

Collaborative Innovations in Organ Procurement: A Deep Dive into NRP Implementation – What Have We Learned?

TODAY'S PRESENTERS



Doug Butler

Chief Operating Officer



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Trauma Surgeon



Charles Strom

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Surgical Director



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MD, PHD
Medical Director; Transplant Surgeon

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in Organ Donation & Transplantation*

Thursday, February 23, 2024, 3:00pm – 4:00pm ET

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Deanna Fenton

Senior Manager, Program
Development and
Operations



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Meet Our Moderators



Faith Hilterbrand

Director,
External Partner Relations



Cheryl Edwards CPTC

Regional Team Lead; Senior Donation
Coordinator



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Moderators: Cheryl Edward, New England Donor Services
Faith Hilterbrand, Lifeline of Ohio

Today's Panel



Doug has 25+ years in healthcare, with over 18 of it in organ procurement. He's a registered nurse and has a master's degree in healthcare administration. Doug has held many roles within the OPO and found his passion for DCD many years ago as a front-line organ coordinator when he fought to eliminate the use of predictor tools. Fun fact: At his current OPO, he's known as DCD Doug. He's excited to talk to you today about Southwest Transplant Alliance's success with NRP.

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Dr. Charles Strom is a board certified transplant surgeon serving as Surgical Director of New England Donor Services. He earned his MD from the University of Massachusetts Medical School, completed his residency in General Surgery at St. Elizabeth's Medical Center in Boston and pursued fellowship training in Abdominal Organ Transplant at the Massachusetts General Hospital. Prior to his role as Surgical Director at NEDS, he went into practice at Tufts Medical Center as an Attending Surgeon in the Division of Kidney Transplant Surgery, and became Associate Director of the General Surgery Clerkship at Tufts Medical School. He was recruited to New England Donor Services in late 2019 to take on the newly-created role of Surgical Director, focusing on optimizing the surgical practice and increasing efficiencies in deceased donor organ procurement. Dr. Strom takes an active role in placing organs for transplant particularly with late declines and marginal organs.

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Objectives

1. Collaborative strategies to increase organ utilization through NRP policy and protocol development.
2. Internal and External communication strategies ensuring support of NRP protocol.
3. Best practice clinical considerations including staffing, supplies, and training to maximize donation through NRP.

NRP: An OPO's Experience

Doug Butler RN, MBA
Chief Operating Officer



Getting Started

- First case 5/11/2021
- TA-NRP case
- 32 minutes WIT
- 5 minutes to cannulate and start NRP
- Heart, Lungs, Kidneys transplanted



Next Steps

- Internal review of process
- Stance of OPO on topic
- OPO hosted NRP Forum (8/11/2021)
 - Experts in TA-NRP/A-NRP
- Advisory Board involvement

What Now?

- Conflicts with teams (NRP or no NRP)
- Hospital concerns
- Our team's comfort level
- Family considerations
- Policies
- Public perception
- Authorization process

Questions in an Ideal State

- What's your organization's stance?
- What infrastructure is needed to support?
- How do you create buy in?
- How do you communicate internally and externally?
- *What's at stake if you don't do it?*



What's Your Stance?

- STA stands by NRP being an ethical and legal way of maximizing donation
- TA-NRP and A-NRP is a method of reconditioning organs for transplant after death
- Machine preservation and reconditioning is not new, and NRP is in the same category

ETHICS ISSUES IN ORGAN DONATION



Infrastructure

- Policies
- Authorization
- Workflows
- Documentation
- Escalation pathway



Buy In

- Rely on the experts
- Data driven approach
- Normalizing
- Staying the course



Communication

- Normalizing
 - Stick to the positives
- Preparation
 - Technical and staffing
- Basic and clear
- Leadership presence
- Wins



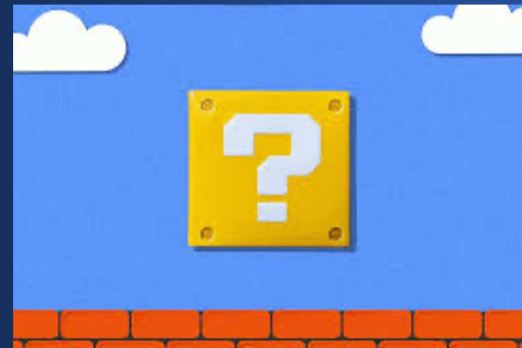
What's at Stake

- Lives
 - 2.82 vs. 1.70 OTPD difference
- Unrealized donor potential
 - WIT, Age, unstable pts
- OPO decertification
- Patient outcomes



Common Questions

- Authorization
- Hospital Communication Plan
- Allocation
- Preparation for OR



Authorization

- “Therapeutic interventions”, “Medical interventions” in authorization form
 - Details dependent on family needs/requests
- Pre-cannulation requires hospital consent
- NRP status not know at initial authorization
 - No re-approach needed if central NRP



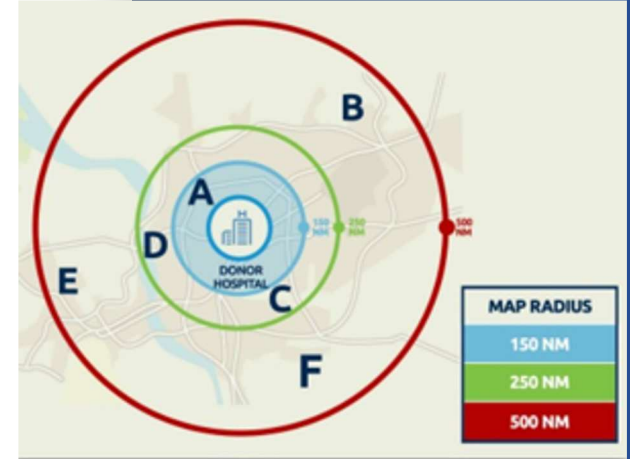
Hospital Communication Plan

- Standard practice
- Policy review
- Opportunity for procedures
- Proactive OR approach
- Huddles early on



Allocation

- All organs allocated
 - Similar to BD criteria
- NRP is the priority
 - Escalation to MD and AOC if issues
- Inform centers when it becomes NRP



Preparation for OR

- Staffing and equipment
- OR room size
- Huddle, huddle, and more huddles
- Documentation
 - Internal forms
- Extubation in OR or pre-cannulation

What If?

- Centralized DCD
- NRP as a standard
- Consistent DCD policies
- Maastricht II donors



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donor today!**

donatelifetexas.org

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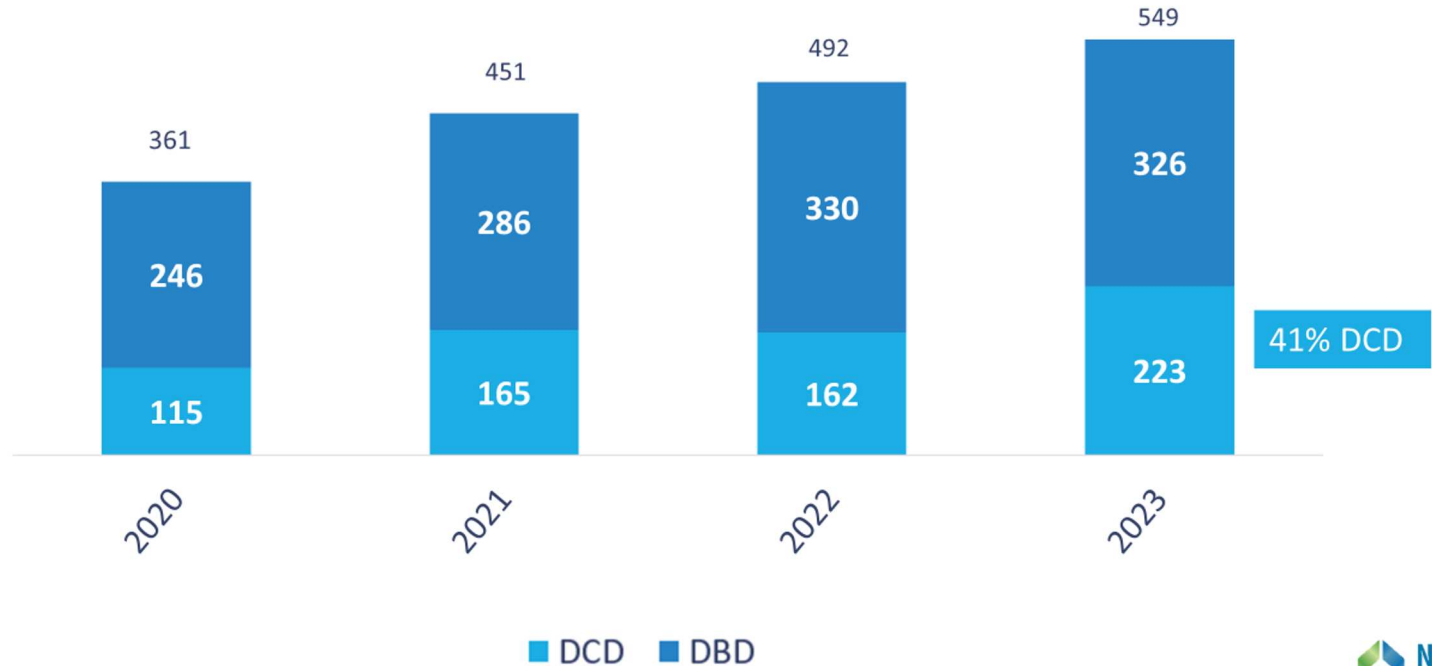
Normothermic Regional Perfusion

CHARLES STROM, MD
SURGICAL DIRECTOR
FEBRUARY 22, 2024

NEDS Organ Donors

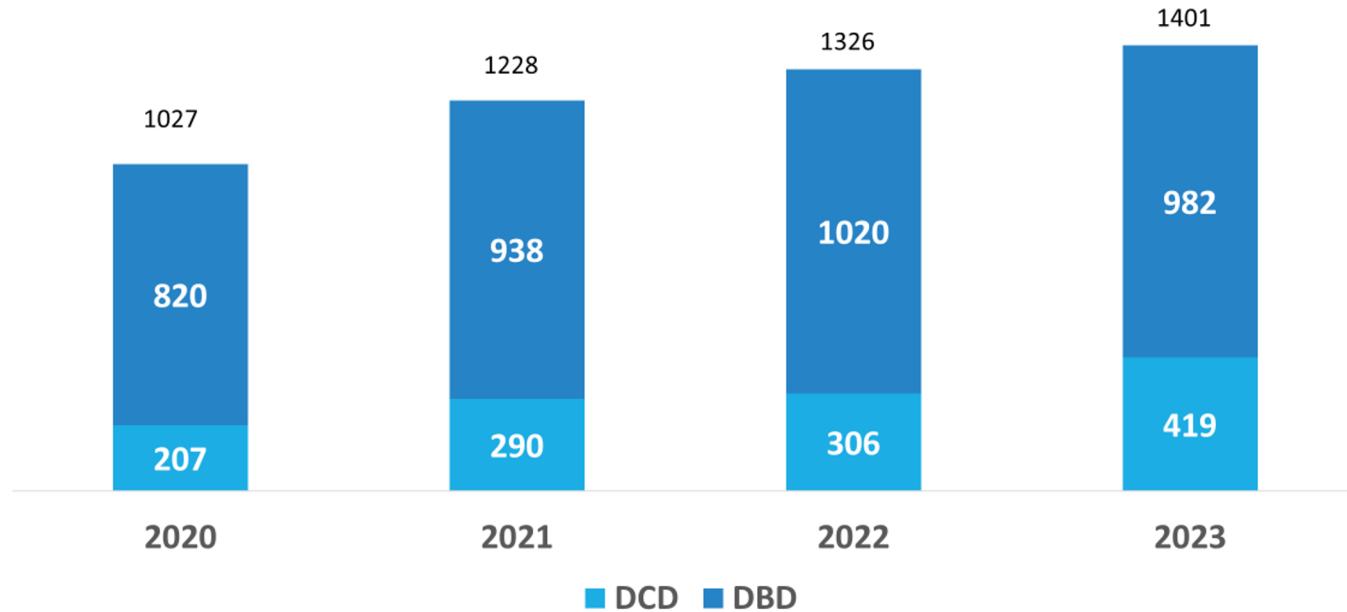
Fourth Largest OPO by Donor Volume in US

53% Increase since 2020

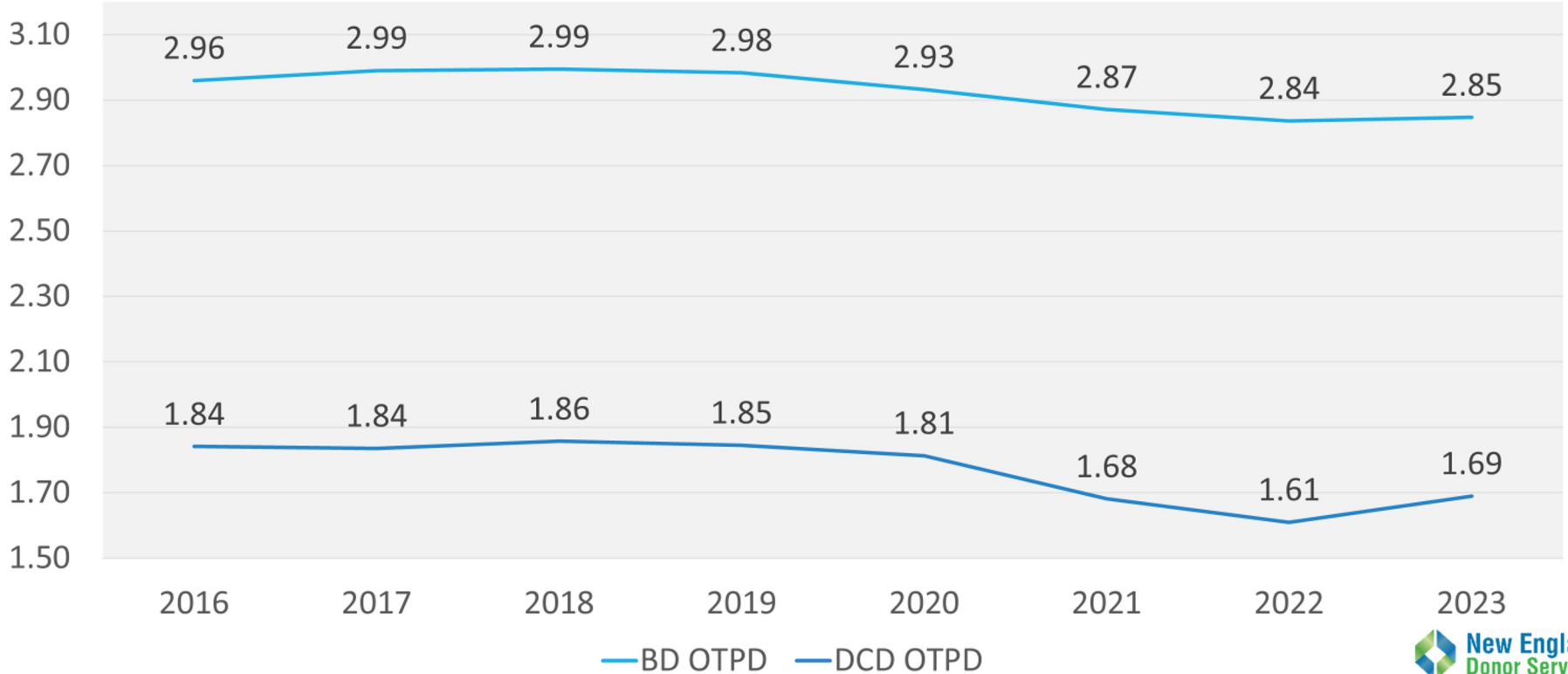


NEDS Organs Transplanted

35% Increase since 2020



Rate of Organs Transplanted per Donor



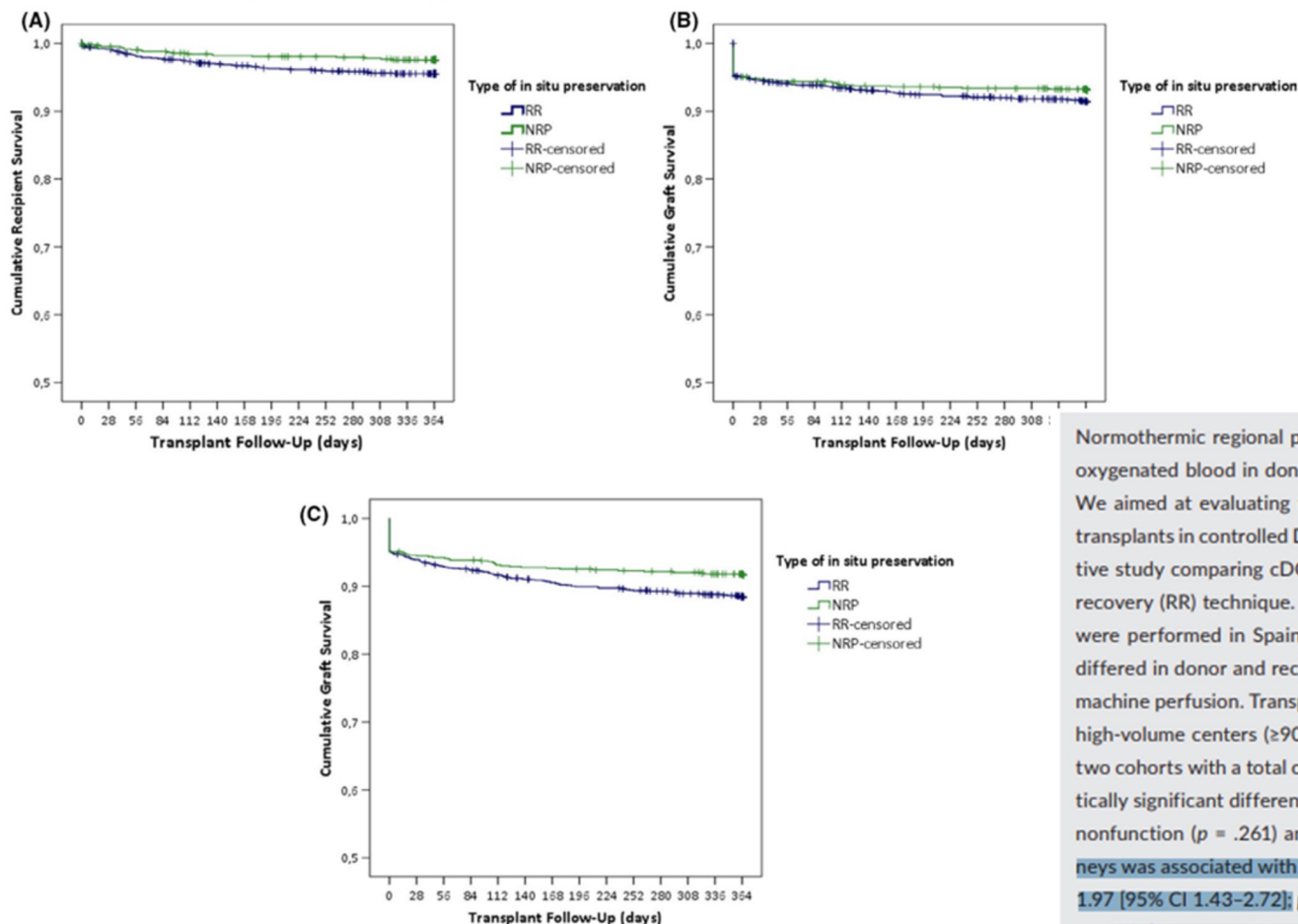
Strategies to Increase Utilization and Transplant Outcomes

- Pursuit of medically complex/older DCD
- Opportunities to increase organs transplanted from DCD
 - Rate of extra-renal organ transplant from DCD remains low
 - Data supports better kidney transplant outcomes with NRP
 - Higher rate of biliary complications in livers from DCD vs BD
- Machine perfusion technologies
 - Effective but expensive

Improved short-term outcomes of kidney transplants in controlled donation after the circulatory determination of death with the use of normothermic regional perfusion

María Padilla¹ | Elisabeth Coll¹ | Cristina Fernández-Pérez^{2,3} | Teresa Pont^{4,5} | Ángel Ruiz⁶ | Marina Pérez-Redondo⁷ | Eva Oliver⁸ | Lander Atutxa⁹ | José M. Manción¹⁰ | Domingo Daga¹¹ | Eduardo Miñambres^{12,13} | José Moya¹⁴ | Bárbara Vidal¹⁵ | José M. Dueñas-Jurado¹⁶ | Fernando Mosteiro¹⁷ | Alberto Rodríguez-Salgado¹⁸ | Esperanza Fernández-García¹⁹ | Ramón Lara²⁰ | Domingo Hernández-Marrero²¹ | Belén Estébanez²² | María Luisa Rodríguez-Ferrero²³ | María Barber²⁴ | Fernando García-López²⁵ | Amado Andrés²⁶ | Carlos Santiago²⁷ | Ana Zapatero²⁸ | Rafael Badenes^{29,30,31} | Francisco Carrizosa³² | José J. Blanco³³ | José L. Bernal^{34,3} | Francisco J. Elola³ | Cristina Vidal¹ | Christel Terrón¹ | Pablo Castro³⁵ | Jordi Comas³⁶ | Beatriz Domínguez-Gil¹

Normothermic regional perfusion (NRP) allows the in situ perfusion of organs with oxygenated blood in donation after the circulatory determination of death (DCDD). We aimed at evaluating the impact of NRP on the short-term outcomes of kidney transplants in controlled DCDD (cDCDD). This is a multicenter, nationwide, retrospective study comparing cDCDD kidneys obtained with NRP versus the standard rapid recovery (RR) technique. During 2012–2018, 2302 cDCDD adult kidney transplants were performed in Spain using NRP ($n = 865$) or RR ($n = 1437$). The study groups differed in donor and recipient age, warm, and cold ischemic time and use of ex situ machine perfusion. Transplants in the NRP group were more frequently performed in high-volume centers (≥ 90 transplants/year). Through matching by propensity score, two cohorts with a total of 770 patients were obtained. After the matching, no statistically significant differences were observed between the groups in terms of primary nonfunction ($p = .261$) and mortality at 1 year ($p = .111$). However, the RR of kidneys was associated with a significantly increased odds of delayed graft function (OR 1.97 [95% CI 1.43–2.72]; $p \leq .001$) and 1-year graft loss (OR 1.77 [95% CI 1.01–3.17]; $p = .034$). In conclusion, compared with RR, NRP appears to improve the short-term outcomes of cDCDD kidney transplants.



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Benefits of NRP

- Opportunity to increase organ utilization from DCD
- In situ functional assessment of organs
- Improved recipient outcomes compared to DCD
- Allows increased time from extubation to circulatory cessation
- Expansion of DCD suitability criteria
- Reallocation of organs declined intraoperatively while on NRP
- More controlled dissection, lower risk of surgical error
- Reduced cost compared to ex situ normothermic machine perfusion
 - In conjunction with machine perfusion options

Different Approaches to NRP in US

- Transplant center driven implementation
- NRP transplant program travel team
 - Accepting team members and supplies travel to donor
 - Challenges with logistics, transportation, resources
- NY model
 - Move the donor to NY DCU
- Some OPOs developing NRP capabilities

Implementation Strategy

- Partner with perfusion service company for perfusion expertise
 - Independent service
 - Capability to facilitate NRP anywhere in NEDS service area
- NEDS recovery surgeons perform in situ post-mortem cannulation
- Enables thoracic rapid recovery
 - Blood collection for heart/transmedics

Normothermic Regional Perfusion Equipment

NRP Circuit:

- Maquet Rotaflow Pump Console
- Terumo FX15 Oxygenator with Cardiectomy Reservoir
- CSZ Mini Heater Cooler
- Perfusion Tubing Pack with one sucker line
- Vacuum Regulator
- Oxygen Tank
- Mini Perfusion Cart

NRP Perfusion Disposables:

- 3/8 Tubing Pack with Rotaflow Centrifugal Head with Sterile Clamshell for Table Lines

Cannulae:

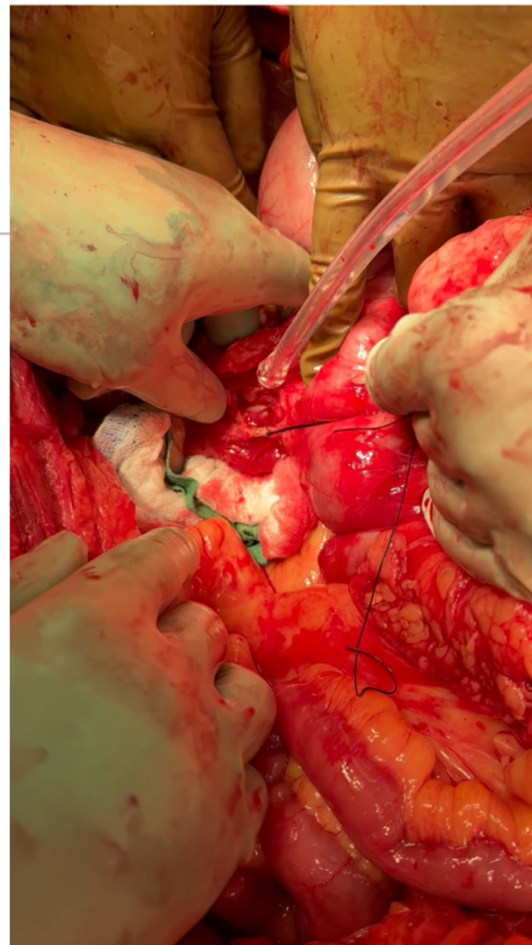
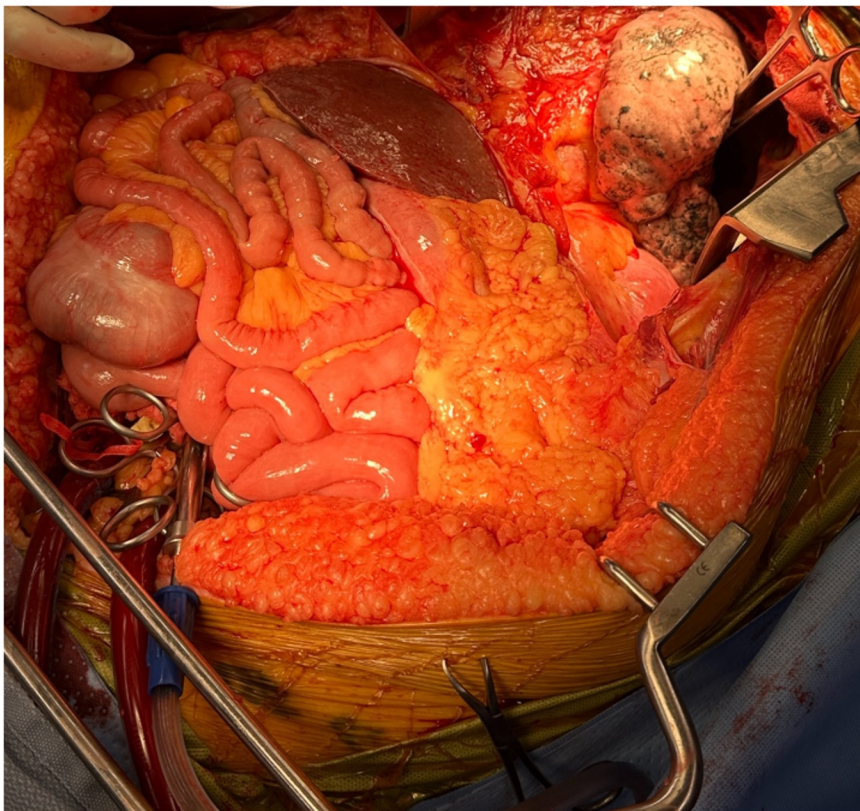
- Arterial Cannula for blood return to patient
- Venous Cannula to drain venous return

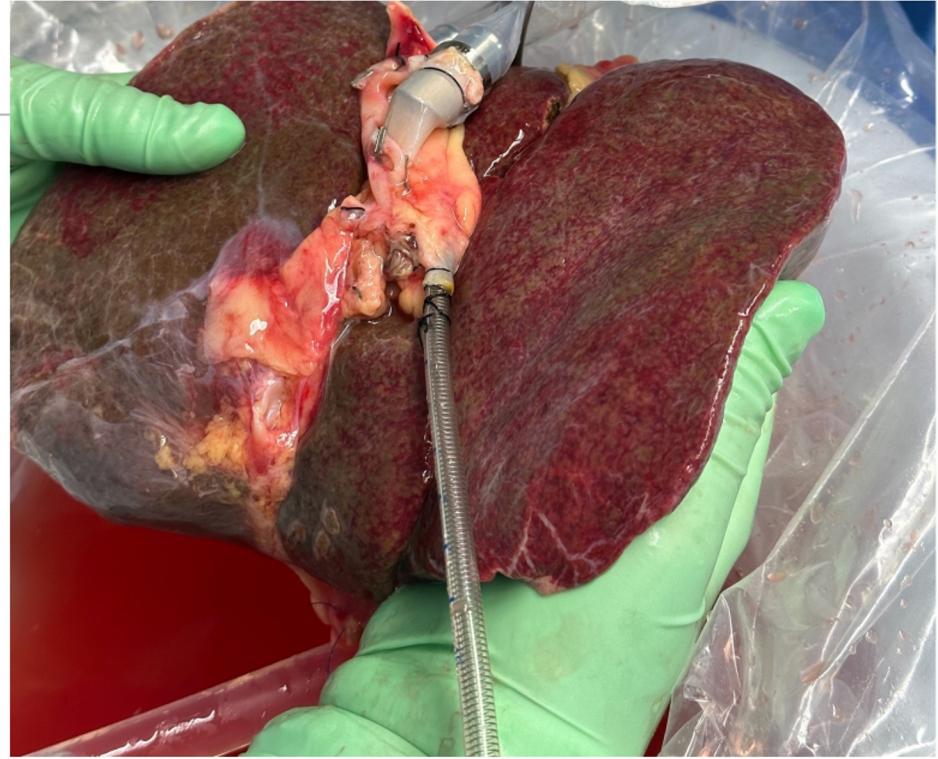
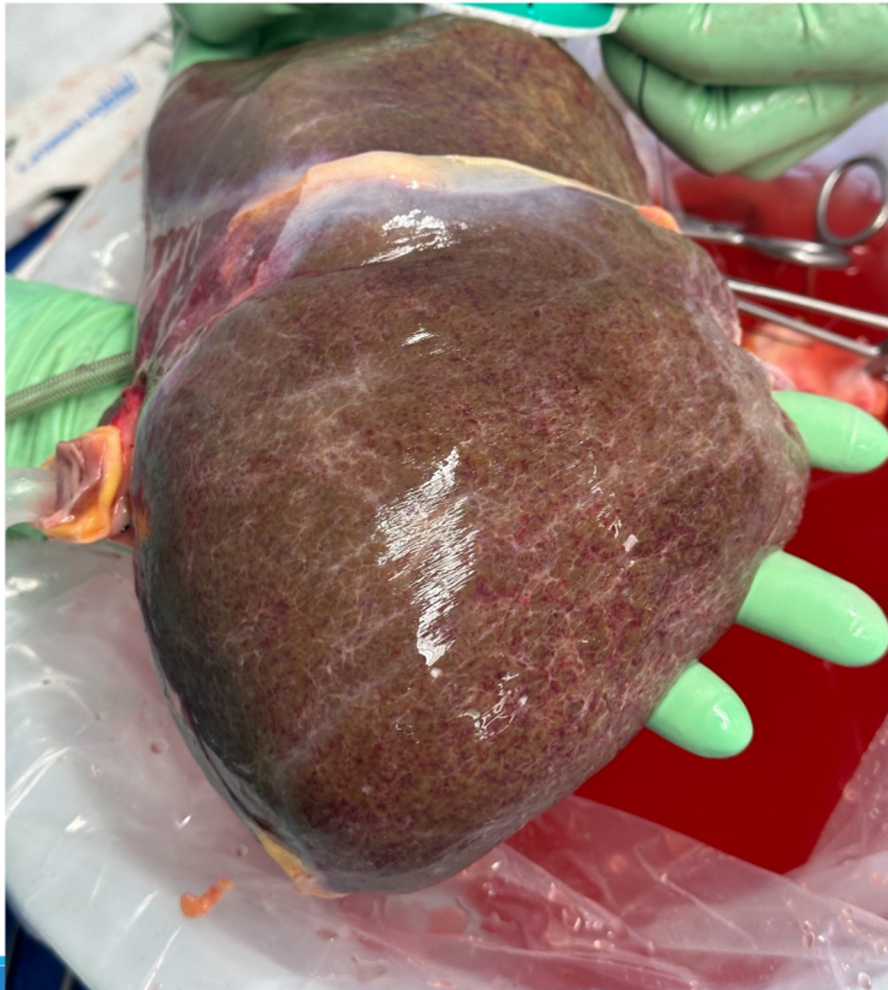


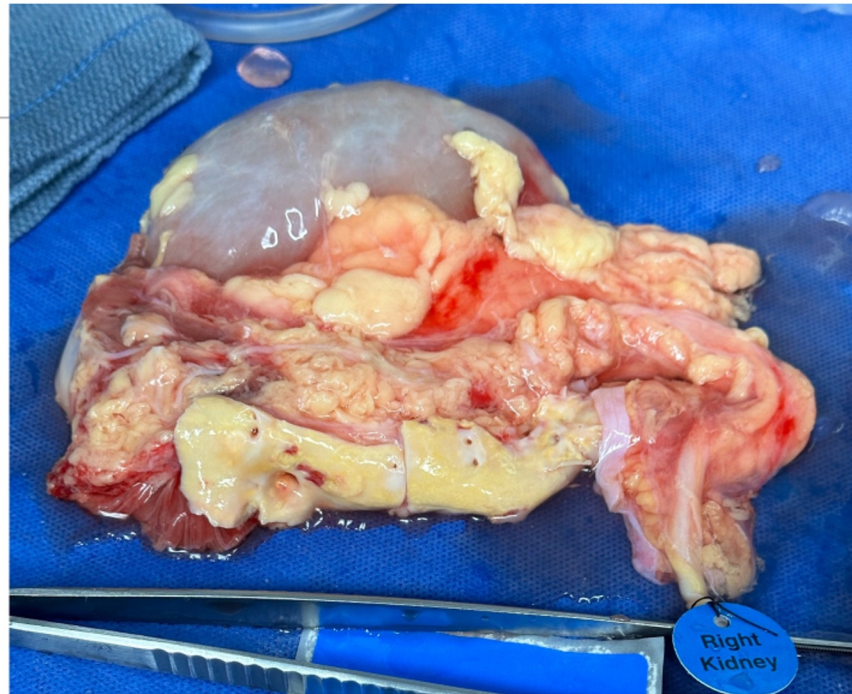
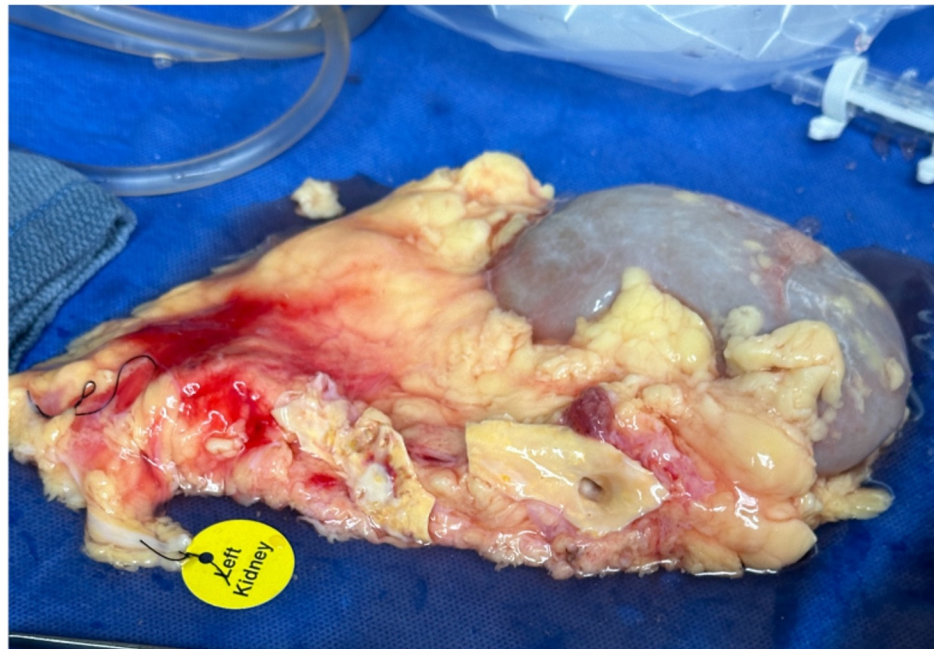
Organ Evaluation During A-NRP

- Appearance and function of the organs
 - UOP
 - Bile production
- Serial point of care (POC) testing (ideally)
 - Lactate
 - Blood Gases
 - ACT, Hgb, Hct
 - Electrolytes
- 90 minutes to 2 hours of NRP
 - Can go longer if needed
 - Additional case times in OR







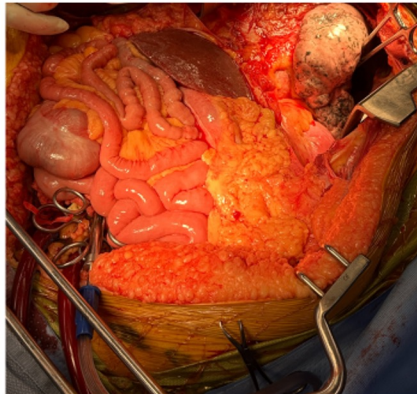


NEDS Currently Performing A-NRP

- Legal and Ethical Debates surrounding TA-NRP
 - Resumption of heart function
 - Occlusion of Aortic Arch Vessels (head vessels)
 - Uniform Determination of Death Act
 - “Death occurs when an individual has sustained either (i) irreversible cessation of circulatory and respiratory functions or (ii) irreversible cessation of all functions of the entire brain, including the brain stem. A determination of death shall be made in accordance with accepted medical standards.
- A-NRP not subject to same legal and ethical debates as TA-NRP
 - No resumption of heart function in A-NRP
 - No occlusion of aortic arch vessels

NRP Implementation Challenges

- Perfusion
- POC testing
- Operative
- Education (donor)
- Education (recipient)



A-NRP Allocation

- Verbally communicate to programs during allocation plans on utilizing A-NRP
- Standard language in Donornet highlights if plan for A-NRP
 - “NEDS plans to perform A-NRP recovery on donor”
- Standard language in Donornet Highlights if A-NRP recovery occurs
 - “New England Donor Services performed Abdominal Normothermic Regional Perfusion (A-NRP) on this donor. Please see the NRP flow sheet along with NEDS' standard DCD data page.”
 - A-NRP times clearly called out in Donornet highlights

Program consideration?

- Education for transplant center staff about NRP & NRP timeframes to expect
 - NEDS has experienced programs code out for “WIT” due to NRP circuit time
- Organ offer filters
 - Organ offer filters unable to differentiate if OPO is performing standard DCD recovery vs A-NRP recovery

Future A-NRP Direction

- Initial A-NRP use cases
 - Donor age > 40
 - Liver transplant potential
- NEDS perfusion capability and resources
 - Perfusionist and supplies
- A-NRP as the standard for DCD
- Increase DCD age criteria to 75
- Continue kidney pumping
- Explore other methods of machine perfusion for liver

Growing an abdominal NRP program

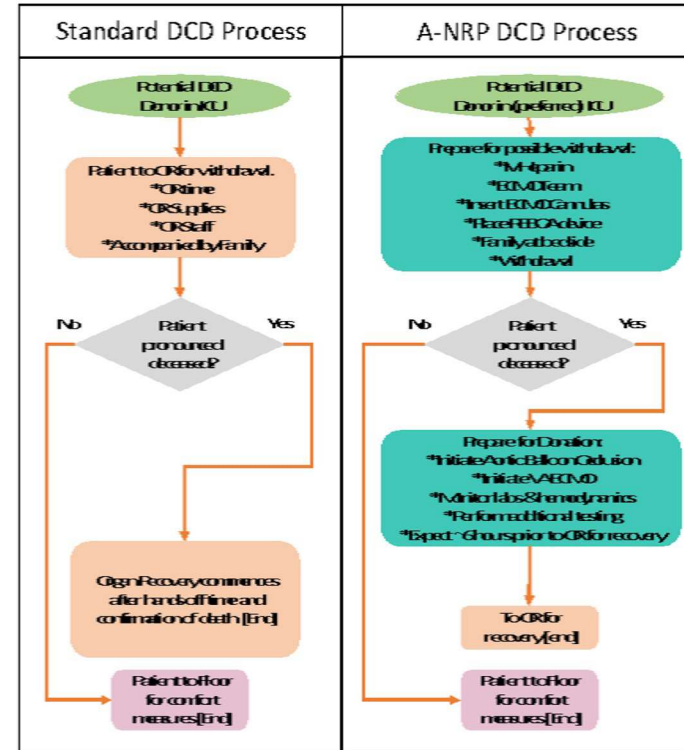
Anji Wall, MD, PhD

Abdominal Transplant Surgeon

Baylor University Medical Center

Start of the program

- Own hospital
 - Location
 - High volume DCD
 - Transplant friendly
- Donor type
 - Liver
- Cannulation type: peripheral
- Withdrawal location: ICU



Expansion
should be
iterative

Do a few cases with the same teams,
location, and process



Think about the next step for expansion
based on team bandwidth, expertise

Different
hospitals

Different
OPOs

Local vs
Fly-out

Expansion stage 1a: Local mobile team

Same OPO

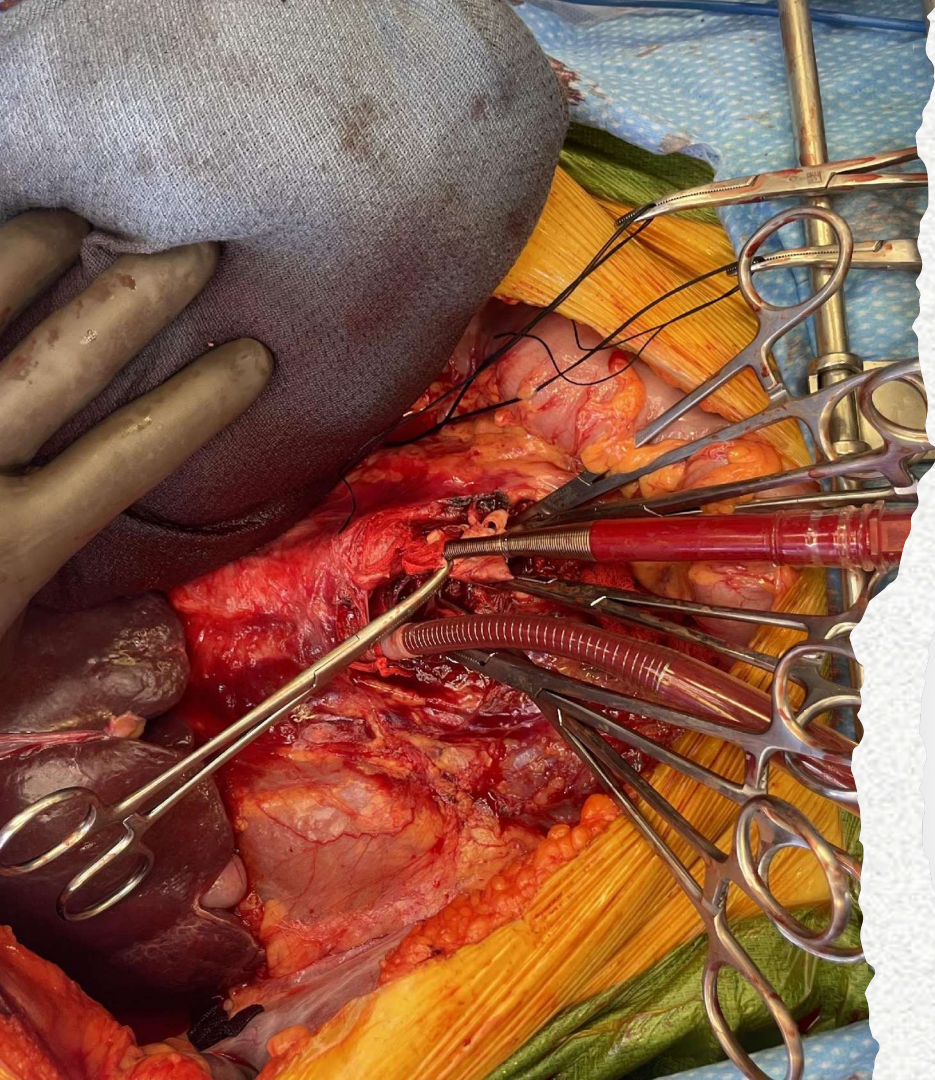
Different hospitals

OR rather than ICU withdrawals

To make it happen

- Mobile supplies
- POC lab testing
- Pharmacy box

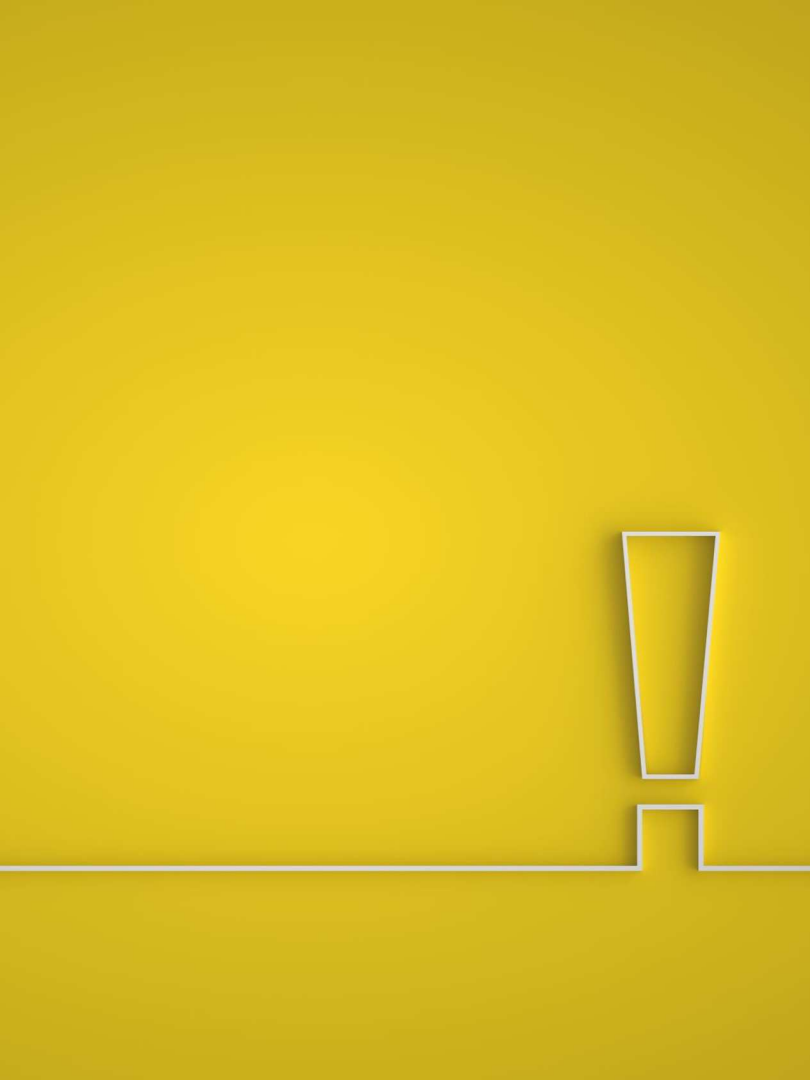






Expansion stage 2: flyouts

- Additional OPOs
- Ability to fit equipment and personnel on the plane
- To make it happen
 - Soft-sided bags to replace pelican case
 - Removed Terumo console from equipment (only POC testing)



Expansion stage 3: Pushing donor risk

- Increased fWIT threshold
- Increased donor age
- Abdominal-only cannulations to decrease staffing needs
- More complicated cases:
 - combo lung SRR: modifications to improve opportunity
 - heart SRR/OCS with A-NRP: blood drainage technique

EXPANSION TIMELINE

20
21

09-08-2021

First in-house A-NRP pathway
DCD. 53 M, normal LFTs, BMI 26,
head trauma. fWIT 66 minutes. 1
kidney transplanted, IGF

A-NRP ICU

OLTx

20
22

11-20-2022

Local hospital. 51F, normal
LFTs, WLST sheath placement
in OR. Donor did not expire

Mobile

Lung SRR

20
22

12-03-2022

Lifegift donor: central
cannulation 12-8-22 second
LG donor: 60 M, 22 min fWIT;
recip 69M MELD 16, 4 day LOS

New OPO

Abd only

20
22

06-18-2022

First successful in-house A-NRP
DCD pathway liver transplant.
36F, normal LFTs, 18 min fWIT,
liver/ kidneys. LTX: 69M, 4d LOS

20
22

11-25-2022

First mobile LTX: 42F, BMI 19,
normal LFTs, 27 min fWIT;
Recip: 57F, MELD 26, 6 d LOS
Curveball: Tandem lung SRR

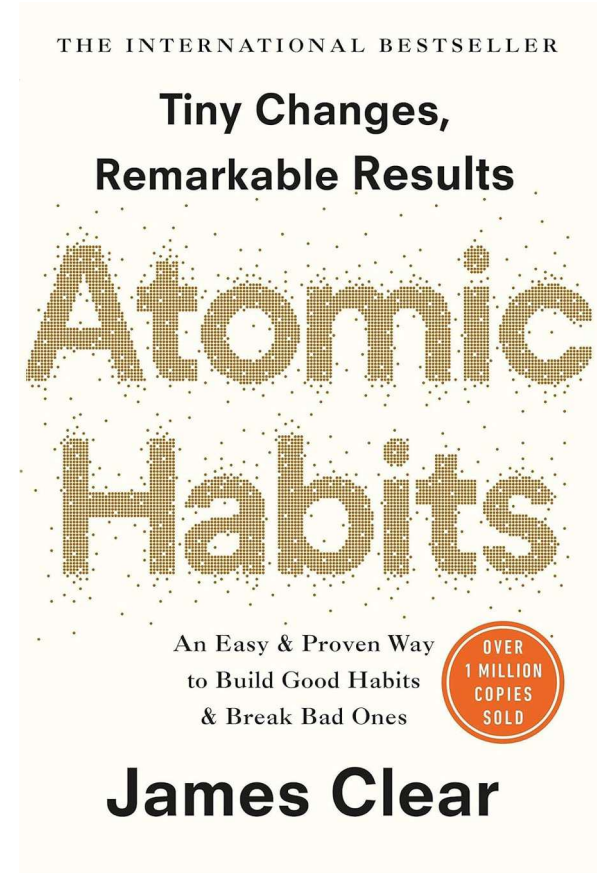
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23

02-20-2023

Intra-abdominal cannulation
by txp team. 48F, BMI 42, 21
min fWIT. 68M MELD 11, 5 d
LOS

Making it happen

Obvious
Attractive
Easy
Satisfying



Today's Panel



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Q&A

QUESTIONS & ANSWERS