

Organ Preservation Part I: The Benefits and Challenges of Local Organ Procurement

TODAY'S PANELISTS



Christine Radolovic

Chief Clinical Officer



Maria B. Majella Doyle

MD, MBA, FRCS
Vice Chair for Clinical Affairs,
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MD, MHCM
Professor & Division Chief,
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*Equipping a Modern Profession of Lifesavers
in Organ Donation & Transplantation*

Tuesday, December 17, 2024, 2:00pm – 3:30pm ET

Continuing Education Information

Evaluations & Certificates

Nursing

The Organ Donation and Transplantation Alliance is offering **1.0 hours of continuing education credit** for this offering, approved by The California Board of Registered Nursing, Provider Number CEP17117. No partial credits will be awarded. CE credit will be issued upon request within 30 days post-webinar.

CEPTC

The Organ Donation and Transplantation Alliance will be offering **1.0 Category I CEPTC credits** from the American Board for Transplant Certification. Certified clinical transplant and procurement coordinators and certified clinical transplant nurses seeking CEPTC credit must complete the evaluation form within 30 days of the event.

Certificate of Attendance

Participants desiring CE's that are not being offered, should complete a certificate of attendance.

- Certificates should be claimed within 30 days of this webinar.
- We highly encourage you to provide us with your feedback through completion of the online evaluation tool.
- Detailed instructions will be emailed to you within the next 24 hours.
- You will receive a certificate via email upon completion of a certificate request or an evaluation
- Group leaders, please share the follow-up email with all group participants who attended the webinar.



Deanna Fenton

Senior Manager, Program
Development and
Operations



Need Assistance?

Contact Us via Zoom Chat, or
info@organdonationalliance.org
786-866-8730

Meet Our Moderator



Austin Williams MS, FACHE

Senior Director of Business
Development



Meet Our Presenters



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Leadership & Engaged Learning in Organ Donation & Transplantation

Local Procurement - Abdominal

Shimul A. Shah, MD, MHCM

The James and Catherine Orr Endowed Chair in Liver Transplantation

Professor and Chief, Solid Organ Transplantation

Director, Transplant Service Line

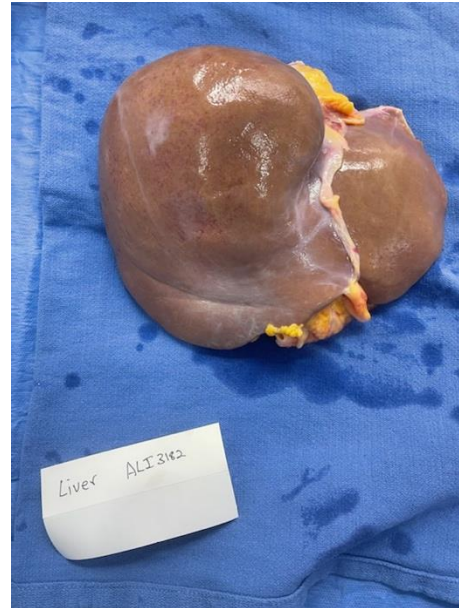
University of Cincinnati College of Medicine

Procurement - 2024

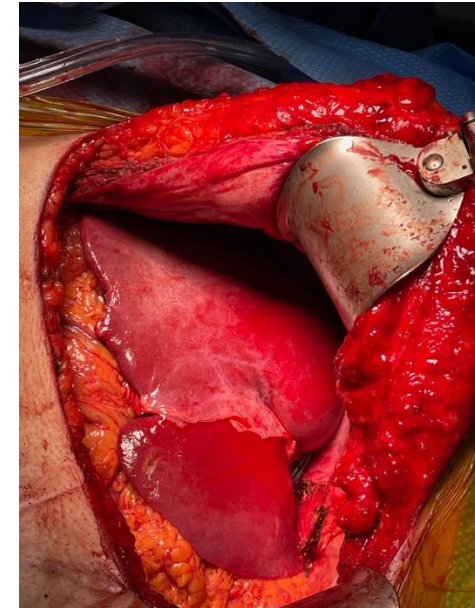
62yo DCD with
local recovery from
remote OPO
Donor died in 21
min
Agonal time 17 min
Flushed well
Pics attached



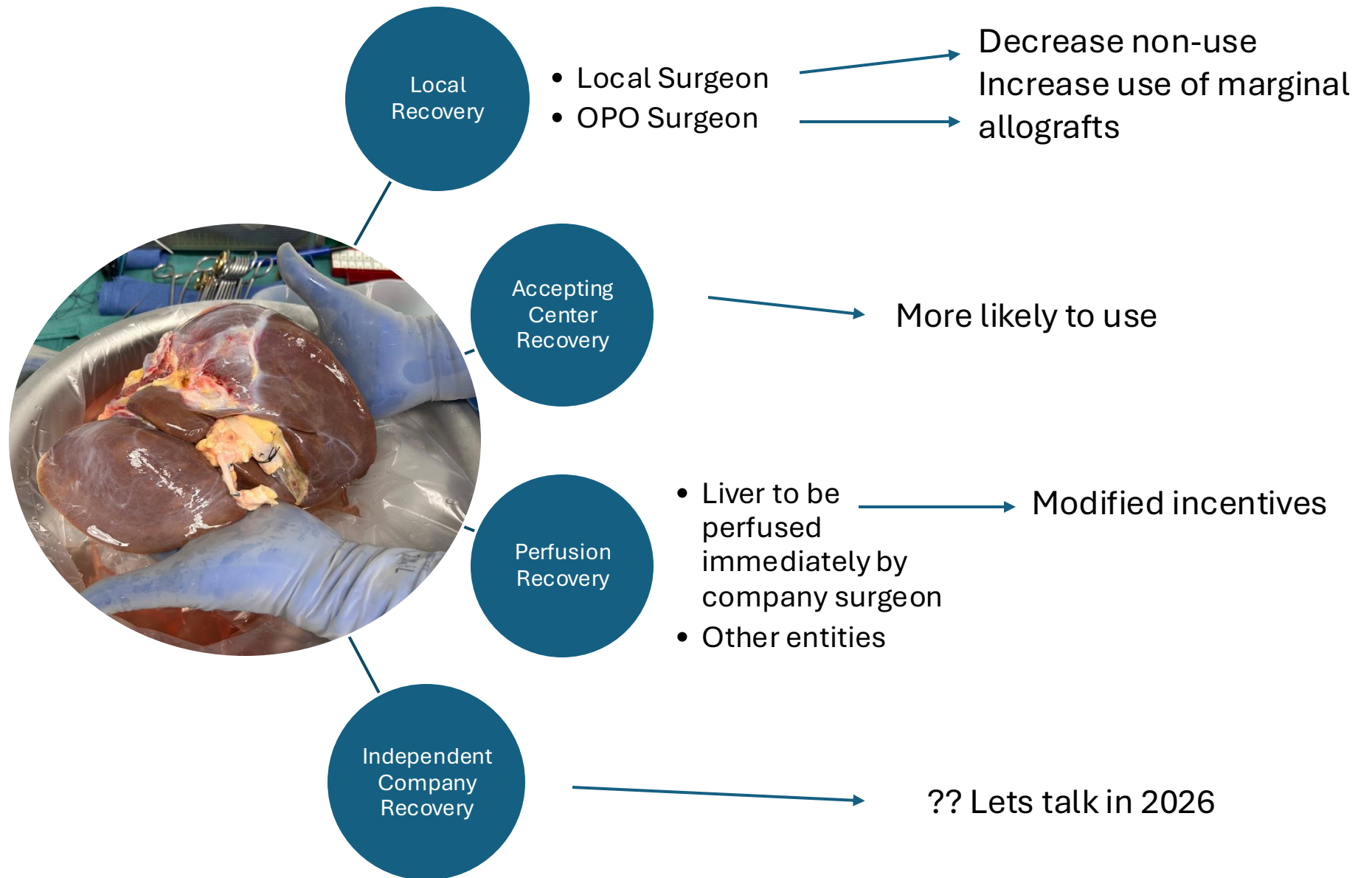
Surgeon 1



Surgeon 2



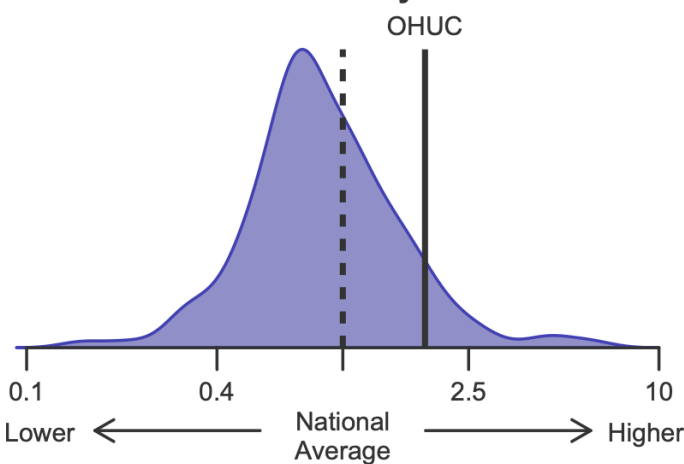
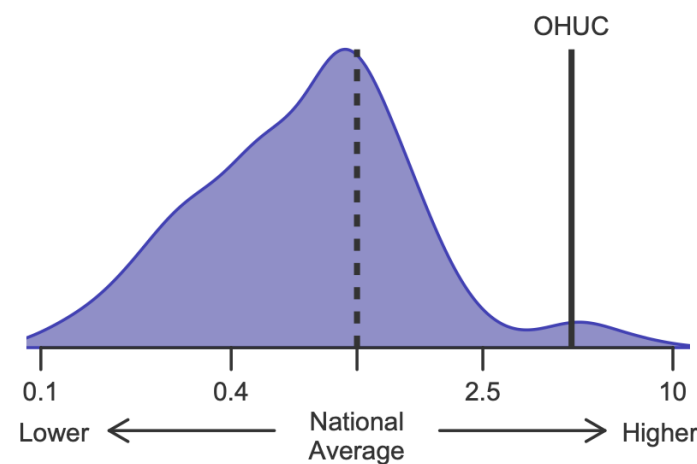
Surgeon 3/4



Our program - Cincinnati

Figure B14. Offer acceptance: Offer number > 50

Figure B15. Offer acceptance:
Donor more than 500 miles away



Transplant Characteristic

Donor Location (%)

Local Donation Service Area (DSA)
Another Donation Service Area (DSA)

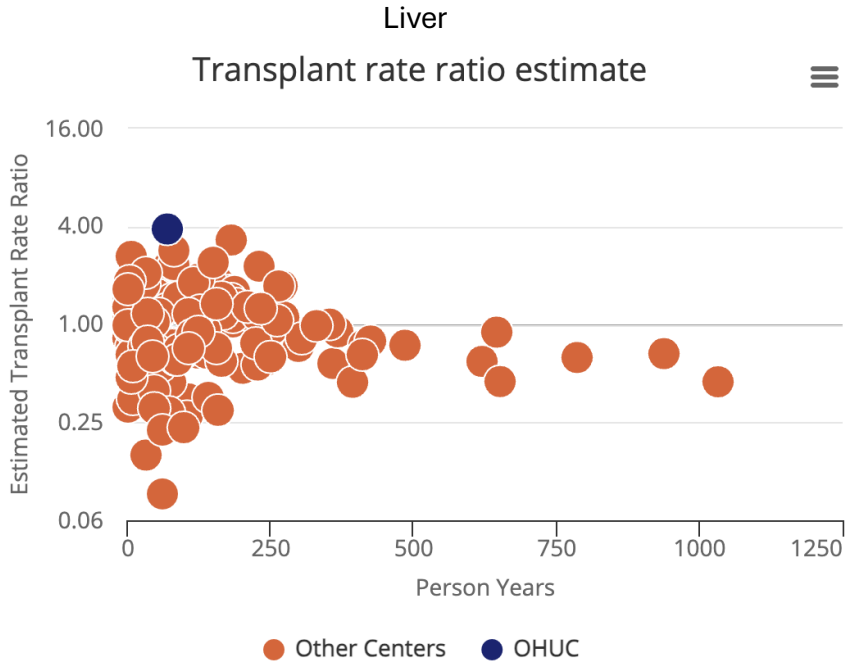
Percentage in each category		
Center (N=160)	Region (N=970)	U.S. (N=9,518)
11.2	23.4	35.3
88.8	76.6	64.7



Transplanting livers
4x faster than the
national standard
for wait times.

uchealth.com/transplant

**4x
FASTER**

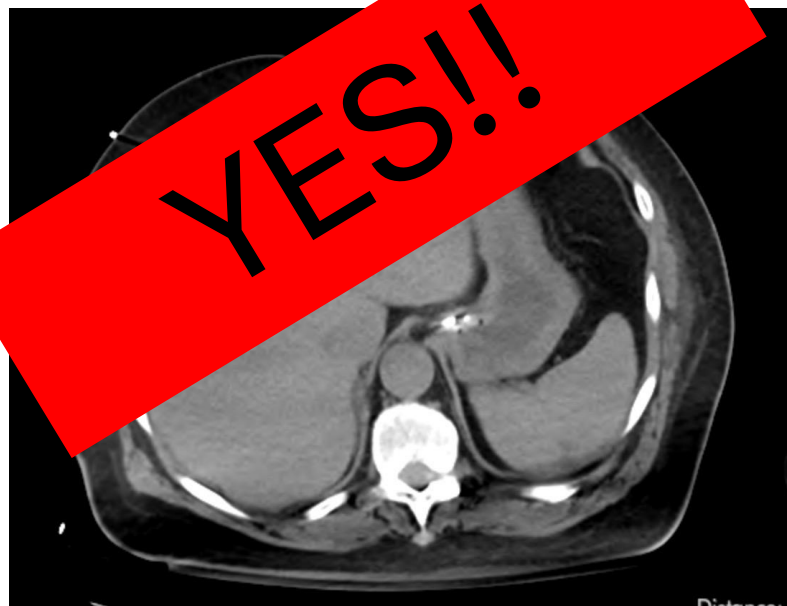
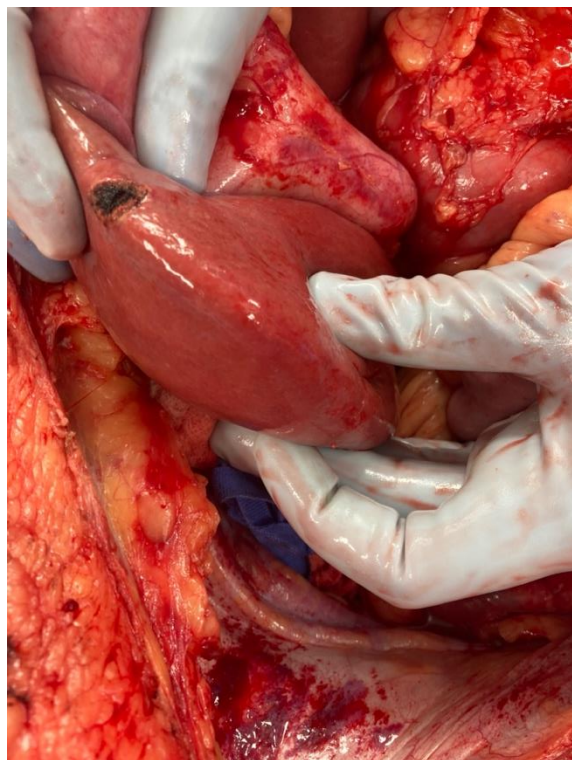




What goes into the optimization analysis tool?

Attribute	What is the purpose of this attribute?
Medical Urgency	Prioritize candidates who are most likely to die/be removed from the waitlist without a transplant
Blood type	Provide equal access to transplant for candidate regardless of their blood type
Height/BSA	Provide equal access to transplant for candidates regardless of their height or body surface area
Pediatric Priority	Prioritize pediatric candidates for pediatric donors
LI/IN	Prioritize liver-intestine (MVT) candidates for liver-intestine (MVT) donors
Living Donors	Prioritize living donors
Split	Prioritize those candidates willing and likely to initiate a split liver transplant
Geographic equity	Provide equal access to transplant regardless of location of transplant program
Proximity	Increase efficiency in organ placement system
Travel	Reduce distance between donor hospital and transplant program

Do we have a discard issue?



Liver Utilization Rate in the United States by Region

➤ Liver utilization = Number of livers transplanted / total number of organ donors recovered

Table 23. Liver Utilization Rate by OPTN Region and Era

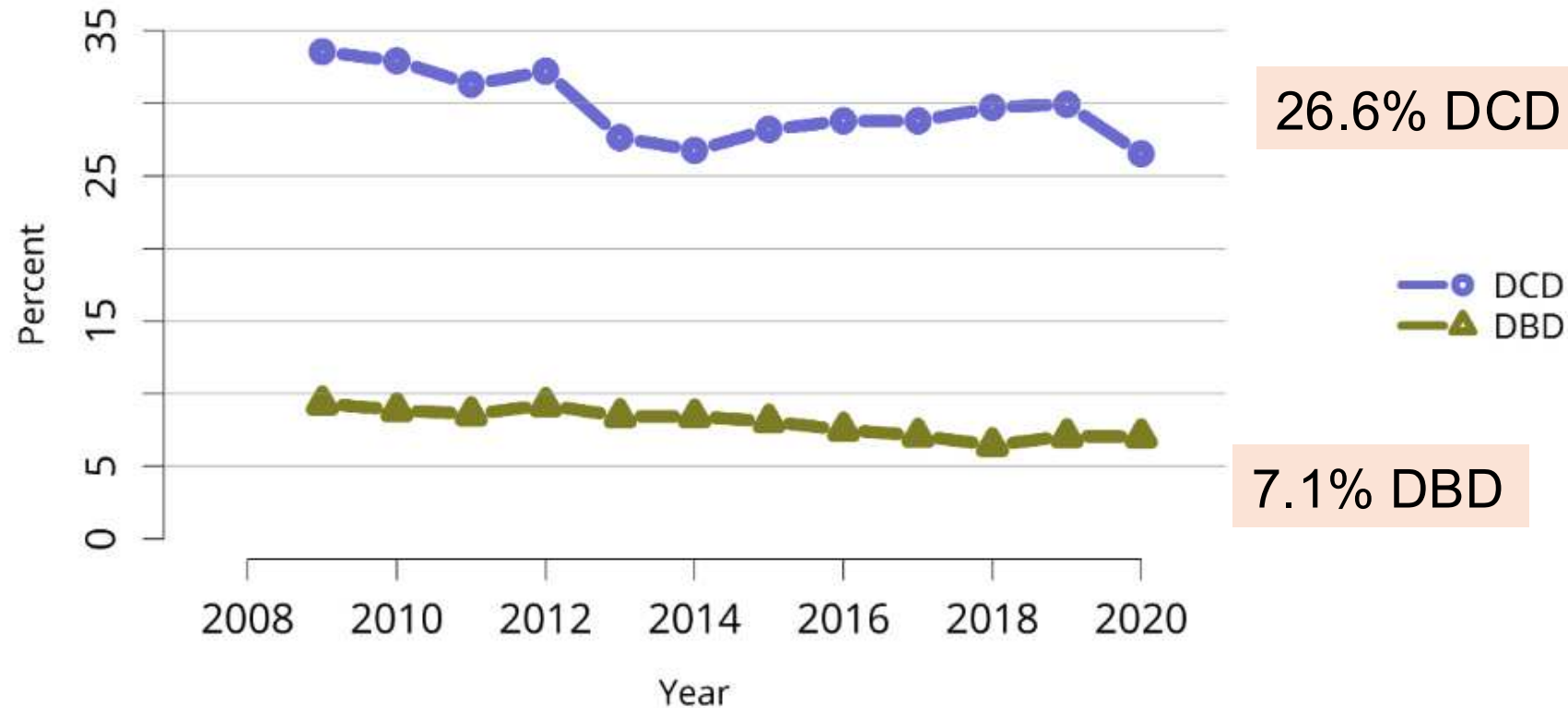
OPTN Region	Pre-Policy %	Post-Policy, Pre-COVID %	Post-Policy, COVID Shutdown %	Post-Policy, COVID Stabilization %	Post-Policy (overall) %
1	63.80	67.44	78.00	55.99	59.33
2	64.53	68.94	69.79	61.97	63.39
3	80.17	68.32	80.17	76.01	75.77
4	70.96	68.80	72.55	69.00	69.29
5	66.67	65.55	67.89	62.78	63.47
6	70.11	50.00	57.45	63.36	61.68
7	77.69	73.77	72.73	67.78	68.73
8	71.34	64.63	74.50	65.11	66.01
9	71.37	67.62	71.60	66.42	67.04
National	71.37	67.62	71.60	66.42	67.04

Current liver utilization rate is 67%





US Liver Discard Rate 2020

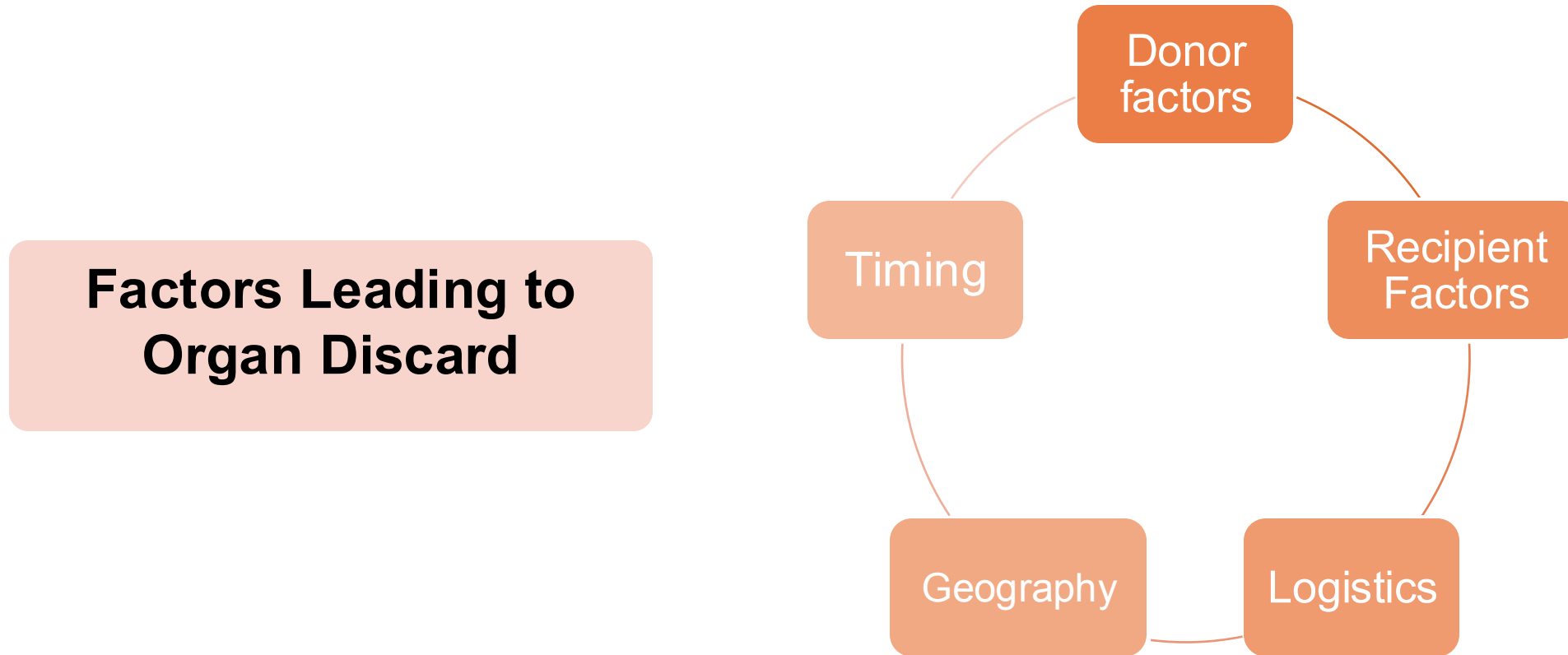


OPTN/SRTR 2020 Annual Data Report



The Discard Issue

When livers are turned down around the time of donation, they must be placed quickly to remain usable



Solution # 1 – Better performance in donor recoveries

Types of injury

1. Parenchymal
2. Vascular (arterial, venous)
3. Biliary

Surgery is about two things: **Details and Complications.** You pay attention to **details** to prevent **complications**, and when complications do occur, **because they will**, you pay attention to details to make the complications better.

Recovering livers is a complex business

Procurement related injury

BMJ Open Surgical quality in organ procurement during day and night: an analysis of quality forms

Jacob de Boer,^{1,2} Koen Van der Bogt,^{1,3} Hein Putter,⁴ Kirsten Ooms-de Vries,² Bernadette Haase-Kromwijk,² Robert Pol,⁵ Jeroen De Jonge,⁶ Kees Dejong,⁷ Mijntje Nijboer,¹ Daan Van der Vliet,⁸ Dries Braat¹

Retrospective study Dutch
Transplant Foundation Quality
forms (3/12 – 9/13)

- Injuries 33/133 livers (36% - **0.8% discarded**)

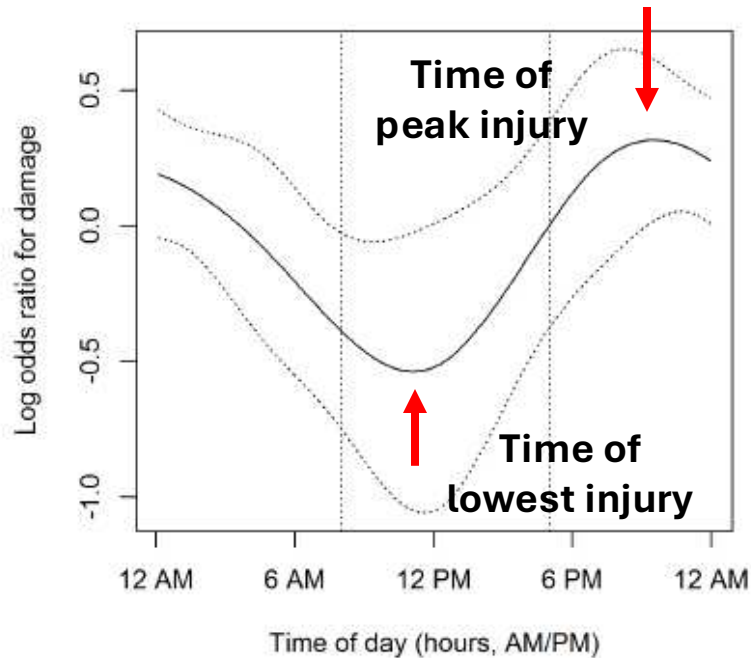
Procurement related injury

21% of injuries reported by surgical team.

LIVER TRANSPLANTATION 12:1365-1370, 2006

BMJ Open Surgical quality in organ procurement during day and night: an analysis of quality forms

Jacob de Boer,^{1,2} Koen Van der Bogt,^{1,3} Hein Putter,⁴ Kirsten Ooms-de Vries,² Bernadette Haase-Kromwijk,² Robert Pol,⁵ Jeroen De Jonge,⁶ Kees Dejong,⁷ Mijntje Nijboer,¹ Daan Van der Vliet,⁸ Dries Braat¹



ORIGINAL ARTICLE

Surgical Injuries of Postmortem Donor Livers: Incidence and Impact on Outcome After Adult Liver Transplantation

Danielle M. Nijkamp,¹ Maarten J.H. Slooff,² Christian S. van der Hilst,³ Alexander J.C. IJtsma,² Koert P. de Jong,² Paul M.J.G. Peeters,² and Robert J. Porte^{1,2}

¹Section of Transplantation and Organ Donation, ²Section of Hepatobiliary Surgery and Liver Transplantation, Department of Surgery, and ³Department of Medical Technology Assessment, University Medical Center Groningen, Groningen, The Netherlands

241 whole OLT 1996-2004

34% - anatomical injury

- 12% capsular tears
- 12% arterial injuries -- **3x** more likely with **aberrant anatomy**

Increased HAT with arterial injury

OPOs are paying attention to surgical damage

Documentation of surgical damage from OPO.

Severity Level	Organ	Comments
2	Liver	Small left lobe laceration
2	L. Kidney	Injury left vein cut accidentally left of adrenal
3	L. Kidney	Aortic dissection extending deep in the left artery
1	Liver	Small injury
1	Liver	Cut replaced right hepatic artery
3	Liver	Crack on top from incision
3	Liver	2 surgical lacerations, one 2in, one 1 in, both 3mm deep.

DCD Donor hypoxic upon entry to OR for withdrawal



OPOs are paying attention to surgical damage

Documentation of surgical damage from OHC

Organ	N	Surgical Damage	Capsular Tear	Not Rearded
Liver	59	25% (15)	4%	3% (2)
Left Kidney	26	58% (15)	31%	31% (8)
Right Kidney	28	61%	21% (6)	11% (3)

Data only reflects live organ transplants recovered.

CMS OPO performance measure

CMS OPO documentation rate measure

OPOs are keeping score – tracking surgical injuries could be metric to increase OPO performance

Makes sense for them to regulate/track quality in donor recoveries

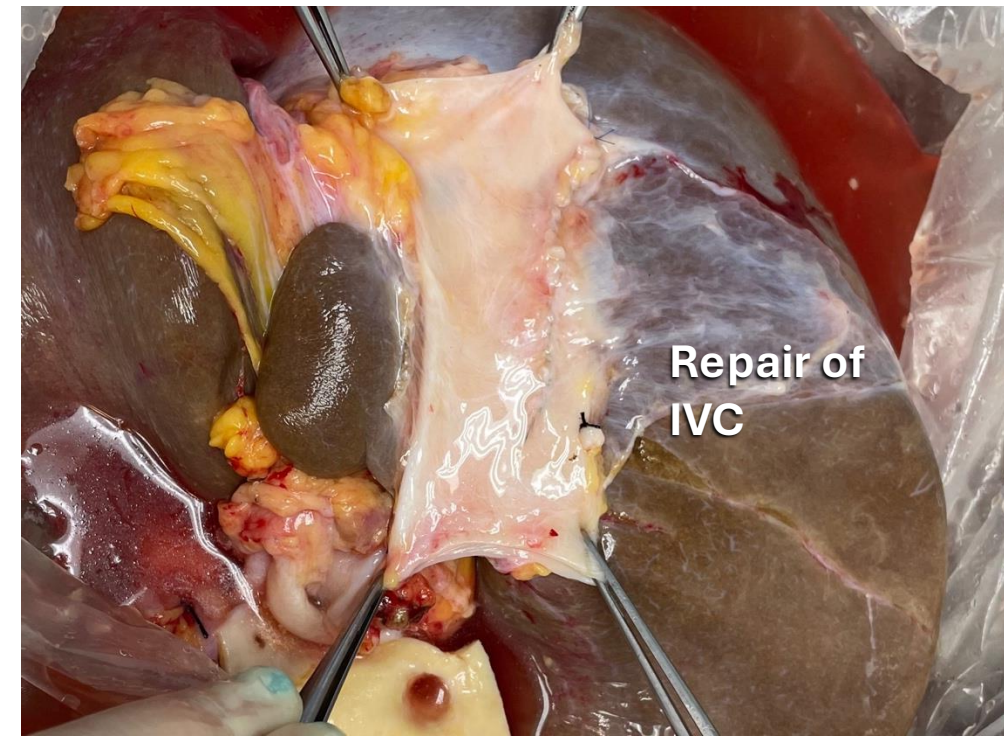
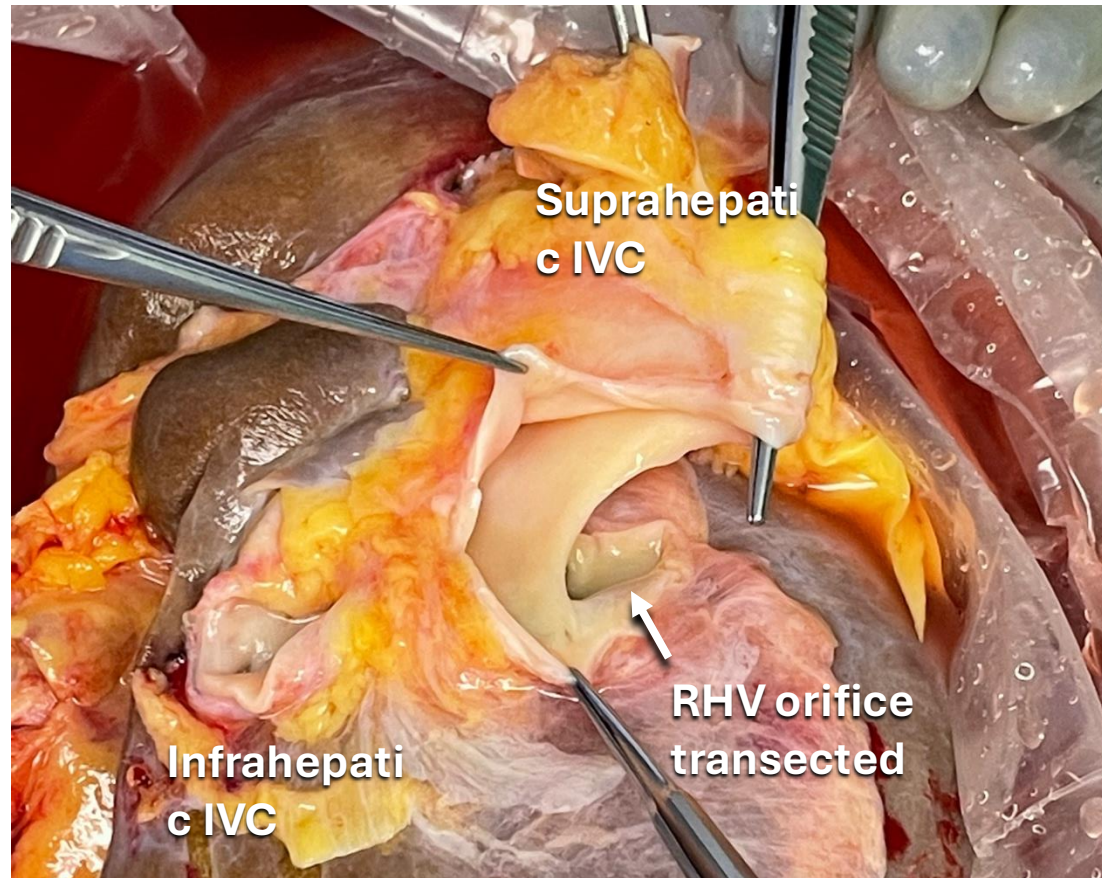
Case #1

Recipient: 66 y/o M ETOH cirrhosis w/ ascites, HE, b-EV s/p TIPS and PVT. MELD 17

Donor: 73 y/o DBD, BMI 44.2. Normal LFTs, No steatosis on biopsy

Call from recovery surgeon about 30 minutes after cross clamp.

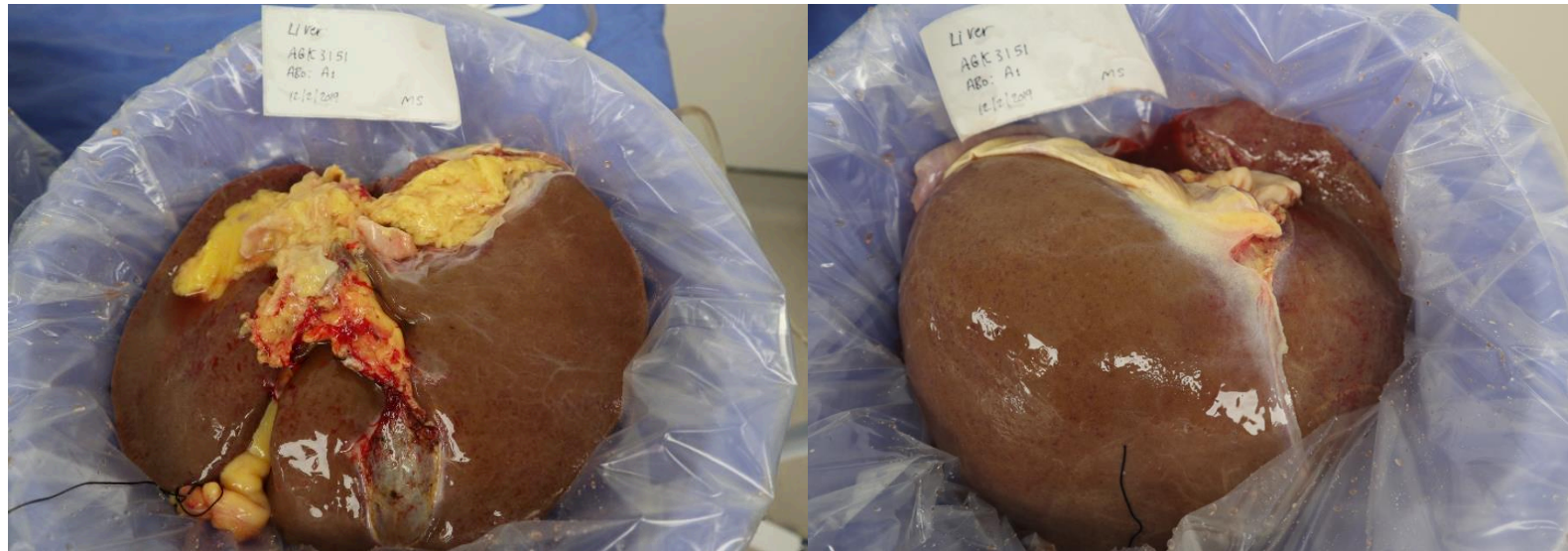
Procurement acquired RHV/IVC injury



Case #2

Recipient: 74 y/o M HBV cirrhosis w/ HCC, HE, PVT, hepatic hydrothorax. MELD 19

Donor: 60 y/o DBD, BMI 37. Normal LFTs, estimated 10% steatosis



Surgical Damage: Yes

Comments:

There is a tiny left accessory artery that was surgically cut by mistake.

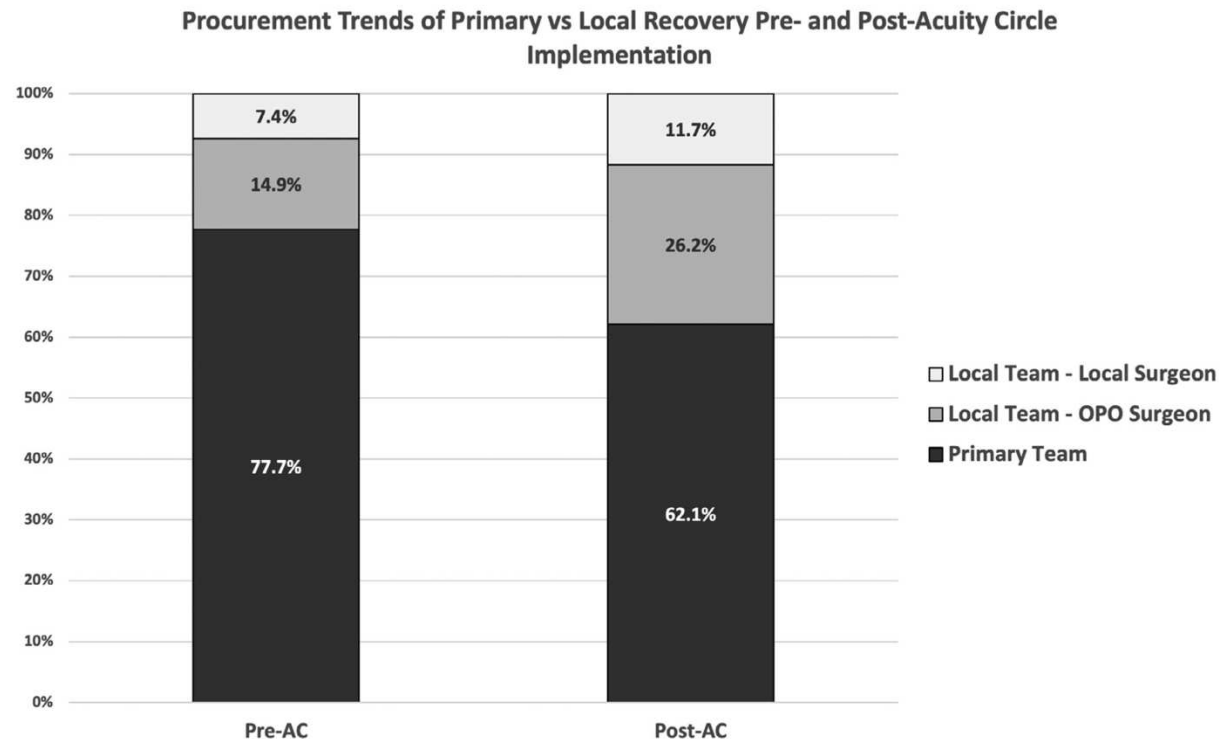
ORIGINAL ARTICLE **OPEN ACCESS**

Primary Team Versus Local Recovery in Liver Transplantation in the Modern Era: A National Analysis of the United Network for Organ Sharing Database

Jenna N. Whitrock¹ | Stephanie Sisak¹ | Catherine G. Pratt¹ | Aaron M. Delman¹ | Adam D. Price¹ | Koffi Wima¹ | Shimul A. Shah² | Ralph Cutler Quillin III²

¹Cincinnati Research in Outcomes and Safety in Surgery (CROSS) Research Group, Department of Surgery, University of Cincinnati College of Medicine, Cincinnati, Ohio, USA | ²Division of Transplantation, Department of Surgery, University of Cincinnati College of Medicine, Cincinnati, Ohio, USA

- Local recovery increasing
- Highest use in OPO surgeon
- No difference in outcomes



Local Recovery

- **Benefits**

- Travel safety
- Cost savings
 - No loss on "dry runs"
- Logistical burdens
- Quality of life – recipient team
- Decreased burnout
- Training
- Potential financial gain

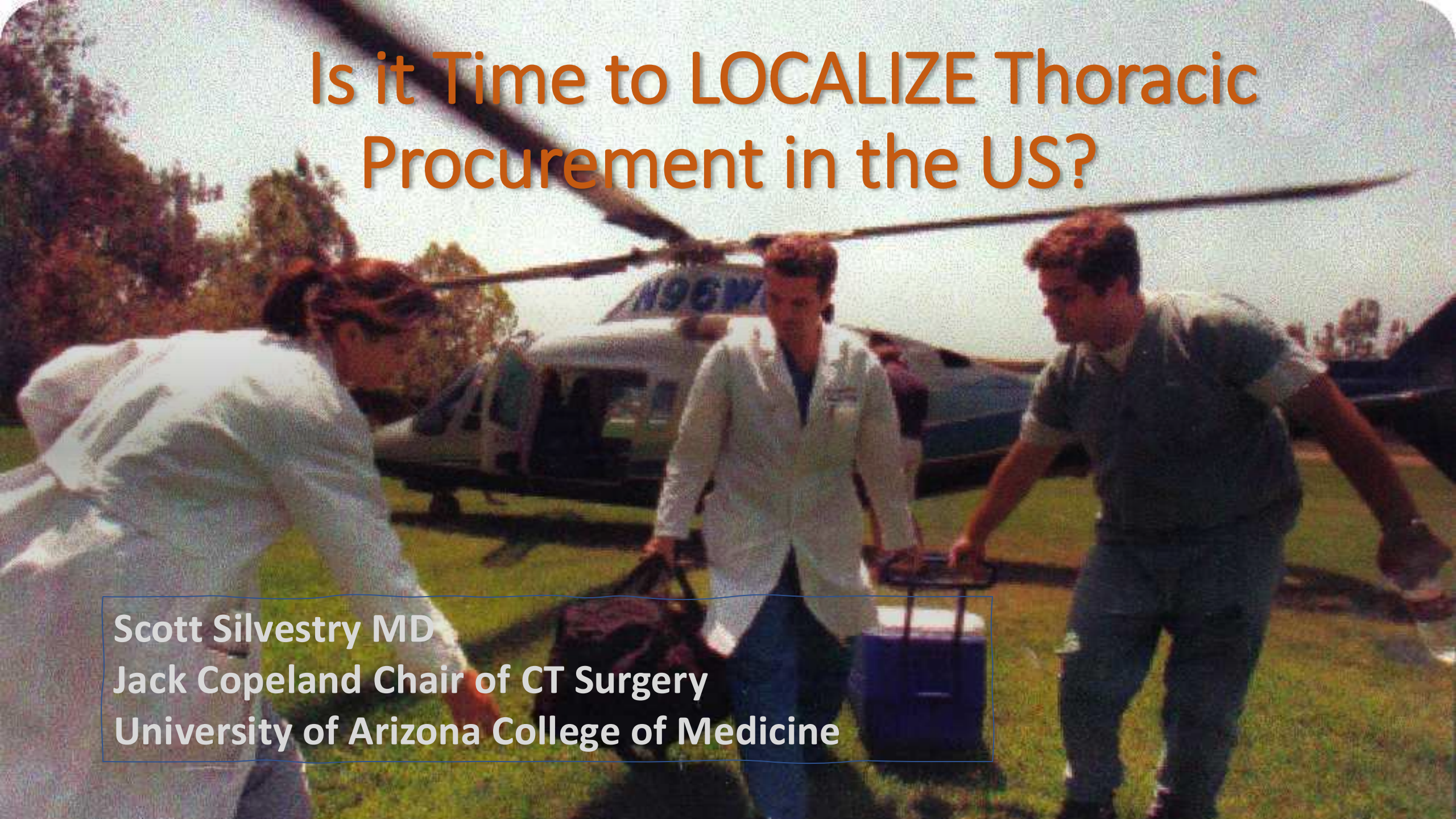
- **Opposition**

- Donor judgment / experience
- Trust
- Extended cold time / travel logistics

Summary / Perspectives

- Local procurement
 - Is necessary and increasing
 - Need to align goals
 - Safety
 - Cost effective
 - Appears to be effective and could it be more effective?
- Future perspectives
 - Broader allocation coming
 - Organs increasing -> can transplant centers keep up?

Is it Time to LOCALIZE Thoracic Procurement in the US?

A photograph showing three medical professionals in white coats and scrubs running across a grassy field towards a helicopter. The helicopter has the number '1196W' on its side. The scene suggests an emergency medical transport or a time-sensitive procedure.

Scott Silvestry MD
Jack Copeland Chair of CT Surgery
University of Arizona College of Medicine

Disclosures

Consultant

Abbott

Abiomed

Medtronic

DMSB

Carmat

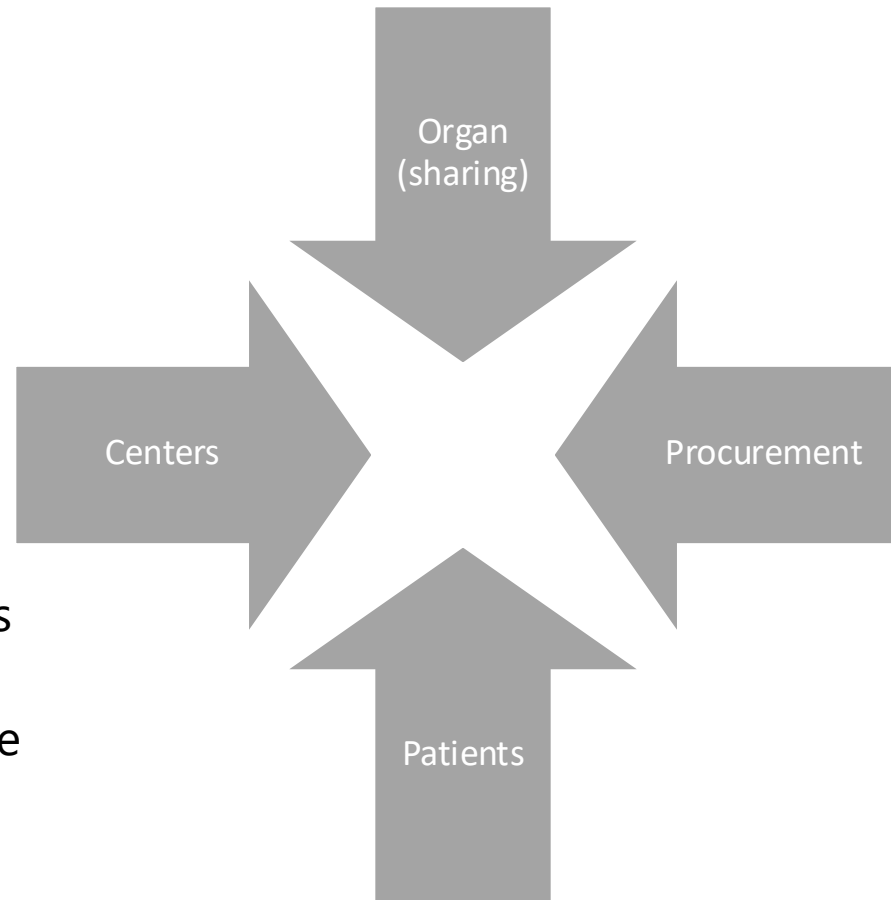


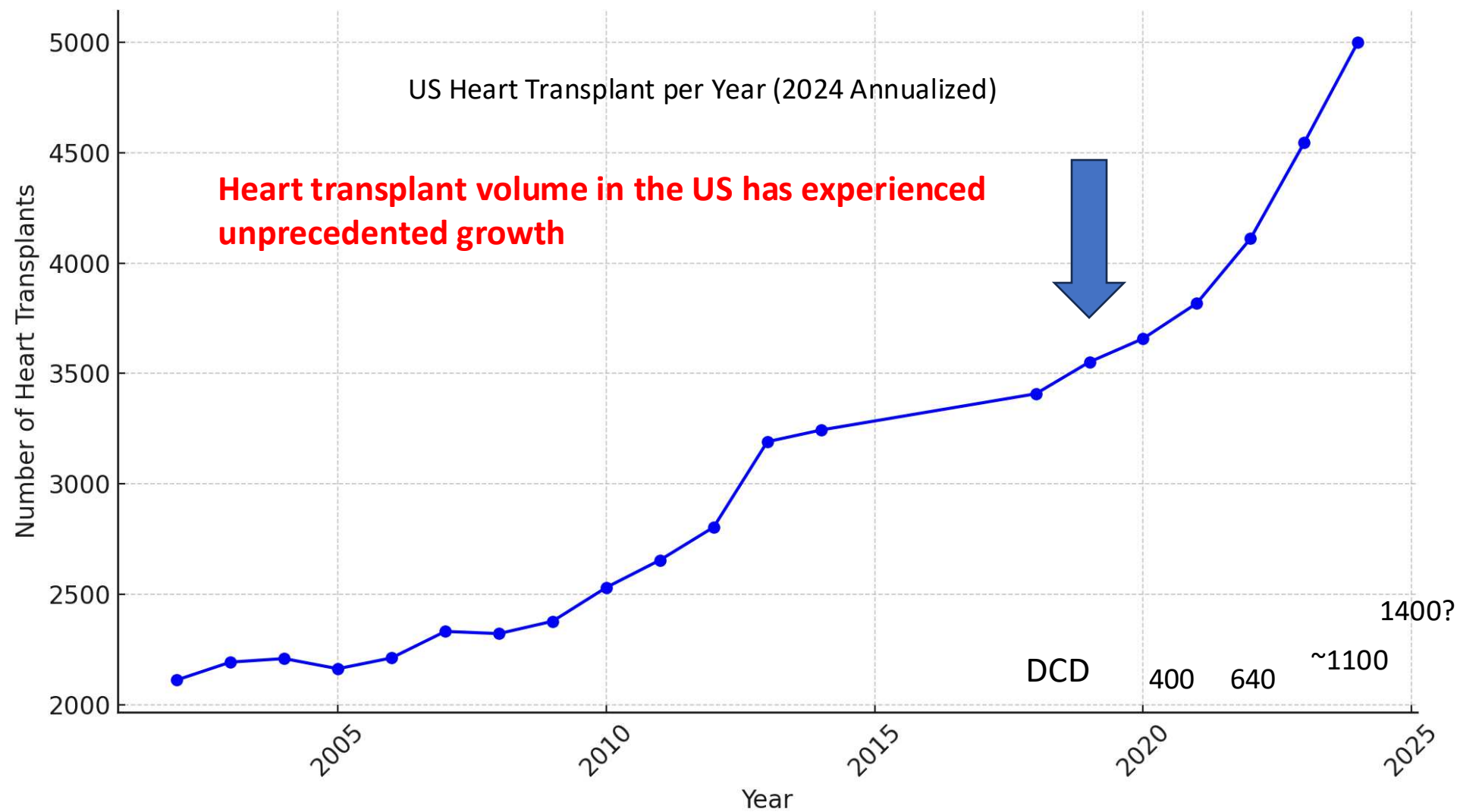
“If you want to go fast, go alone;
if you want to go far, go
together.”

African (Burkina Faso) Proverb

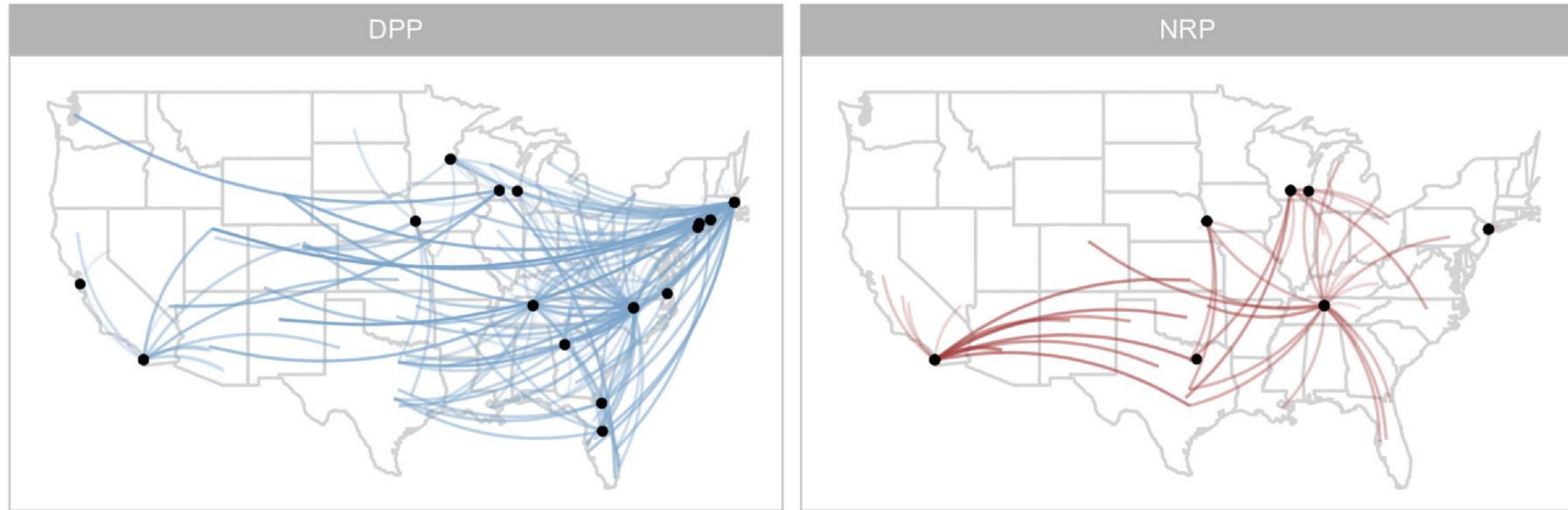
What does Regionalization in transplant mean?

Transplant regionalization refers to the practice of organizing and distributing transplant services across different regions or areas. This approach is aimed at improving access to transplantation for patients while ensuring that the distribution of organs is fair and equitable.





Transplant Center Perspective



Procurement Type — DPP — NRP

Distance (NM) — 500 — 1000 — 1500

Additional Estimated \$48 million Q2, marking a 64% increase compared to the same period in 2023.

~190 million FY

Estimated additional \$40 million NRP costs FY

NEW ERA
CHALLENGES-DCD/MP

TRANSPLANT CENTER

LABOR
OPORTUNITY COST OF LABOR
DRY RUN COST
TRANSPORT COST
BURNOUT
UNCOVERED COST
Donor CONVERSION

WHY? The need for Local Procurement

As technology has increased so has cost.

Improve patient access to transplantation for all technologies

Reduce geographic disparities in organ allocation.

Reduce cost (overall, system)

Improve outcomes

Access is key issue for smaller programs with limited access to advanced procurement technology.

Principle

☐ Access

☐ Equity

☐ Value

☐ Outcome

Financial Impact-Simple

Simple Math:

STD procurement	\$30K	0 dollars added
Sherpa procurement	\$40K	\$10K x 1500= \$15M added
TA-NRP	\$54K	\$54K x 300= \$16.2M added
DMP (us)	\$104K	
DMP (vendor)	\$89K	89K x400= \$35.6 Million added

SUBTOTAL	\$66.8 Million added
-----------------	-----------------------------

Increased Plane cost 10-20K per DMP/NRP x 700= \$14M

TOTAL	~\$80 Million add'l cost for Procurement
--------------	---

Cost Savings

Donation after Circulatory Death: Extending the Boundaries of this New Frontier

Yael Peled, MD,^a Simon Messer, MD, PhD,^b Stephen R. Large, MD,^b and Michelle M. Kittleson, MD, PhD^c

- NRP Eliminates disposable cost of up to \$ 57,000 dollars per run
- NRP circuit may cost as little as \$1,500
- Still requires significant personnel cost

Benefits of OPO DRIVEN NRP

INCREASED ORGAN RECOVERY OPPORTUNITIES FOR THE OPO

- OPO-driven NRP maximizes DCD recovery opportunities using low-cost, local NRP teams
 - Allows pursuing rapid DCD opportunities
- OPO-driven NRP helps ensure equity of capabilities for all centers
- If fully operationalized, NRP could eliminate the liver transplant wait list within ~ 5 years

ABILITY TO RE-ALLOCATE ON NRP

- In the event a Transplant Center declines, can re-allocate while on circuit and place the organ with another center
- Maximizes intra-operative donation opportunities



How?

PARTNERSHIP

Regionalization strategies

Different strategies for implementing
transplant regionalization

Regional/LOCAL organ procurement
network,

Regional transplant centers in
different regions (Planned/Legacy)

Development of regional organ
sharing networks.

Variable Impact and invasiveness- positive networks, exclusive rights and mandatory metrics



What We Offer:

Comprehensive NRP Service

- Perfusion Staffing: (2 Perfusionists in Beginning)
 - 1 Perfusionist & 1 NRP Tech
- All Necessary Perfusion Equipment
- All Necessary Perfusion Disposables:
 - Cannulas
 - Perfusion Circuit
 - Drugs
 - Point of Care Testing
- Electronic Documentation
 - NRP Record
 - Customized Data and QI Capture

Comprehensive Recovery Service (DBD/DCD)

- Cannulating Surgeon
- Thoracic Recovery Surgeon
- Abdominal Recovery Surgeon
- Surgical 1st Assist
- Preservation Solutions
- All Transportation & Logistics

Emphasis on Customer Service & Communication

Examples?

ABDOMINAL Transplant

Procurement	☒
Organ sharing	☒
Center	☐

Pediatric Transplant

Procurement	☐
Organ sharing	☒
Center	☒

Non US Countries

Procurement	☐
Organ sharing	
Center	

The Uber logo, consisting of the word "Uber" in white lowercase letters on a black rectangular background.

T. Ryan, J. Um, A. Castleberry, B. Lowes, M. Moody and M.

“There was a trend toward lower cost and the greater contribution margin in TA-NRP when compared to both DBD and DP-NMP DCD. The greater cost associated with DP-NMP is likely offset by shorter length of hospital stay.”

	DBD (N = 36)	DCD (N = 12)	P - value
Recipient age, years	61 (43;65)*	60 (47;67)*	.54
Hospital length of stay, days	26 (13;40)*	20 (17;44)*	.84
Male gender (%)	26 (72)	10 (83)	.71
Ischemic etiology of heart failure	14 (39)	4 (33)	.73
Transplantation with explantation of a durable LVAD (%)	15 (42)	6 (50)	.74
Transplantation with explantation of a temporary LVAD (%)	13 (36)	2 (17)	.29
Recipient listed as Status 1 - 3	25 (69)	5 (42)	.39
Commercial payer (%)	14 (39)	3 (25)	.49

*values are displayed as median with 25th and 75th percentile

	DBD (N = 36)	DCD (N = 12)	DBD vs. DCD	TA-NRP (N = 8)	DP-NMP (N = 4)	TA-NRP vs. DP- NMP
			<i>P</i> - value			<i>P</i> - value
Charge, \$	807,412	820,896	.51	748,663	1,032,212	.50
Expected net revenue, \$	398,250	400,587	.68	400,587	437,183	.87
Direct cost, \$	166,335	155,804	.78	143,152	214,391	.50
Contribution margin, \$	226,714	227,948	.62	235,440	172,209	.73
Indirect cost, \$	46,736	43,059	.83	39,926	54,647	.50
Net income, \$	184,739	195,527	.57	199,387	128,251	1
Payment amount, \$	338,143	392,772	.40	392,772	413,277	.87

all values are displayed as medians

SOLVED?

OPO

- ↓ LABOR (local)
- ↓ OPORTUNITY COST OF LABOR
- ↓ DRY RUN COST
- ↓ TRANSPORT COST
- ↓ BURNOUT
- ↓ UNCOVERED COST
- ☒ Donor CONVERSION

Fin

Localization

Will it help?

Likely Benefit

Transplant Center Cost

Transplant rate

Improved organ use

QUALITY/STANDARDS

AVAILABILITY

Unclear Benefit

Strategic equalizer

Initial Steps would be passive cooperation for organ procurement informally working towards a formal network to increase trust and decrease cost. Then, OPO linked Thoracic Procurement

A silhouette of a Saguaro cactus stands on the right side of the frame against a deep purple and blue twilight sky. The cactus has a single tall arm reaching upwards and several shorter arms at its base. The background shows faint horizontal cloud layers and the dark outlines of desert shrubs and mountains along the horizon.

Thank You

SCS4@ARIZONA.EDU



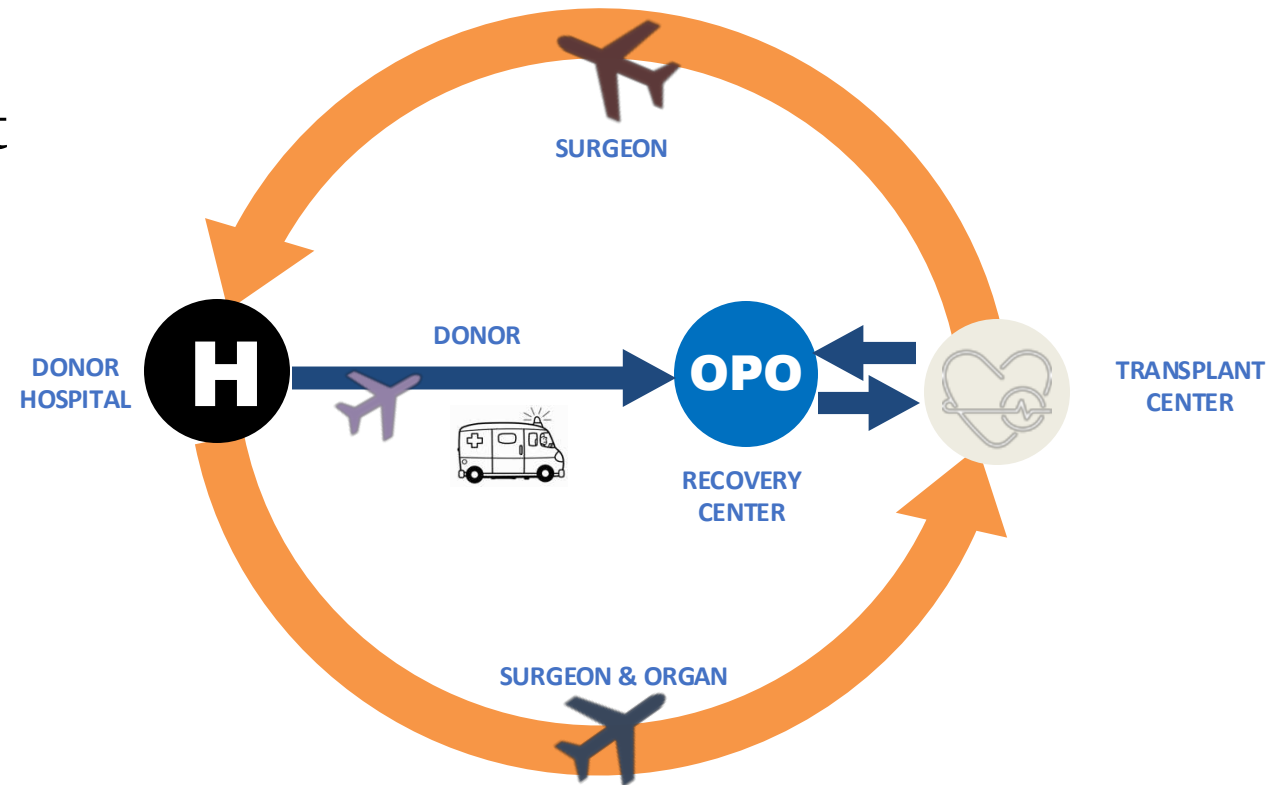
Innovation in Donor Recovery- Organ recovery Center

MTS/Department of Surgery Distinguished Endowed
Chair in Abdominal Transplant
Professor of Surgery, Section of Abdominal Transplant
Executive Vice Chair for the Department of Surgery
Washington University, St. Louis, USA

Disclosures

Educator for OrganOx
Proctor for Intuitive

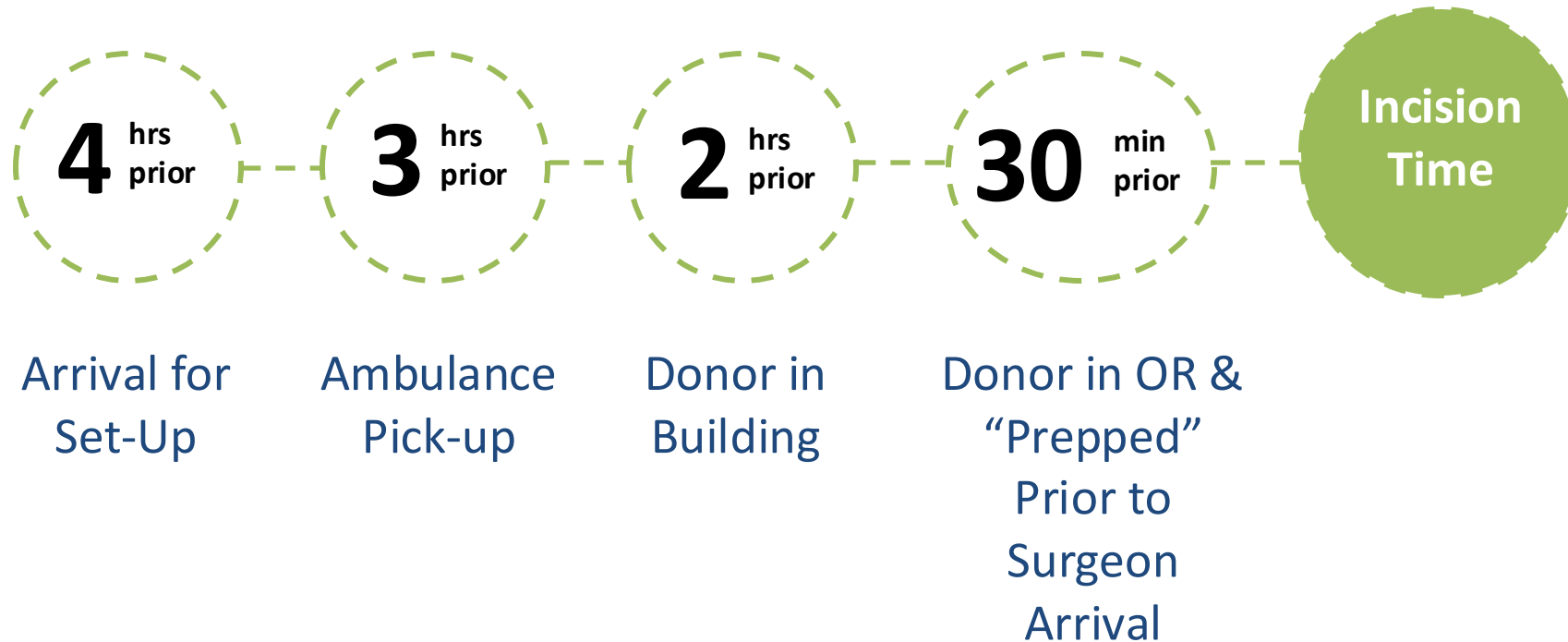
New paradigm in organ donor management





The early transfers

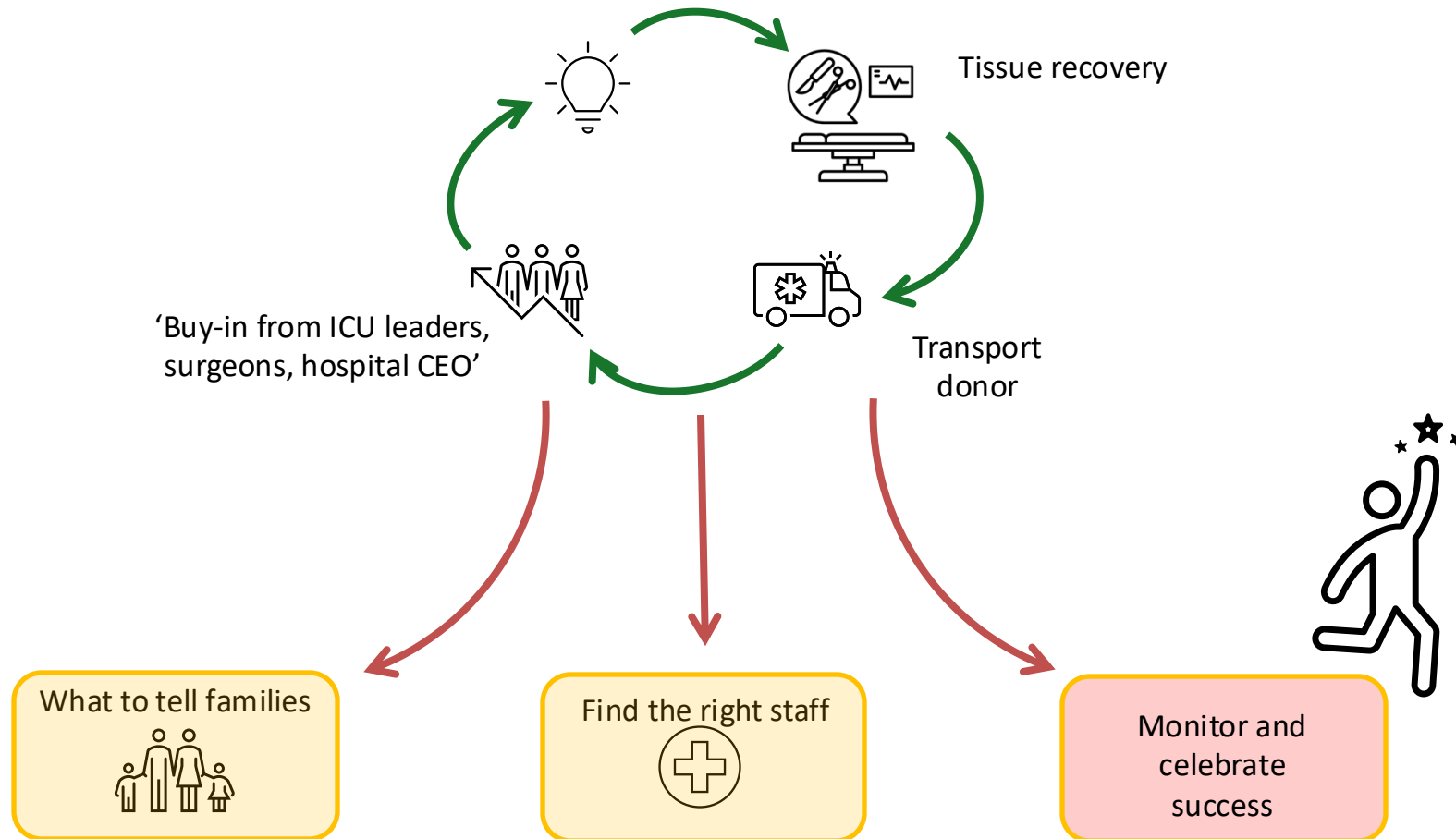
2001: initial Approach to recovery



“We’re going to do what?”



Building an OPO Recovery Center



Mid-America Transplant ORC

- First in the world free-standing onsite organ recovery center established 2001

Cardiac Cath Lab



Donor OR



Air Transportation of the Donor



Advantages of CT Scanner

- Essentially all donors are scanned: liver volumes, vasculature, occult neoplasm
- All lung donors are scanned
- Can repeat CT scans to document infiltrate improvement
- Convenience
- Cost effective
- 30% of donors don't proceed because of CT findings



2018



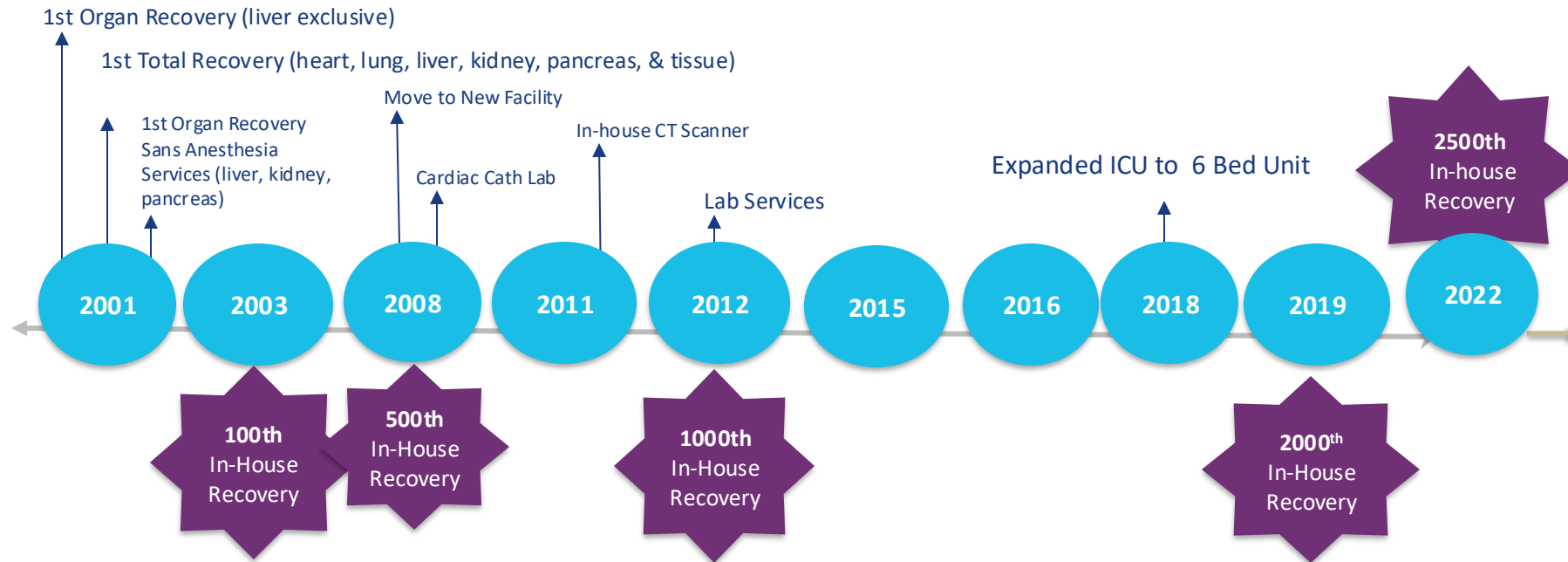
Making the model work

Transplant Partner Satisfaction Survey

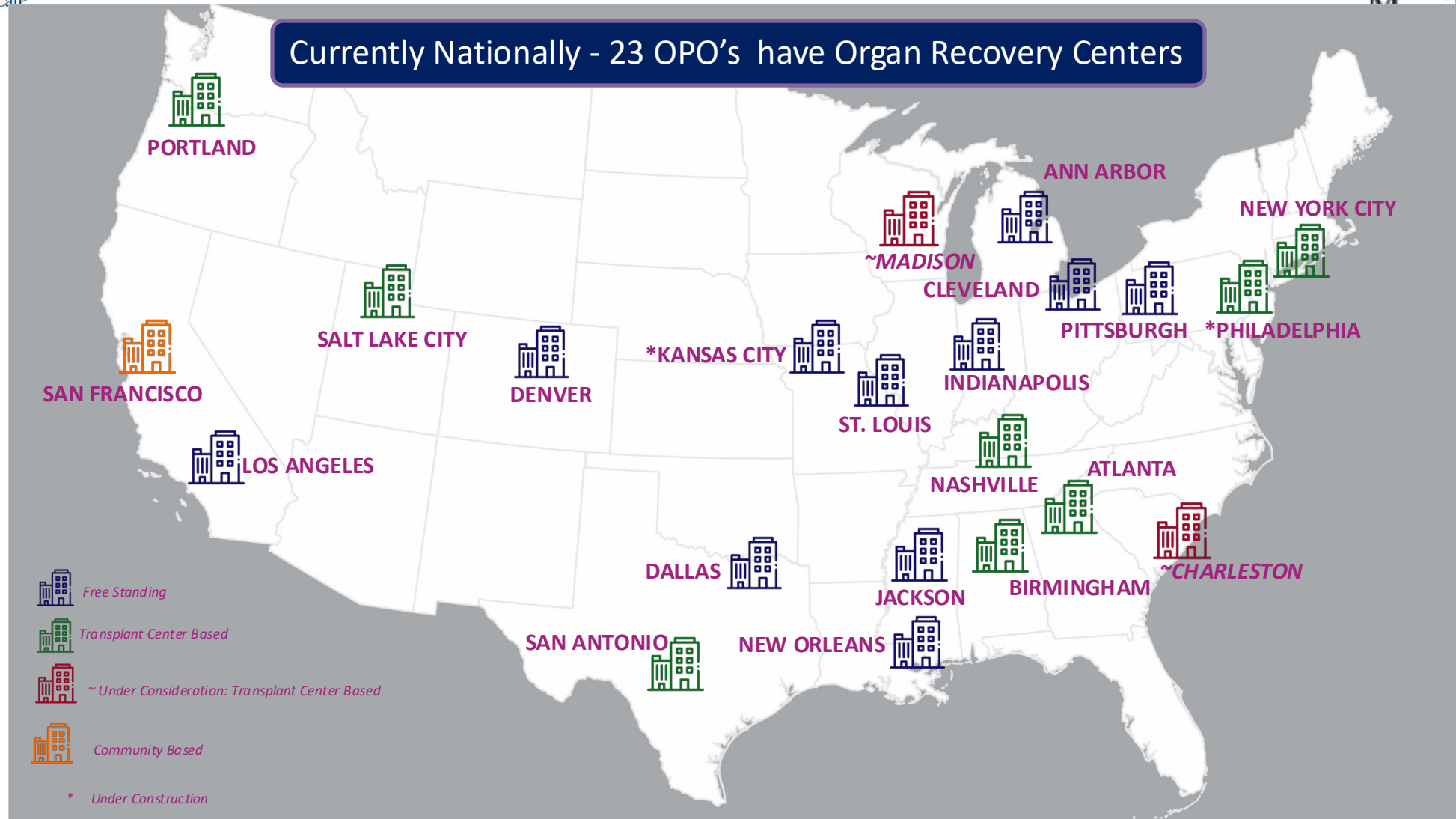
- High initial satisfaction scores demonstrated
- OPO - continue to seek surgeon input
 - Instrumentation
 - Equipment
- Skeptics become advocates
 - Multiple publications
 - National meeting presentations

Time line to Success

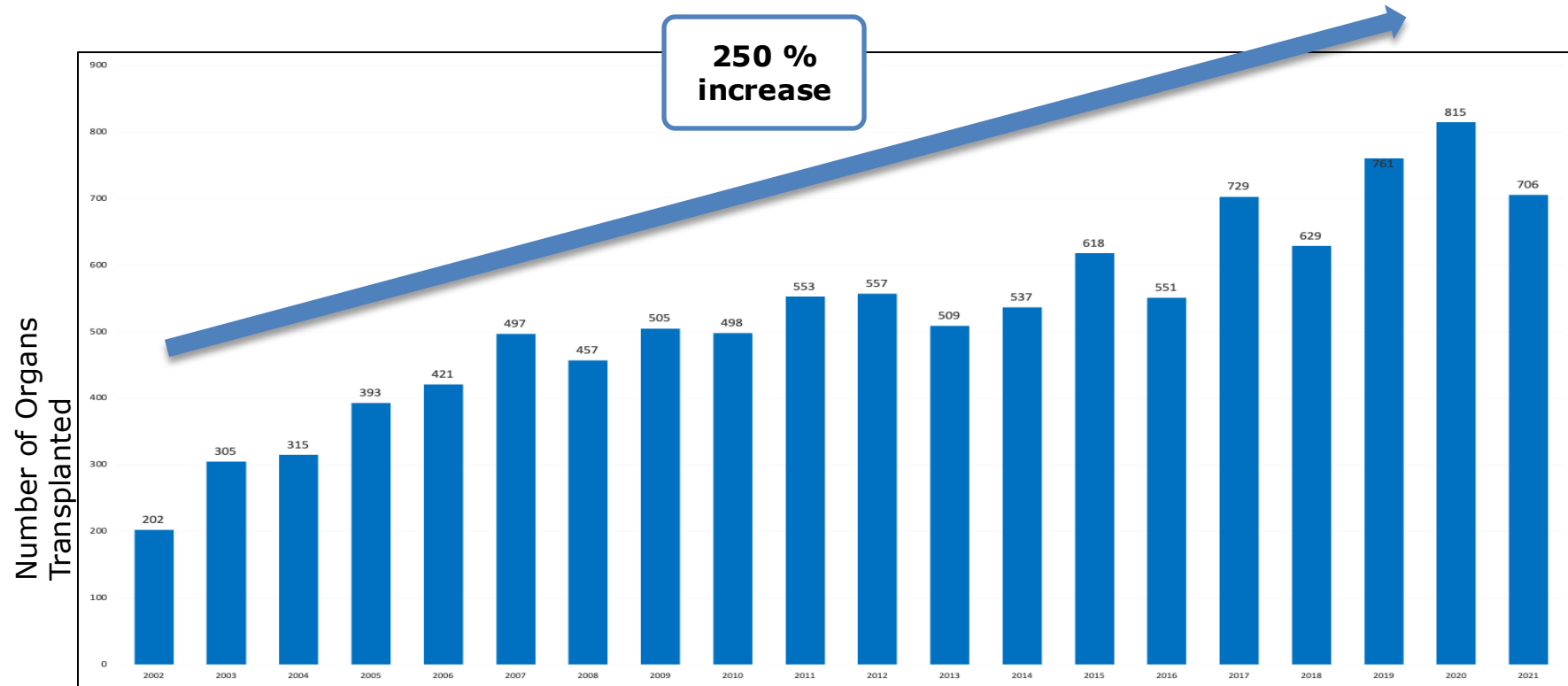
St. Louis Organ Recovery Center: Over 20 Years of Experience



Currently Nationally - 23 OPO's have Organ Recovery Centers

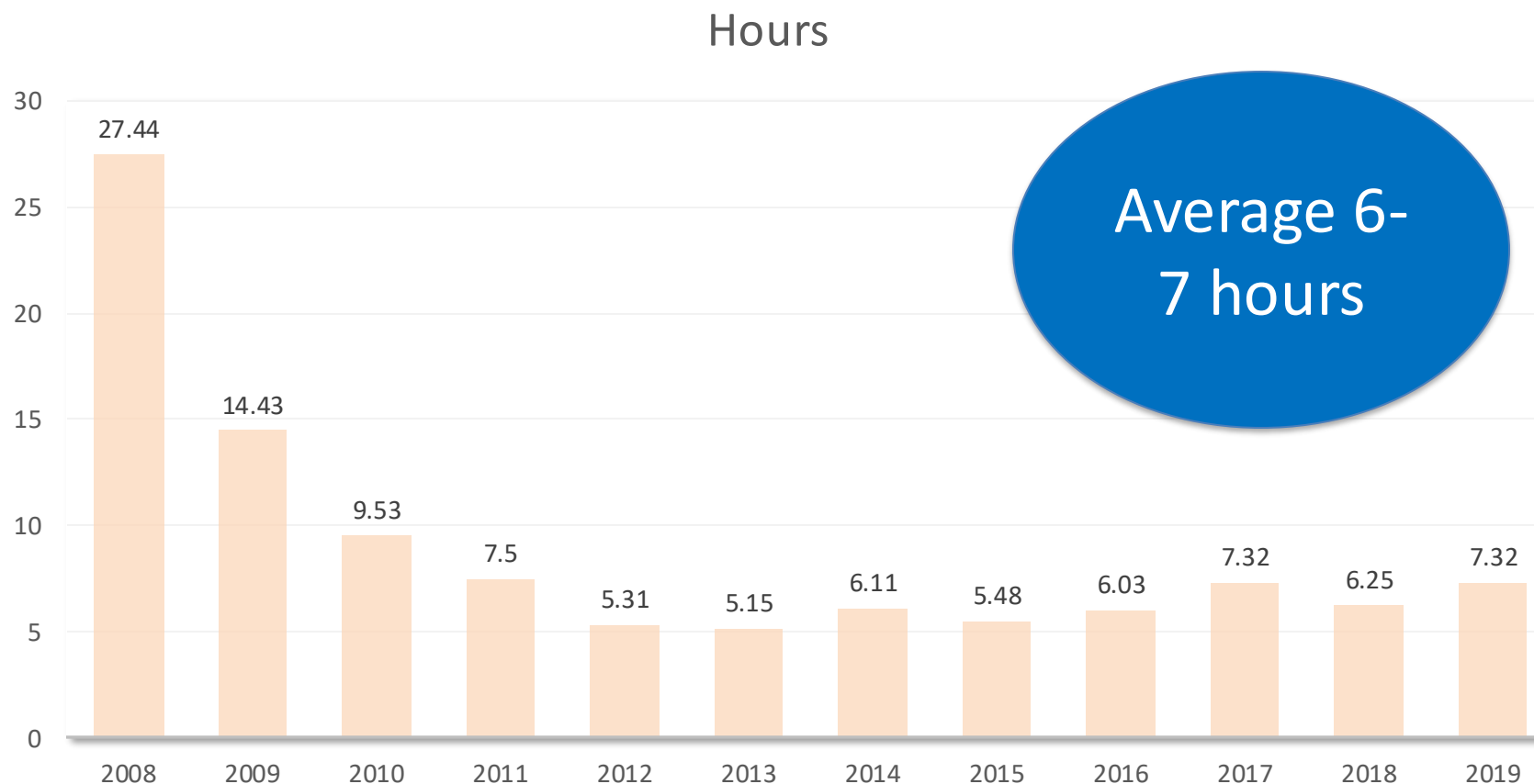


Benefits of an Organ Recovery Center: Number of organs transplanted



Transferring the Donor to the OPO Recovery Center

Time from Authorization to Arrival- “Cycle time”

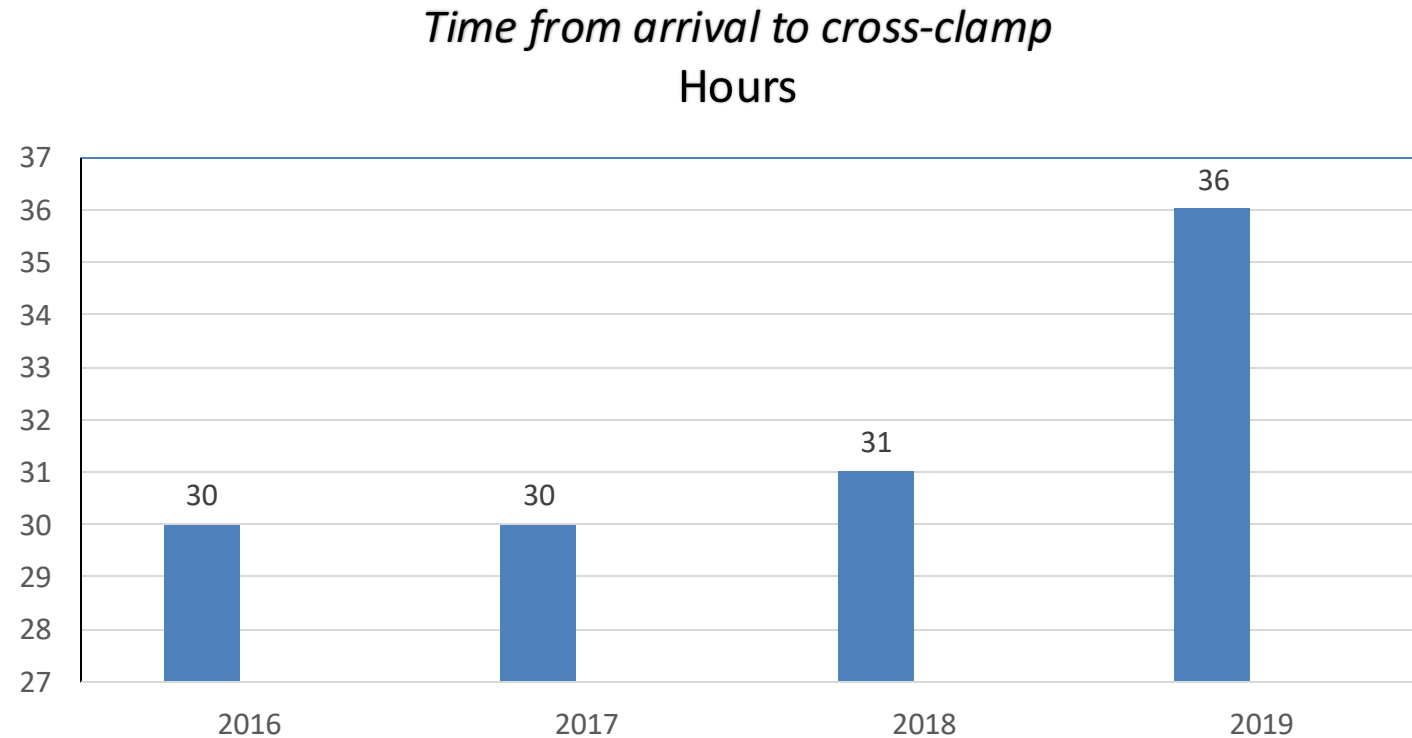


Results : Time at OPO Recovery Center

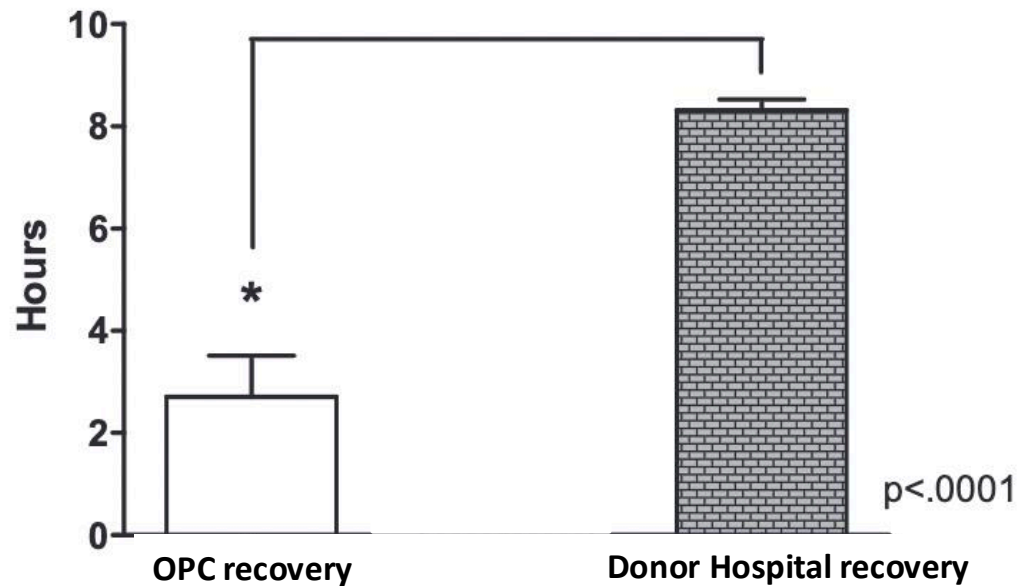
36 hours = mean
time at OPO
(2019)

20-40 hours =
50% of donors

5-60 hours =
range



Benefits: Abdominal Recovery Surgeon Time

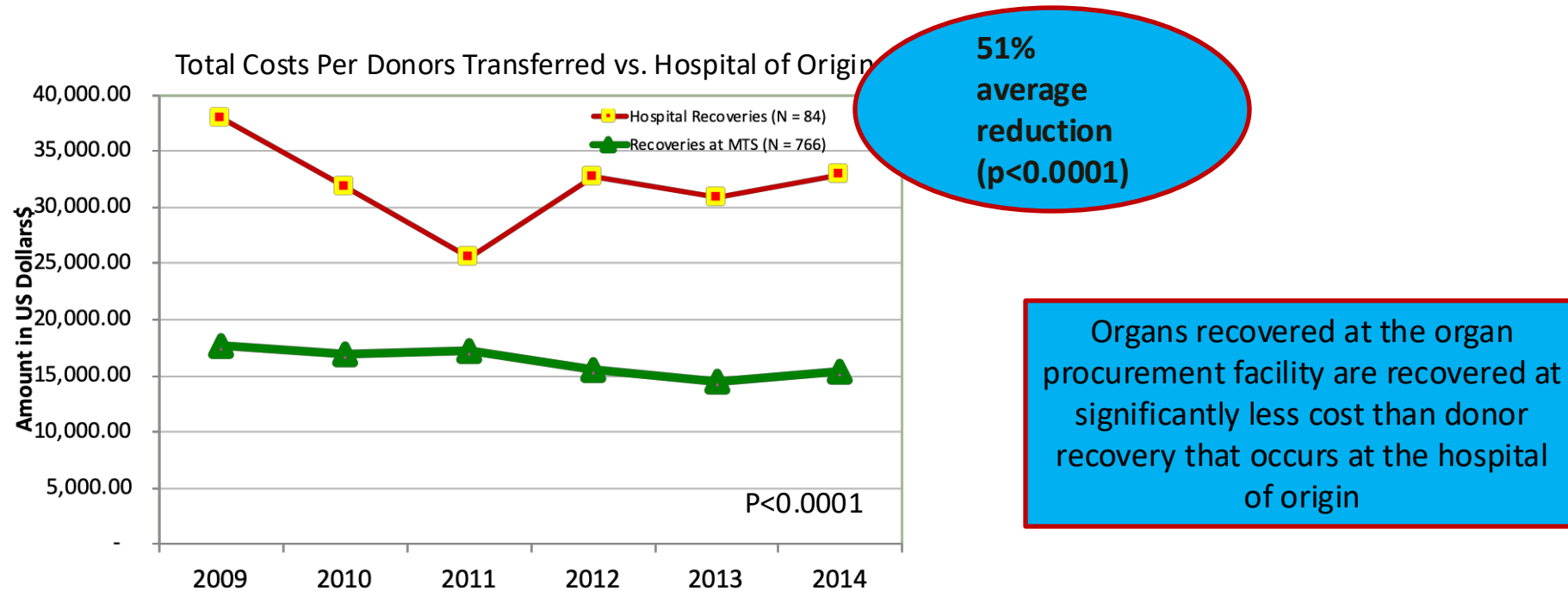


Surgeon travel time was significantly reduced for donors procured at OPOs (2.7 h) compared with those requiring fly outs (8.2 h)

In addition surgical team saw an overall reduction of surgeon fly outs by 93%

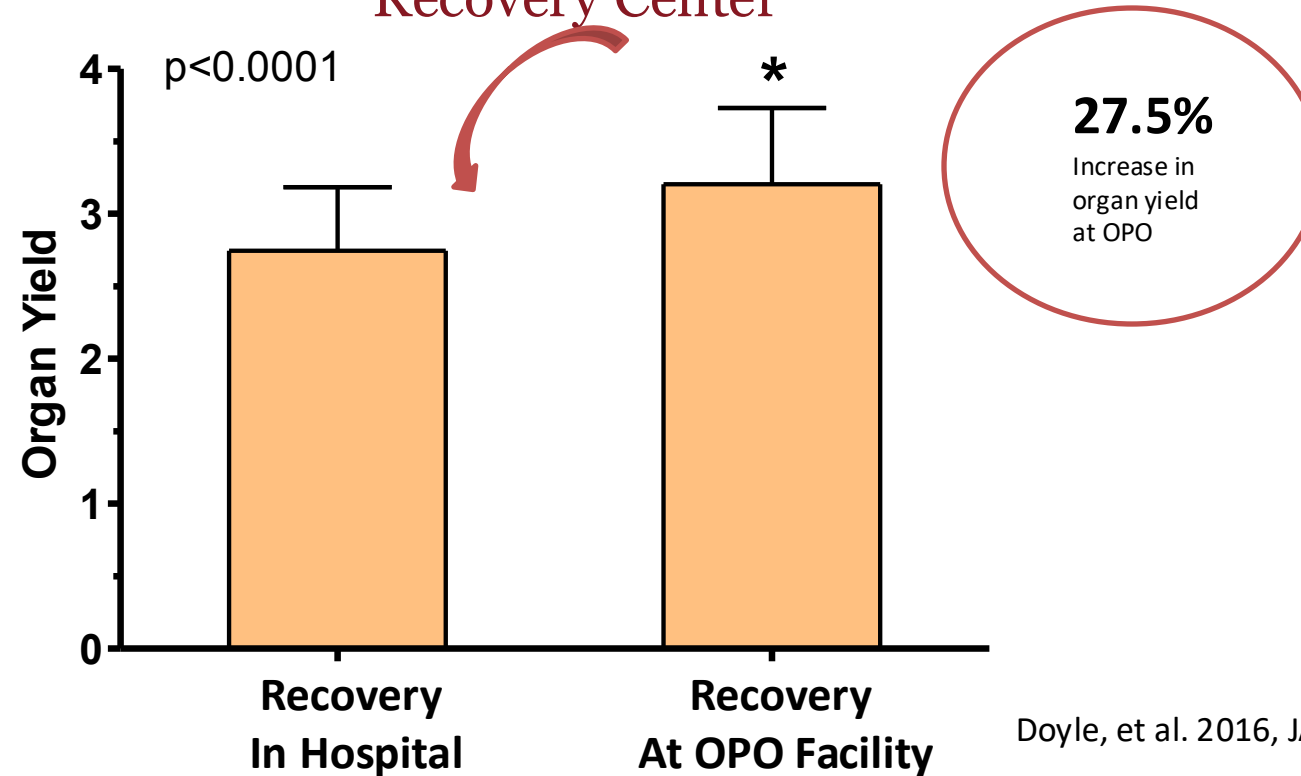
M.B. Doyle, N. Vachharajani, J.R. Wellen, *et al.* A novel organ donor facility: a decade of experience with liver donors
Am J Transplant, 14 (2014), pp. 615-620

Benefits : Total Donor Cost Reduction



Doyle M, et al. J Am Coll Surg. 2016 Apr;222(4):591-600.

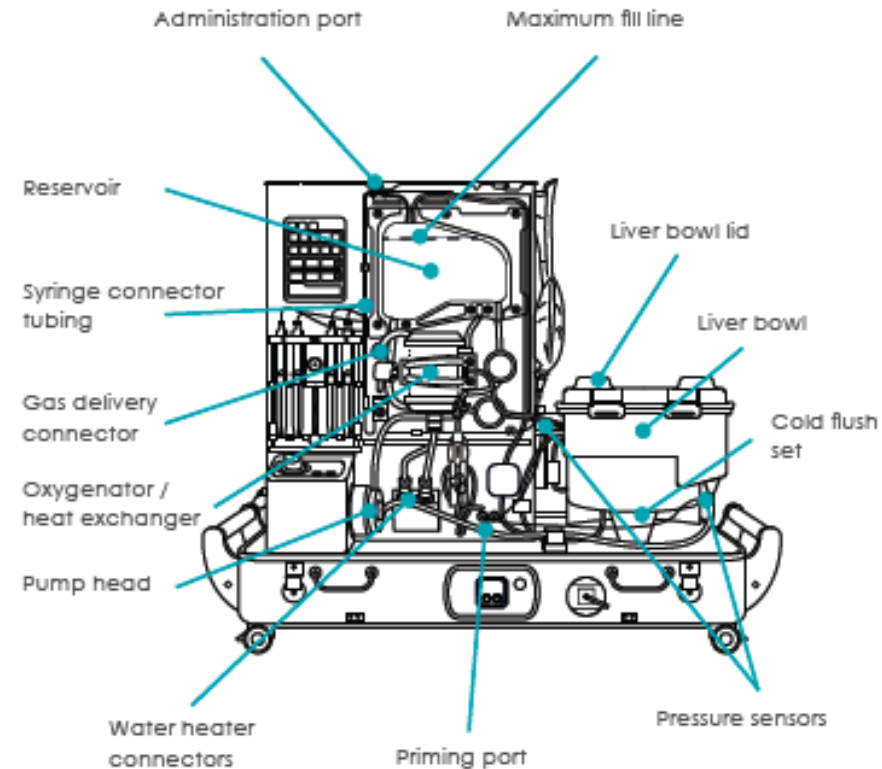
Benefits: Organ Yield Increased for Donors at Organ Recovery Center



Doyle, et al. 2016, JACS; 222: 591

Collaboration to Improve Organ Function after Recovery

Loaded Device

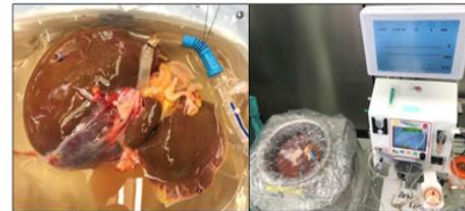


Ex-Vivo Machine Perfusion

Hypothermic



Lifeport Liver Transporter
USA



VitaSmart
USA

Normothermic

Liver Machines



OrganOx Metra
UK



TransMedics OCS Liver
USA



LiverAssist (OrganAssist)
Netherlands

The Organ Is Still Working. But It's Not in a Body Anymore.

Perfusion keeps a donated organ alive outside the body, giving surgeons extra time and increasing the number of transplants possible.

Ex-VIVO - Machine Perfusion

Why NMP?

nature

Article | Published: 18 April 2018

A randomized trial of normothermic preservation in liver transplantation

David Nasralla^{1*}, Constantin C. Coussios^{2*}, Hynek Mergental³, M. Zeeshan Akhtar^{1,4}, Andrew J. Butler^{5,20}, Carlo D. L. Ceresa¹, Virginia Chiochia^{6,7}, Susan J. Dutton⁸, Juan Carlos García-Valdecasas⁹, Nigel Heaton¹⁰, Charles Imber¹¹, Wayel Jassem¹⁰, Ina Jochmans^{12,13}, John Karani^{10,14}, Simon R. Knight^{1,15}, Peri Kocabayoglu¹⁶, Massimo Malago¹¹, Darius Mirza³, Peter J. Morris^{1,15}, Arvind Pallan¹⁷, Andreas Paul¹⁶, Mihai Pavel⁹, M. Thamara P. R. Perera³, Jacques Pirenne^{12,13}, Reena Ravikumar¹, Leslie Russell¹⁸, Sara Upponi¹⁹, Chris J. E. Watson^{5,20}, Annemarie Weissenbacher¹, Rutger J. Ploeg¹, Peter J. Friend^{1*} for the Consortium for Organ Preservation in Europe

Normothermic Machine Perfusion of Donor Livers for Transplantation in the United States

A Randomized Controlled Trial

William C. Chapman, MD,* Andrew S. Barbas, MD,†
Anthony M. D'Alessandro, MD,‡ Rodrigo Vianna, MD, PhD,§
Chandrashekhar A. Kubal, MD,|| Peter Abt, MD,¶ Christopher Sonnenday, MD,#
Rolf Barth, MD,** Josue Alvarez-Casas, MD,†† Hasan Yersiz, MD,‡‡
Devin Eckhoff, MD,§§ Robert Cannon, MD,||| Yuri Genyk, MD,¶¶ Linda Sher, MD,¶¶
Andrew Singer, MD,## Sandy Feng, MD,*** Garrett Roll, MD,***
Ari Cohen, MD,††† Maria B. Doyle, MD,* Debra L. Sudan, MD,†
David Al-Adra, MD, PhD,‡ Adeel Khan, MD,* Vijay Subramanian, MD,†††
Nader Abraham, MD,† Kim Olthoff, MD,¶ Akin Tekin, MD,§ Lynn Berg, MD,‡
Constantin Coussios, PhD,§§§ Chris Morris, CPS,§§§ Lucy Randle,§§§
Peter Friend, MD,§§§ and Stuart J. Knechtle, MD†‡‡

Liver Transplantation 25 436–449 2019 *AASLD*.

Received May 27, 2018; accepted October 17, 2018.

Pilot, Open, Randomized, Prospective Trial for Normothermic Machine Perfusion Evaluation in Liver Transplantation From Older Donors

Davide Ghinolfi¹,¹ Erion Rreka,¹ Vincenzo De Tata,³ Maria Franzini,³ Daniele Pezzati,¹ Vanna Fierabracci,³ Matilde Masini,³ Andrea Cacciatoinsilla,⁴ Maria Lucia Bindi,² Lorella Marselli,⁶ Valentina Mazzotti,⁵ Riccardo Morganti,⁵ Piero Marchetti,⁶ Giandomenico Biancofiore,² Daniela Campani,⁴ Aldo Paolicchi,³ and Paolo De Simone¹

JAMA Surgery | Original Investigation

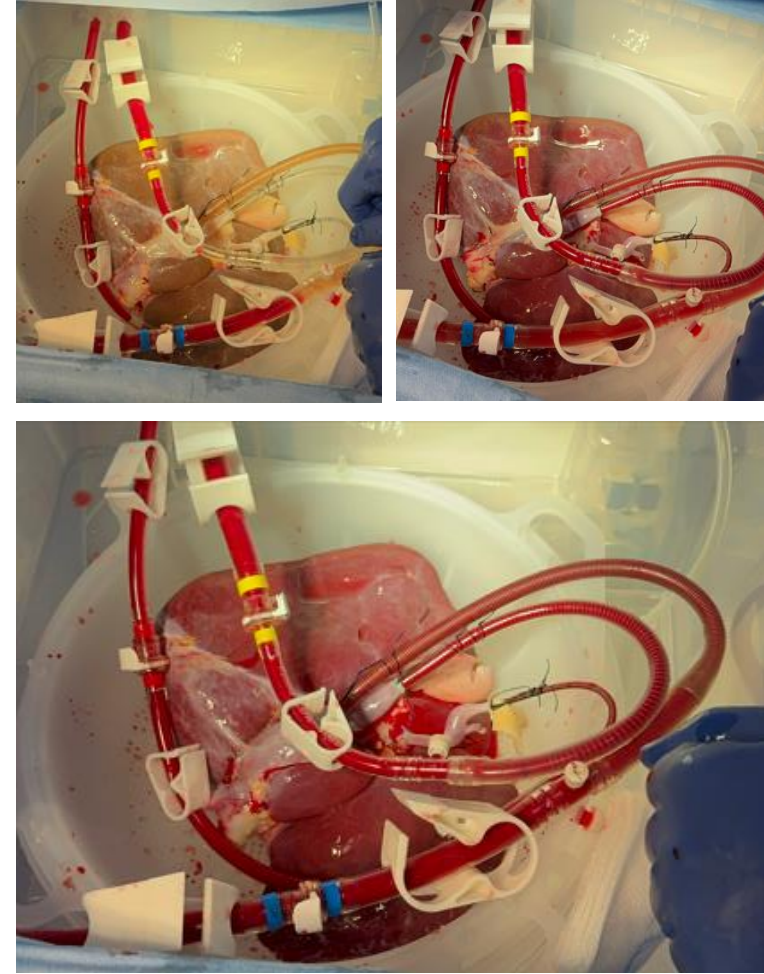
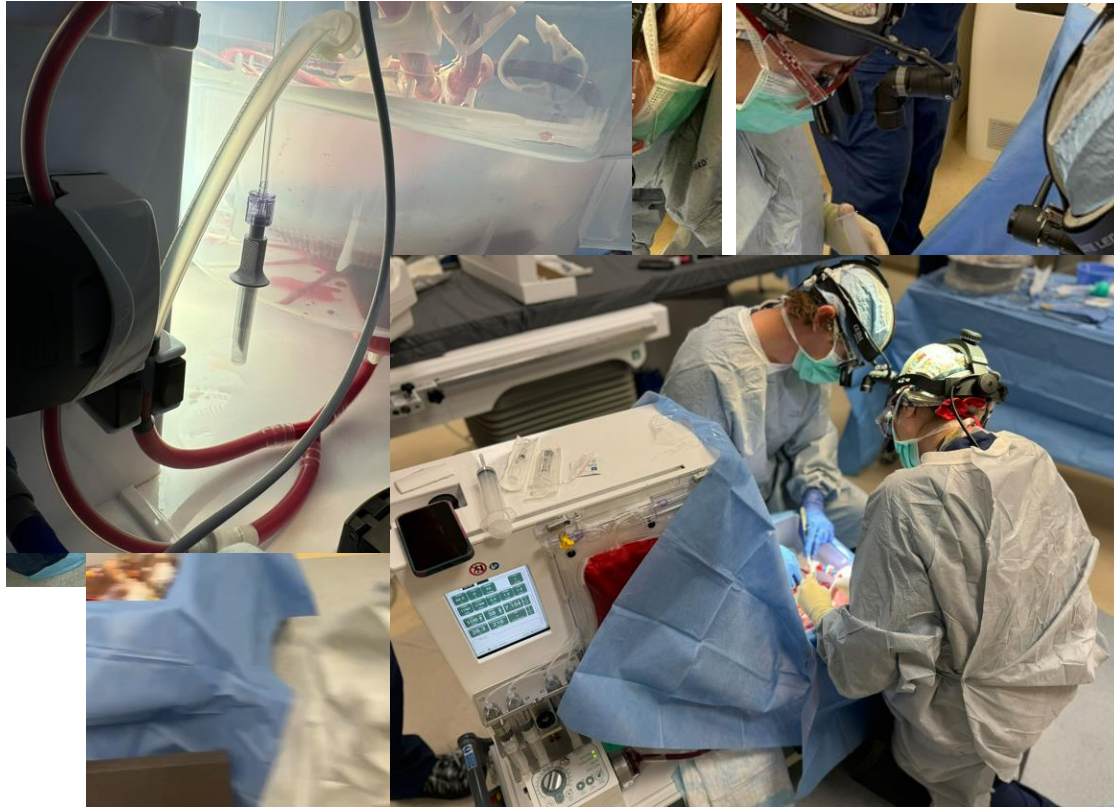
Impact of Portable Normothermic Blood-Based Machine Perfusion on Outcomes of Liver Transplant The OCS Liver PROTECT Randomized Clinical Trial

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

Cannulation/Priming



Going on Pump

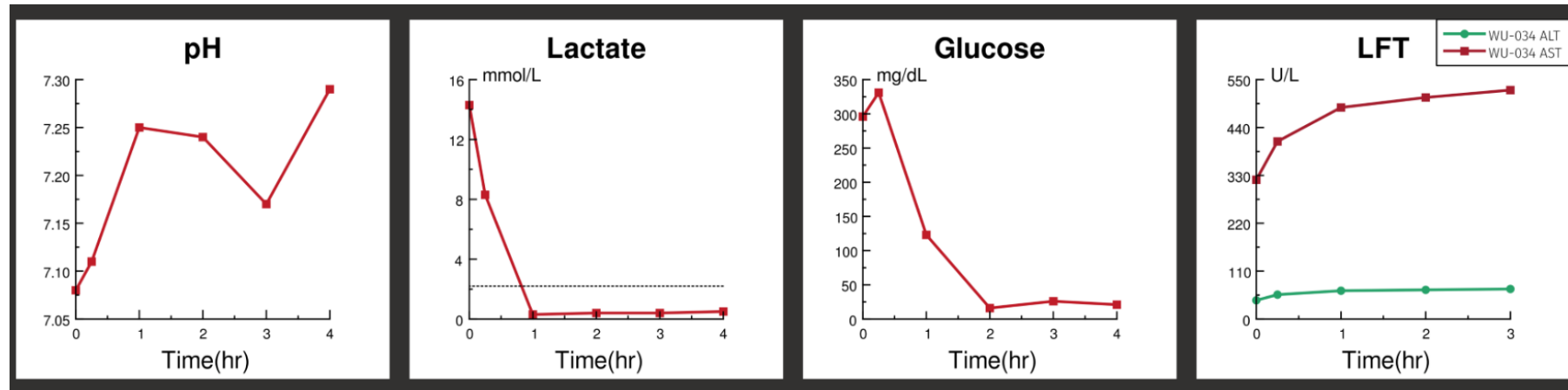


Going on Pump



Viability Assessment

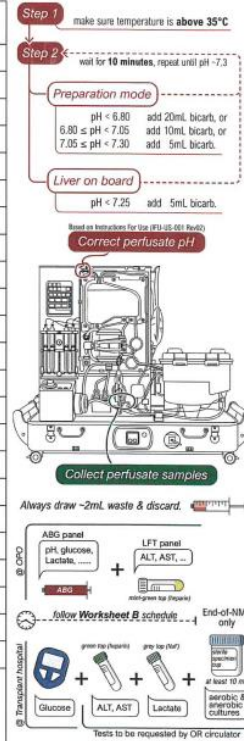
- Perfusion metrics*
 - >150 mL/min (arterial), >500 mL/min (portal)
- Laboratory values



Viability Assessment

Worksheet A OrganOx metra[®] Standard Protocol

Date & Time mm/dd/yyyy HH:mm	pH on-board display	Operation bicarb, pump start/stop, nutrition, etc.
9/13/2024 1815	6.76	20mL Bicarb
9/13/2024 1825	7.20	5mL Bicarb
9/13/2024 1835	7.27	5mL Bicarb
9/13/2024 1910	—	Liver on Pump
9/13/2024 1934	7.06	5mL Bicarb
9/13/2024 1944	7.18	5mL Bicarb
9/13/2024 1959	7.22	5mL Bicarb
9/13/2024 2058	7.23	5mL Bicarb
9/14/2024 0225	7.24	5mL Bicarb
0318	7.23	5mL Bicarb
0318	—	Clinical hung
0330	7.24	5mL Bicarb
0345	7.24	5mL Bicarb
0401	7.24	5mL Bicarb
0416	7.24	5mL Bicarb
0516	7.24	5mL Bicarb
0627	7.24	5mL Bicarb
Comments:		

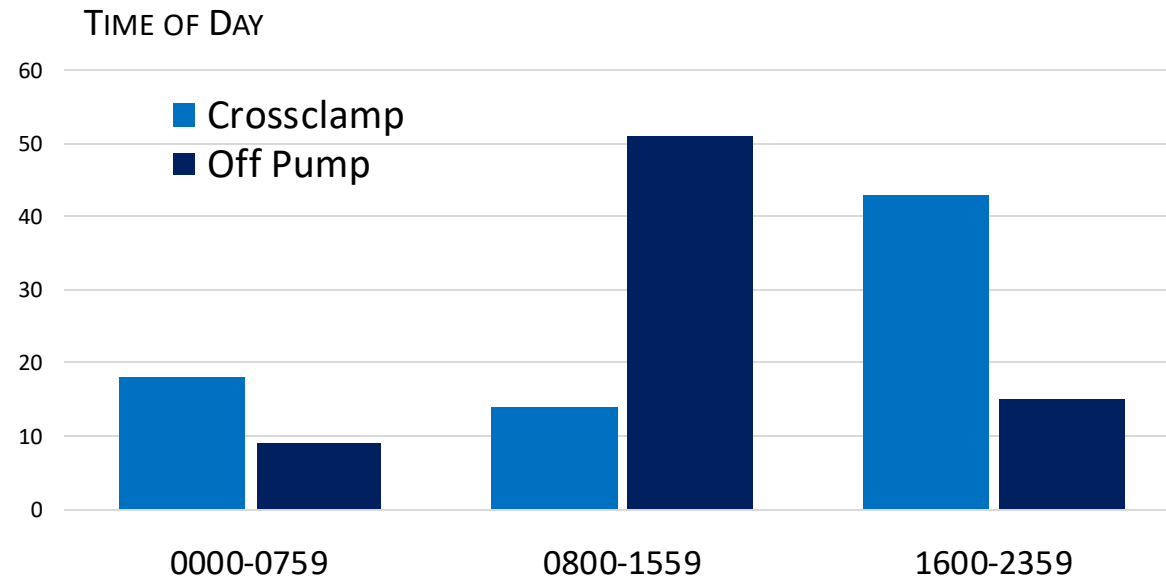


Worksheet B OrganOx metra[®] Standard Protocol

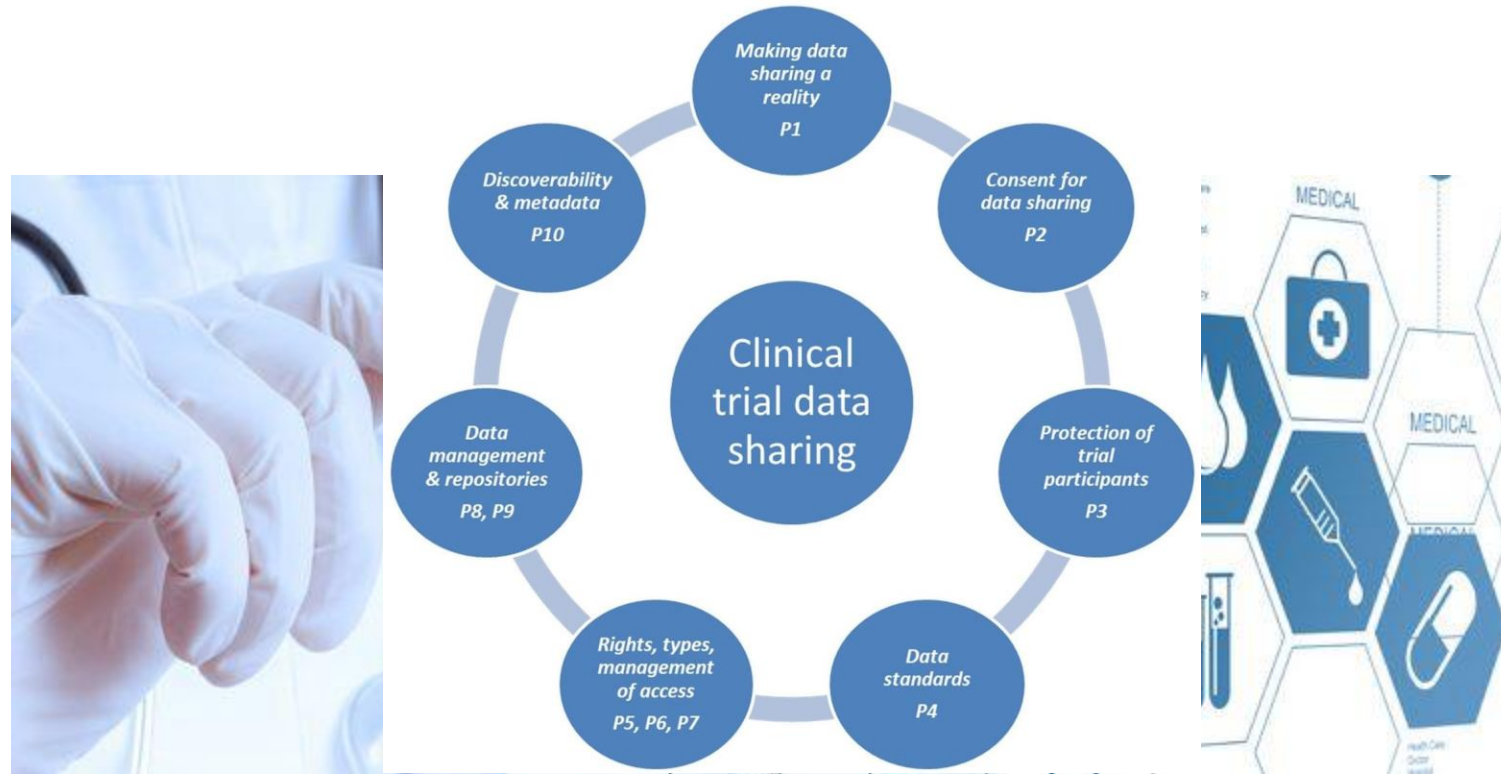
Start of Liver Perfusion				Cessation of Liver Perfusion			
Date & Time		9/13/2024 1910 mm/dd/yyyy HH:mm		Date & Time		09/14/2024 0930 mm/dd/yyyy HH:mm	
All subsequent timings are relative to perfusion start time.							
15 minutes				8 hours			
Date & Time of sample taken		9/13/2024 1925 mm/dd/yyyy HH:mm		Date & Time of sample taken		09/14/2024 0310 mm/dd/yyyy HH:mm	
Lactate	2.0 mmol/L	ALT	2155 U/L	Lactate	1.5 mmol/L	ALT	6875 U/L
Glucose	295 mg/dL	AST	2375 U/L	Glucose	145 mg/dL	AST	6950 U/L
2 hours				12 hours			
Date & Time of sample taken		9/13/2024 2110 mm/dd/yyyy HH:mm		Date & Time of sample taken		09/14/2024 0715 mm/dd/yyyy HH:mm	
Lactate	0.7 mmol/L	ALT	5278 U/L	Lactate	1.8 mmol/L	ALT	>7000 U/L
Glucose	291 mg/dL	AST	5694 U/L	Glucose	251 mg/dL	AST	>7000 U/L
4 hours				Before departure from OPO			
Date & Time of sample taken		9/13/2024 2310 mm/dd/yyyy HH:mm		Date & Time of sample taken		09/14/2024 0810 mm/dd/yyyy HH:mm	
Lactate	1.0 mmol/L	ALT	6509 U/L	Lactate	1.8 mmol/L	ALT	>7000 U/L
Glucose	271 mg/dL	AST	6720 U/L	Glucose	201 mg/dL	AST	>7000 U/L
Liver deemed transplantable by the surgeon?				Before cessation of liver perfusion			
☒ YES ☐ NO				☐ YES ☐ NO			
Comments: 4 Reperf				Date & Time of sample taken 09/14/2024 0915 mm/dd/yyyy HH:mm			
				Labs drawn: ☒ Cultures ☒ ALT, AST ☒ Lactate			
				Samples given to OR circulator? ☒ YES ☐ NO			
Viability Criteria	Lactate @2hr, below 2.2 mmol/L	Perfusion Flow portal > 0.5 L/min artery > 0.1 L/min	pH pH > 7.25	Bicarb less than 7.0 mEq/L after 30-60 min	Glucose decrease in 0-4hrs, or require insulin	Chemistry ALT < 7000 AST < 10000	Bile output bile visible from side-chamber
YES / NO	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Normothermic machine perfusion

- Future directions – **organ optimization, graft rescue**
- Decreased burnout? **Improved quality of life** among transplant teams?



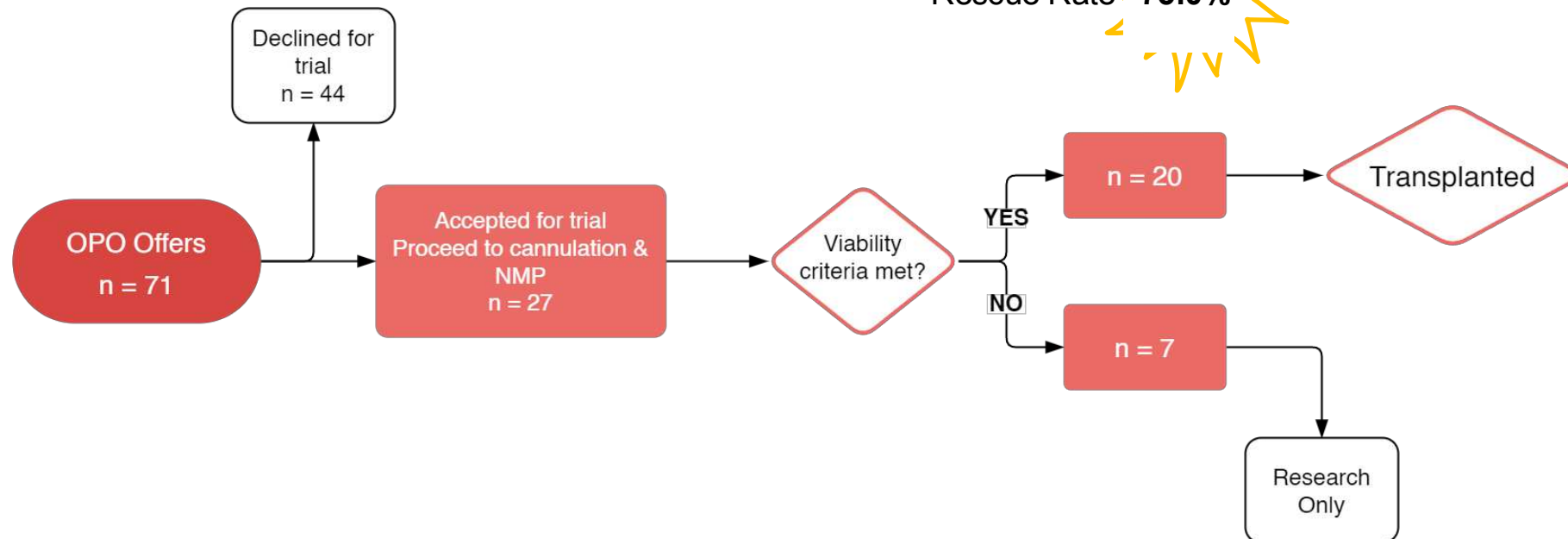
Surgical Collaboration – Clinical Trials



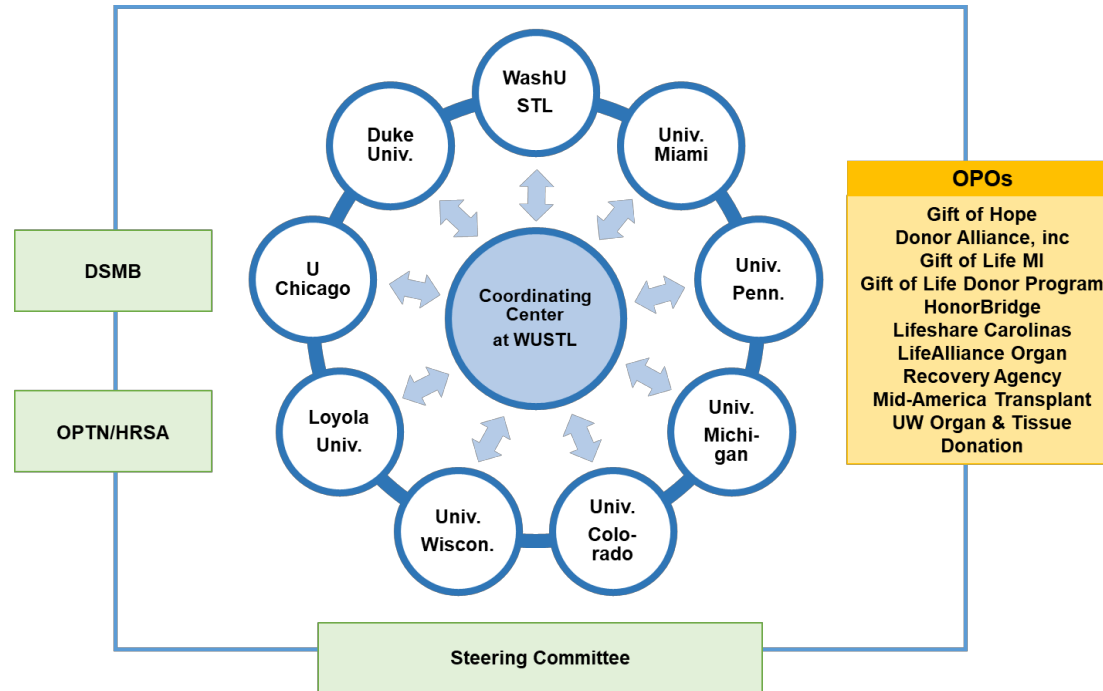
Single Center RESTORE Declined Livers Study

(NCT04483102)

- To test the feasibility of successfully transplanting previously declined NMP-treated livers (n=25)
- Washington University Barnes-Jewish Hospital with the Mid America Transplant (OPO)
- FDA-approved IDE



Coming in 2024: Multicenter RESTORE Trial



	RESTORE Centers (n~900)	All US Centers
Race/Ethnicity		
White	72%	69%
Black	9%	9%
Hispanic	14%	16%
Asian	3%	4%
Others	2%	2%
Gender		
Women	35%	37%
Men	65%	63%

*5 year average





Thank You

The Benefits and Challenges of Local Organ Procurement

Christine Radolovic

Chief Clinical Officer

Gift of Life Donor Program, Philadelphia



- Federally designated OPO for eastern PA, Southern NJ & Delaware
 - 126 Acute Care Hospitals
 - 12 Transplant Centers, 35 Programs
 - 11.3 Million Population
- Donation activity
 - 60% Brain Dead donation
 - 40% Donation after Circulatory Death
 - 50% NRP YTD
 - 7% Uncontrolled DCD
- Gift of Life Donor Care Center at Penn Medicine

Local Recovery Services

Gift of Life abdominal recovery surgeons:

- Dr. Marty Sellers
- Dr. John Renz
- Dr. Alger Aquino
- Dr. Christine Du

Local Transplant Center Renal on-Call
External thoracic recovery and
perfusion partnerships for local cases.

* All surgeons meet Gift of Life’s credentialing requirements and professional standards



GIFT of LIFE
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800-KIDNEY-1 • 888-DONORS-1

METRO ON-CALL KIDNEY RECOVERY TEAM SCHEDULE 2024

CENTRAL PA	METRO		CENTRAL PA	METRO	
PAHH	DEAI	03-25-24 - 03-31-24	PAHH	DEAI	09-09
PAHH	PATJ	04-01-24 - 04-07-24	PAHH	PATJ	09-16
PAHE	PACP	04-08-24 - 04-14-24	PAHH	PACP	09-23
PAHE	PAAE	04-15-24 - 04-21-24	PAHH	PAAE	09-30
PAHE	PASC	04-22-24 - 04-28-24	PAHH	PASC	10-07
PAHE	DECH	04-29-24 - 05-05-24	PAHH	DECH	10-14
PAHH	PAUP	05-06-24 - 05-12-24	PAHH	PAUP	10-21
PAHH	PATU	05-13-24 - 05-19-24	PAHH	PATU	10-28
PAHH	PATJ	05-20-24 - 05-26-24	PAHH	DEAI	11-04
PAHH	DEAI	05-27-24 - 06-02-24	PAHH	PATJ	11-11
PAHH	PACP	06-03-24 - 06-09-24	PAHH	PACP	11-18
PAHH	PAAE	06-10-24 - 06-16-24	PAHH	PAAE	11-25
PAHH	PASC	06-17-24 - 06-23-24	PAHH	PASC	12-02
PAHH	DECH	06-24-24 - 06-30-24	PAHH	DECH	12-09
PAHH	PAUP	07-01-24 - 07-07-24	PAHH	PAUP	12-16
PAHH	PATU	07-08-24 - 07-14-24	PAHH	PATU	12-23
PAHH	DEAI	07-15-24 - 07-21-24	PAHH	DEAI	12-30
PAHH	PATJ	07-22-24 - 07-28-24	PAHH	PATJ	01-06
PAHH	PACP	07-29-24 - 08-04-24	PAHH	PACP	01-13
PAHH	PAAE	08-05-24 - 08-11-24	PAHH	PAAE	01-20
PAHH	PASC	08-12-24 - 08-18-24	PAHH	PASC	01-27
PAHH	DECH	08-19-24 - 08-25-24	PAHH	DECH	02-03
PAHH	PAUP	08-26-24 - 09-01-24	PAHH	PAUP	02-10
PAHH	PATU	09-02-24 - 09-08-24	PAHH	PATU	02-17

METRO TRANSPLANT CENTERS

PAAE Albert Einstein MC
PASC St. Christopher's Hosp
DECH Christiana Care Hospit
PAUP Hospital of the Univers
PATU Temple University Hos
DEAI A. I. DuPont Hospital fo
PATJ Thomas Jefferson Univ
PACP Children's Hospital of

CENTRAL PA TRANSPLANT CENTERS

PAHH UPMC Pinnacle Harrisburg Hospital

NOTE: Teams take call from 8:00am Monday to 8:00am of the following Monday. (Sunday listed as last call day)



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GUIDELINES FOR ON-CALL KIDNEY RECOVERY TEAM SCHEDULE 2024

- Donor hospitals in satellite areas are to be covered by the transplant recovery team centers in those respective areas. The metro centers will rotate on a weekly basis. A schedule will be sent out and the end of each calendar year to remind teams of their kidney recovery responsibilities.
- All in-house transplant center kidney recoveries (ie kidney donors at a transplant center) are to be performed by that center’s team, unless other arrangements are made.
- The on call or in-house kidney recovery surgeon is responsible for performing all kidney recoveries. If a local liver team is recovering the liver, they will act as the on-call kidney recovery team and perform the kidney recovery unless the in-house kidney recovery team elects to perform the kidney recovery.
- A surgeon who has been approved by the GLDP credentialing process must be present at all kidney recoveries. In circumstances where there is a credentialed surgeon from a transplant center outside of Gift of Life’s Donation Service Area present to recover the liver and that surgeon has agreed to recover and package the kidneys according to GLDP’s policies, a GLDP credentialed surgeon will not be required. (This provision will be monitored for surgical error and complaints and reported to the Medical Policy and Advisory Board.)
- A recovery team that anticipates not being able to fulfill their responsibility for recovery must make coverage arrangements with another surgical recovery team and inform the Chief Clinical Officer at GLDP in writing at least two (2) weeks prior to the coverage request.
- On-call recovery team responsibility on the schedule attached shall start on the Monday listed at 8:00 am and end at 8:00 am of the following

Efficiency

- Consistent availability of surgeons and surgical staff dedicated to recovery activities
 - Minimizes impact on resources of both OPO and accepting centers.
 - Reduces stress level of OPO staff
- Faster scheduling of organ recoveries
- Can quickly mobilize especially when distance or timing are factors

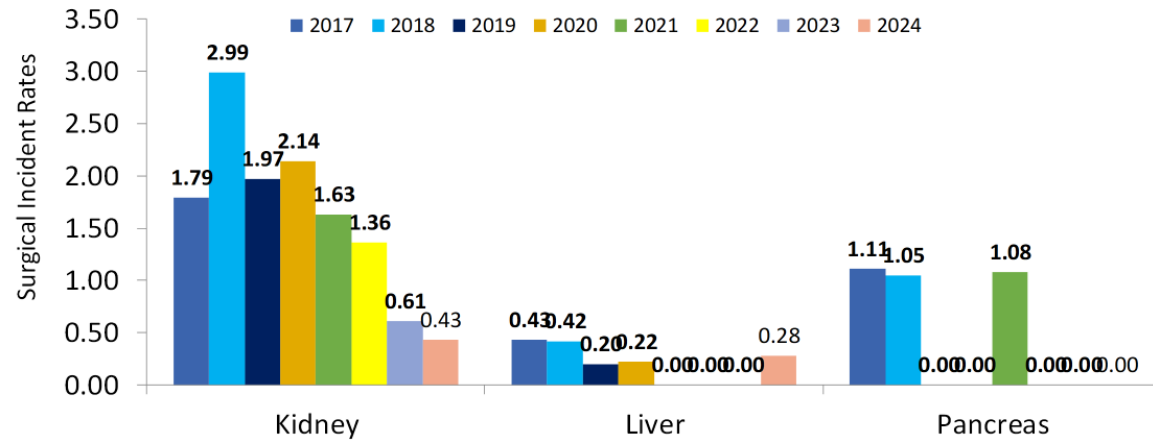


Optimization of Outcomes.....

- Consistency in organ assessment and procurement practices advocating for increased organ utilization and full scope of recovery
- Supporting donor stabilization and viability for all organs during recovery
- Increased organ utilization rates with the expanded criteria of the donor pool
- Experienced recovery surgeons that can handle challenging cases, such as donors with unusual anatomy preserving critical vascular structures, trauma, or older donors.
- Recovery opportunities maximized with reduction of recovery errors

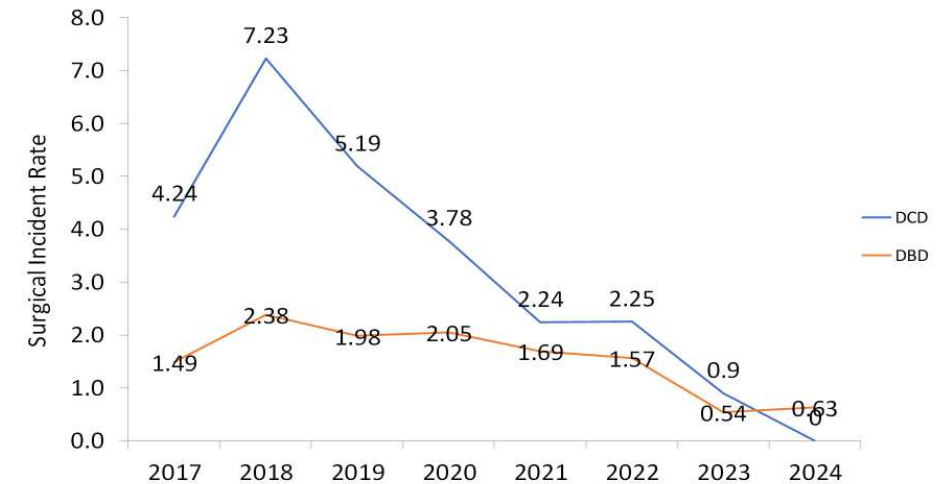
Consistency and Quality Standards

2017 – 2024 YTD Surgical Incidents
Kidney, Liver and Pancreas



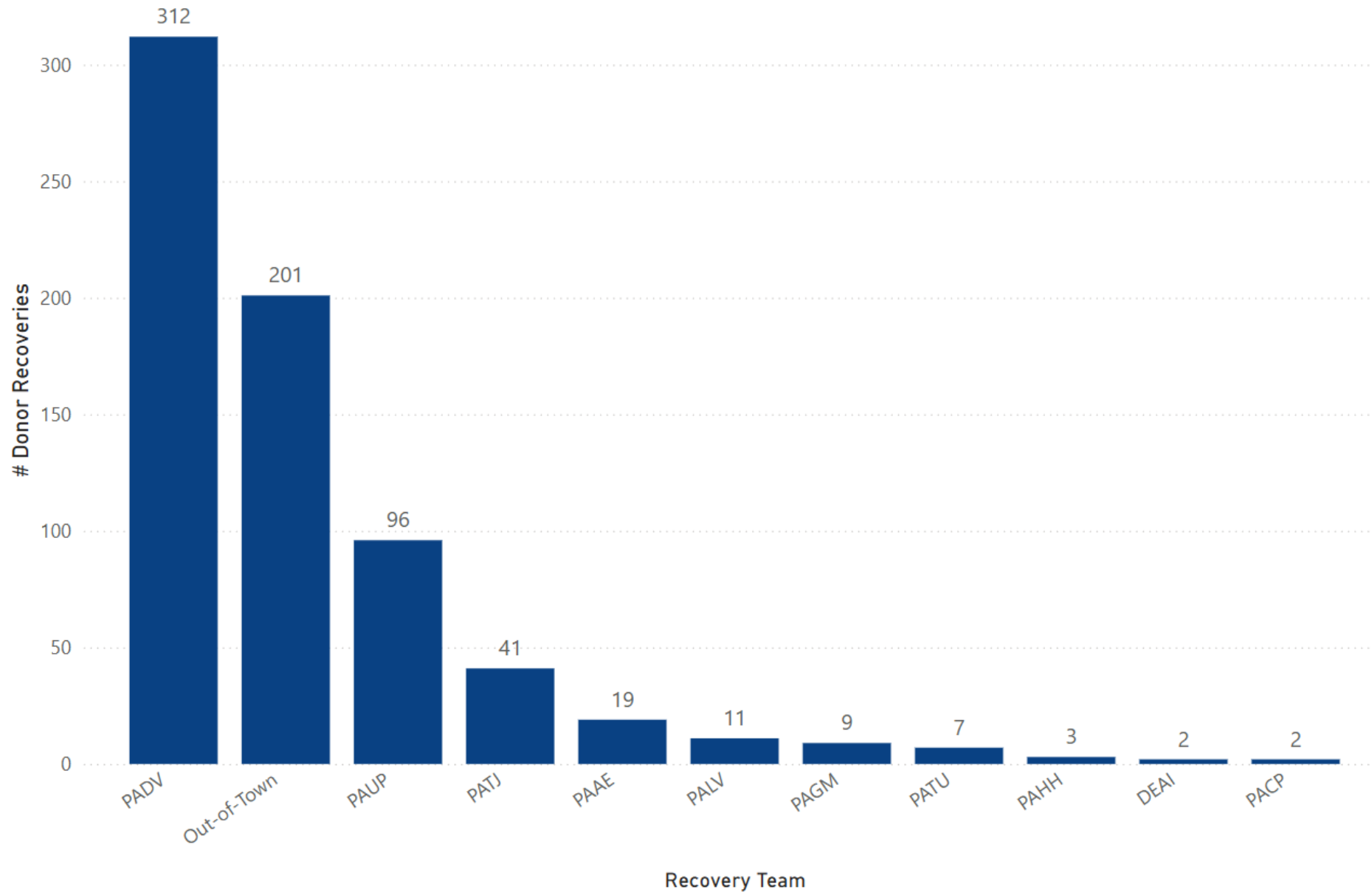
2024 YTD: 1/1/2024 – 9/30/2024

2017 – 2024 YTD Surgical Incident Rates
DBD vs. DCD (Category 1, 2 & 3)
Kidney, Liver and Pancreas



2024 YTD: 1/1/2024 – 9/30/2024

Donor Recoveries by Recovery Team





Support for Research and Innovation

Non-Transplant Organ Recovery: Recovery surgeons can retrieve organs for research, education, or clinical trials, contributing to advancements in transplantation science.

Advanced Technologies: Surgeons can directly coordinate with transplant programs to ensure innovative technologies like Normothermic regional perfusion and machine perfusion systems are implemented.

Collaboration

- Integrated team approach ensuring seamless communication and recovery
- Increased training opportunities for OPO staff
- Relationship building with transplant centers
- Minimizing disruptions of both time and space resources in busy hospital schedules.
- ***Enhancing the Donor and Donor Family Experience***

Other Operational Benefits

Financial Benefits

- **Reduced Costs:** Hiring a recovery surgeon eliminates reliance on external transplant center surgeons; the OPO controls costs while maintaining expertise and high-quality standards. Reduced transportation costs.
- **Operational Savings:** Transplant centers no longer need to provide their own surgical teams or allocate resources for organ recovery, reducing the financial burden.

Alignment with Federal Metrics and Regulations

- **CMS Performance Standards**

Considerations

- Cost of Employment
- Competition for Surgical Expertise
- Transplant Center Partnerships



A Special Thanks to Our Presenters



Christine Radolovic

Chief Clinical Officer



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Vice Chair for Clinical Affairs,
Department of Surgery



Shimul Shah

MD, MHCM
Professor & Division Chief,
Solid Organ Transplantation



Scott Silvestry

MD, FACS
Division Chief,
Cardiothoracic Surgery



QA

QUESTIONS & ANSWERS