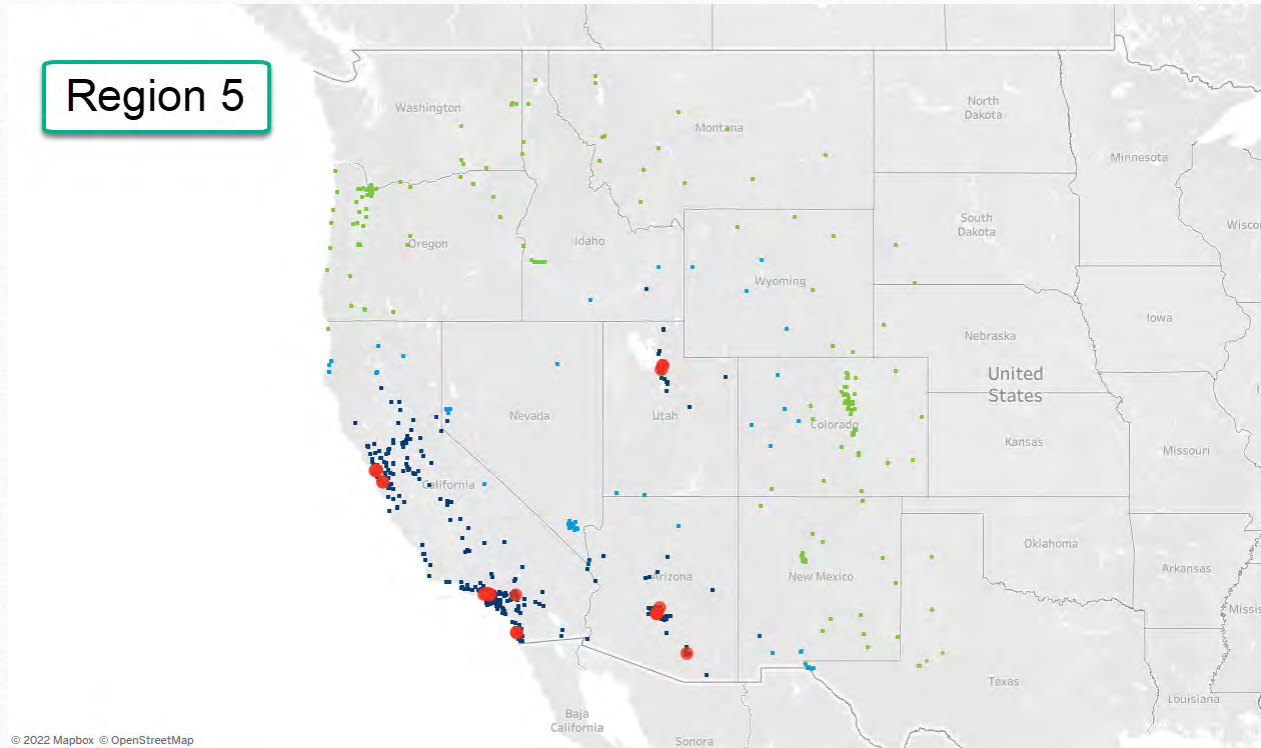
December 2014 –  
New  
**Kidney/Pancreas**  
Allocation System

October 2018 –  
DSA removed from  
**Heart** Allocation

March 2021 – DSA  
removed from  
**Kidney/Pancreas**  
Allocation

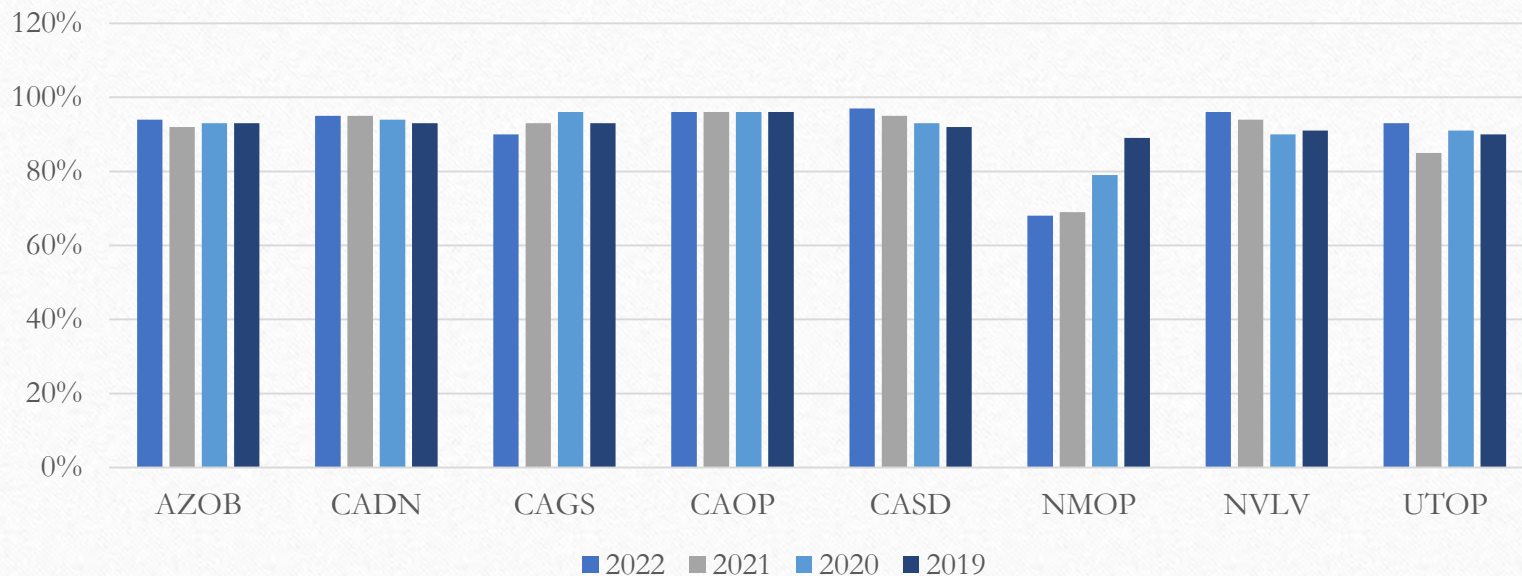


## Region 5

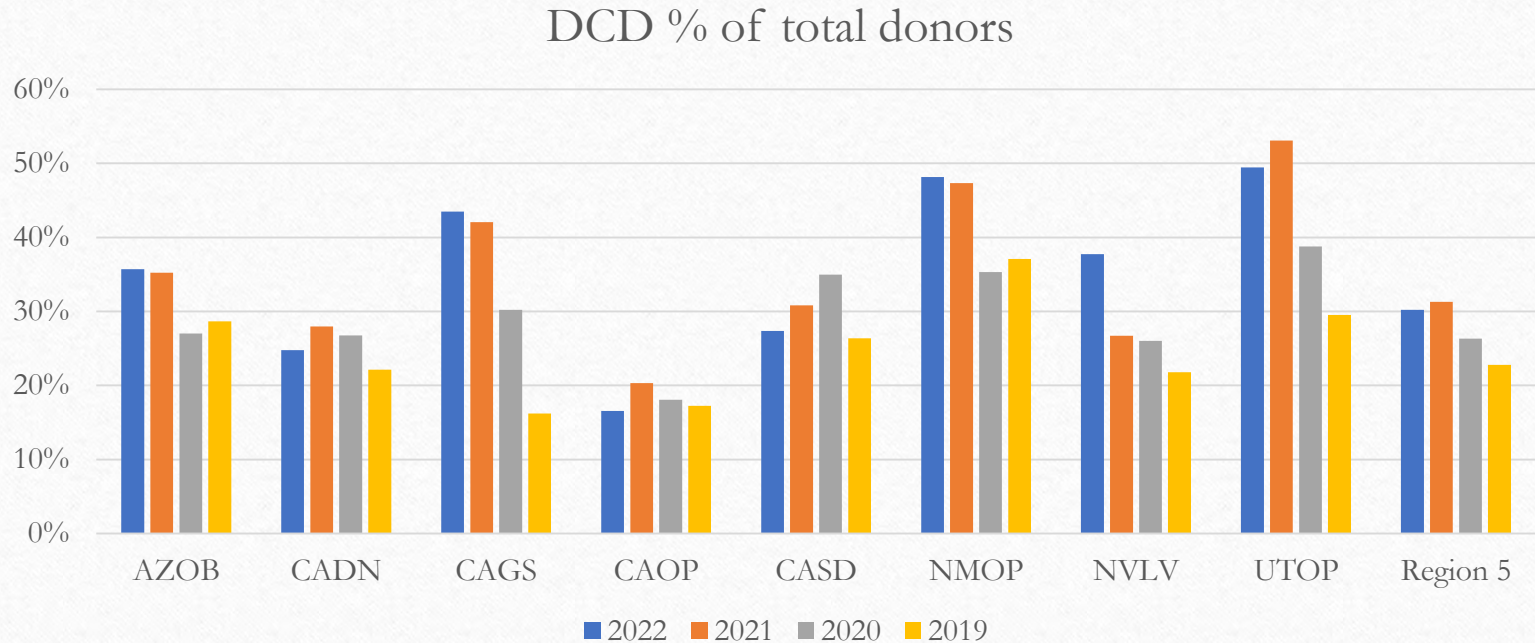


## Region 5 Donation Demographics

% Transplants in Region 5 by OPO



## Region 5 Donation Demographics





## OPO Future considerations

DCD donation growth

Age limit increases

NRP and Perfusion  
increases

Truncated timeline cases

Resource Realignment

Increased hospital  
development

Medical Record Reviews

Referral Response

Increase in Organ Offers

We

will

Offer everything

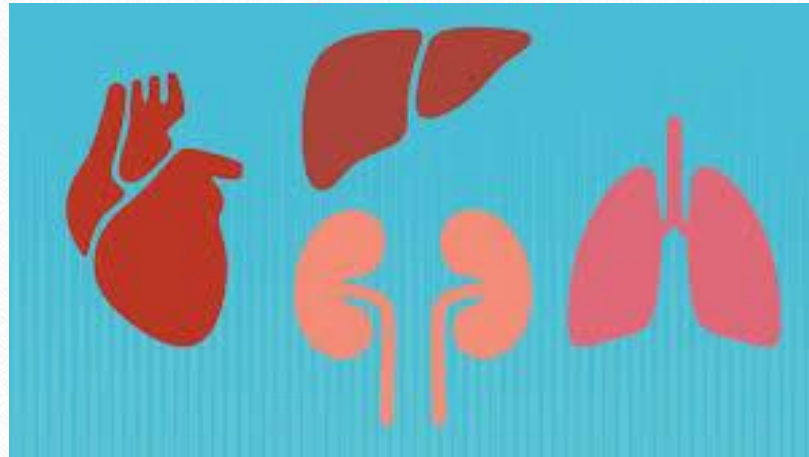
Questions?

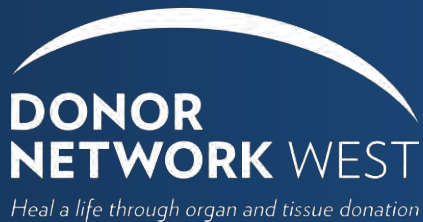
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What impact have the new OPO requirements had so far on transplant centers? What changes has your center had to make?

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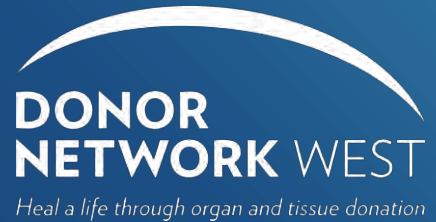




# Better Together: The DEI Journey Continues

Donyale John & Luis Mayen

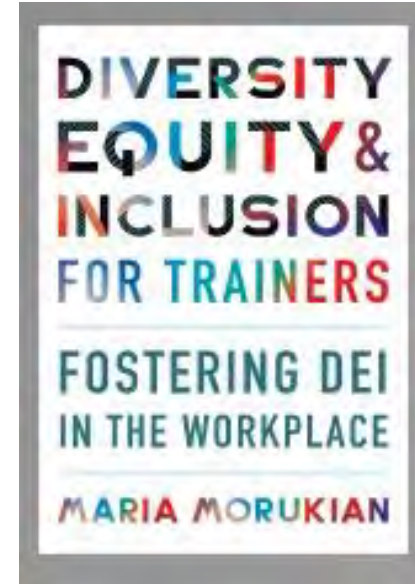
# Maintaining a DEI Council



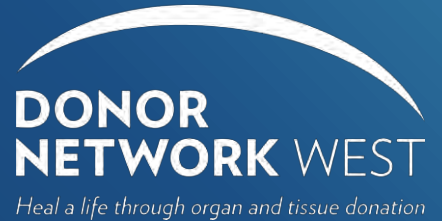
- “Shortly after I was hired, I learned that Donor Network West had a DEI Council and I knew instantly that this was something I wanted to be a part of. I strongly believe that folks who benefit from systemic privilege are tasked with integrating meaningful DEI action into their workplaces. It’s been an incredible learning experience thus far and I look forward to continued reflection on this essential journey towards making the world a kinder, more equitable place for everyone.”  
— Samantha K.

# DEI Council In Action

- Membership
- Commitment
- Ongoing education



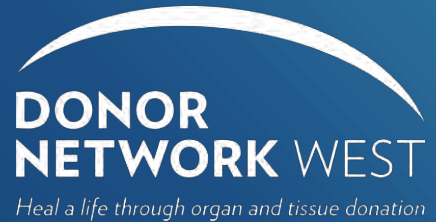
# Safe Spaces for Bold Conversations



# Discussion Topics

- The Power of Allyship: Understanding the Impact and Power of Words
- Exploring Bias
- Cultural Humility vs. Cultural Competence
- Living with Disability
- Schwartz Rounds- Bumping Into Bias: Experiences When Who You Are Impacts What You Do
- Microaggressions

# A Committed Organization







## Passion

DNWest is composed of caring professionals aligned with our mission who give their all to help save lives & inspire our communities to donate life



## Excellence

DNWest is solution oriented, team focused, bold change agents utilizing our experience & expertise to optimize the gift of life

# Core Values



## Diversity, Equity & Inclusion

Team members respect & value people of all backgrounds; appreciate & celebrate differences in others & create an environment of equity & inclusion with opportunities for everyone to reach their potential



## Relationships

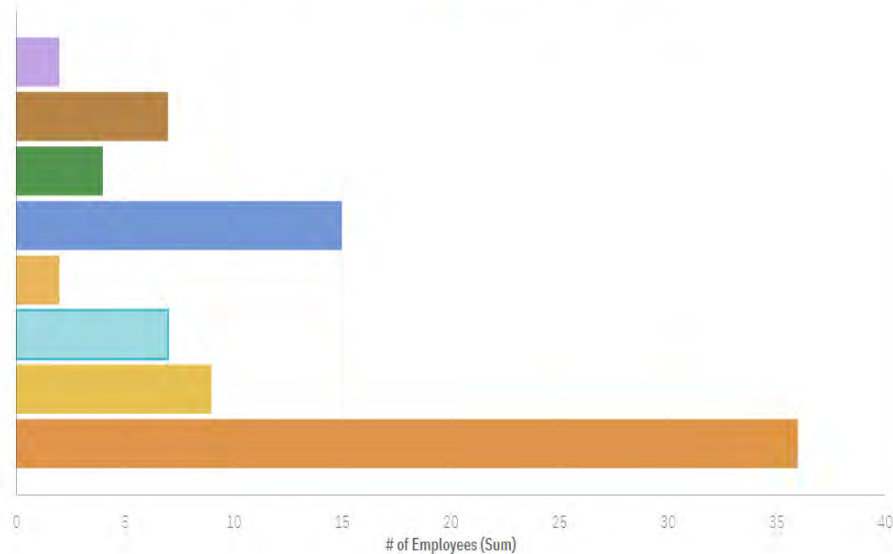
Team members are respectful stewards who honor donors, show compassion and support for donor families, advocate for recipients & empower collaboration with external/internal partners

# New Hires in 2022

New Hires by Ethnicity for 2022

Ethnicities

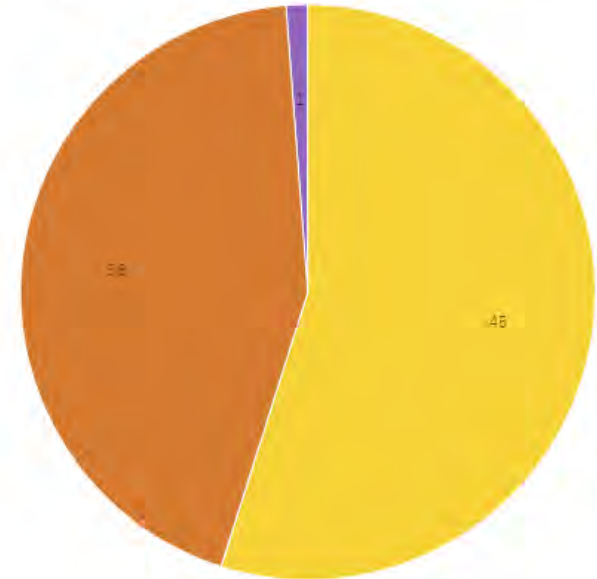
- American Indian/Alaskan Nati...
- Asian
- Black or African American
- Hispanic or Latino
- Native Hawaiian or Other Pacif...
- Not specified
- Two or more races
- White



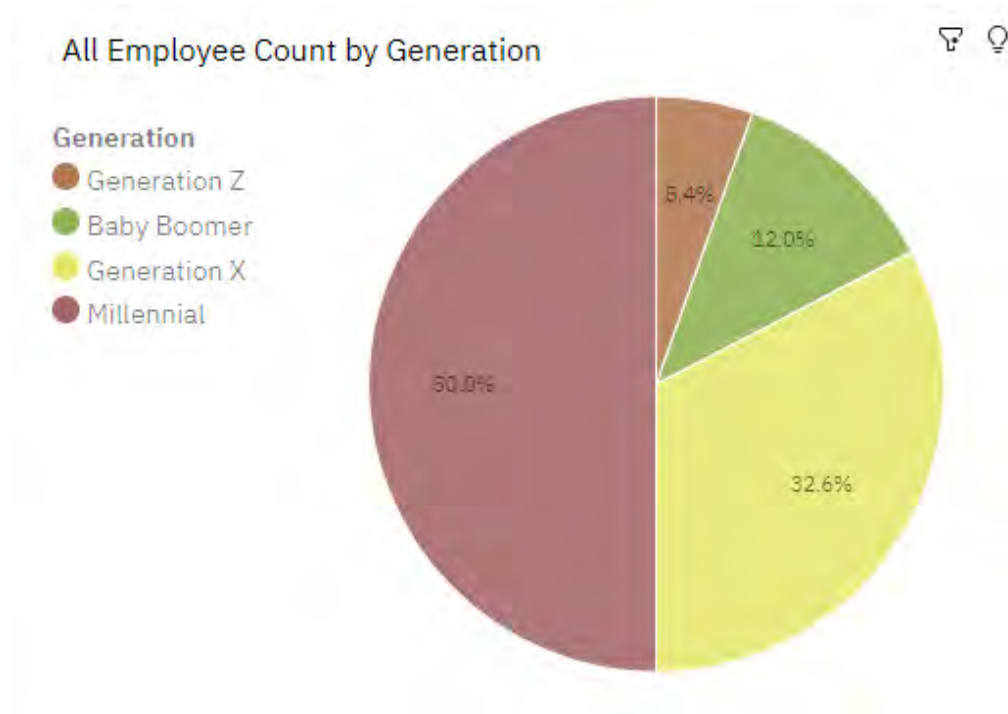
New Hires by Gender in 2022

Genders

- Female
- Male
- Non-Binary



# Employee Count by Generation

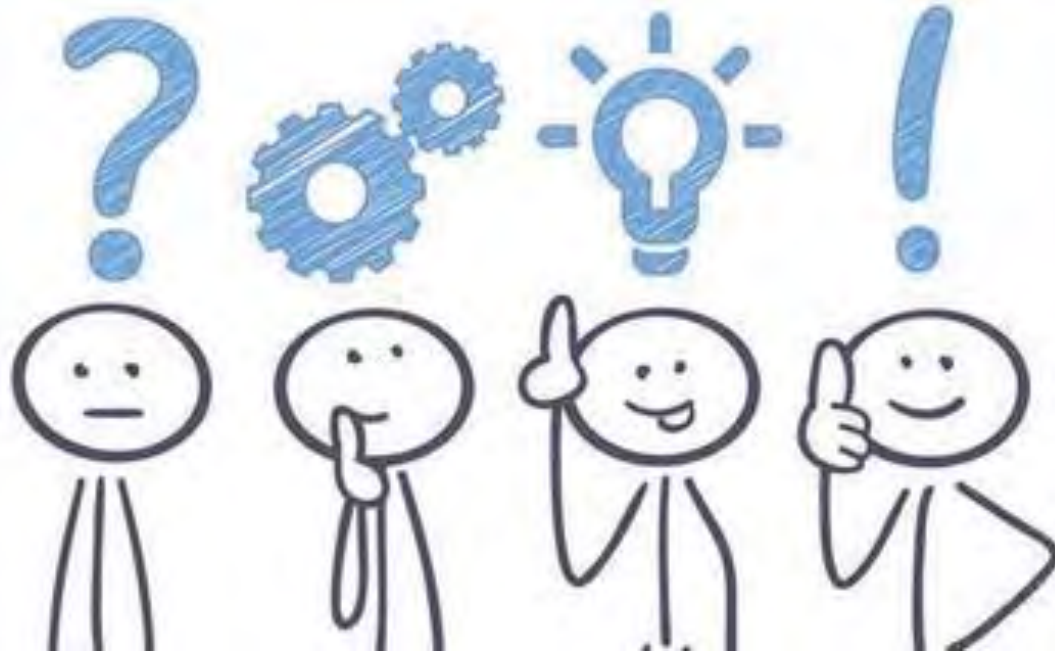


# DEI in the Community



## DONOR NETWORK WEST

# Questions



*Thank You!*

# Connect with us on social media!

- Find and follow us using our handles 



@unosnews



@UNOSNews



@UnitedNetworkforOrganSharing

- Tag us in your posts



@UnitedNetworkforOrganSharing