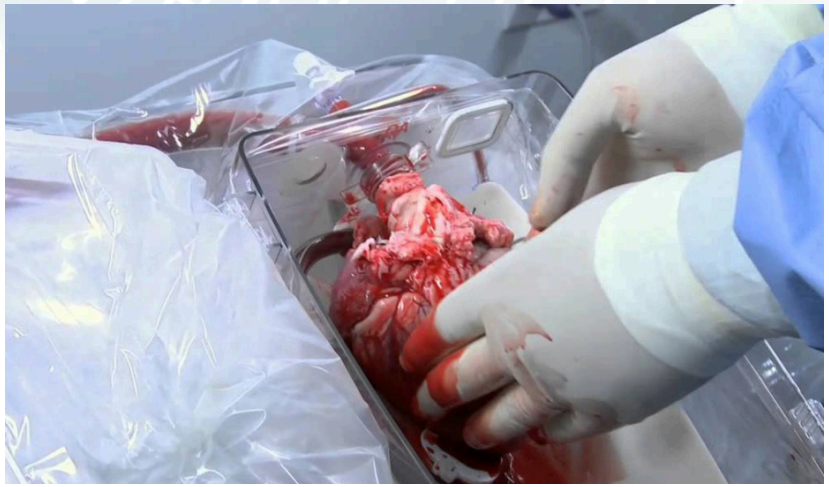
INNOVATION
WEBINAR SERIES



DCDD Heart Recovery: Achieving the Impossible Through Innovative Perfusion Technologies

March 31, 2020 | 2-3pm ET

Speakers: Andrew S. Mullins, MBA, FACHE | Jessica Demchak, BSN, RN, CPTC | Amy L. Friedman, MD, FACS

CEPTC Information

For more information:

Contact The Alliance at

info@odt-alliance.org

The Alliance

- **1.0 Category CEPTC credits** are being offered for this webinar as well as a Certificate of Attendance
- Participants must fill out the evaluation form within 30 days of the event; the link for the evaluation form will be sent to you via email within the next 48 hours
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- **1.0 Nursing contact hour** is being offered for this webinar.
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- Certificates should be claimed within 30 days of this webinar.
- We highly encourage you to provide us with your feedback electronically. 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.

WEBINAR SPEAKERS

Moderator:

Matt Wingler, CPTC
Clinical Resource Lead
Lifeline of Ohio

Amy L. Friedman, MD, FACS
Executive Vice President
Chief Medical Officer
LiveOnNY

Andrew S. Mullins, MBA, FACHE
Chief Operating Officer
Lifeline of Ohio

Jessica Demchak, BSN, RN, CPTC
Asst. Director Clinical & Transplant
Center Relations
LiveOnNY

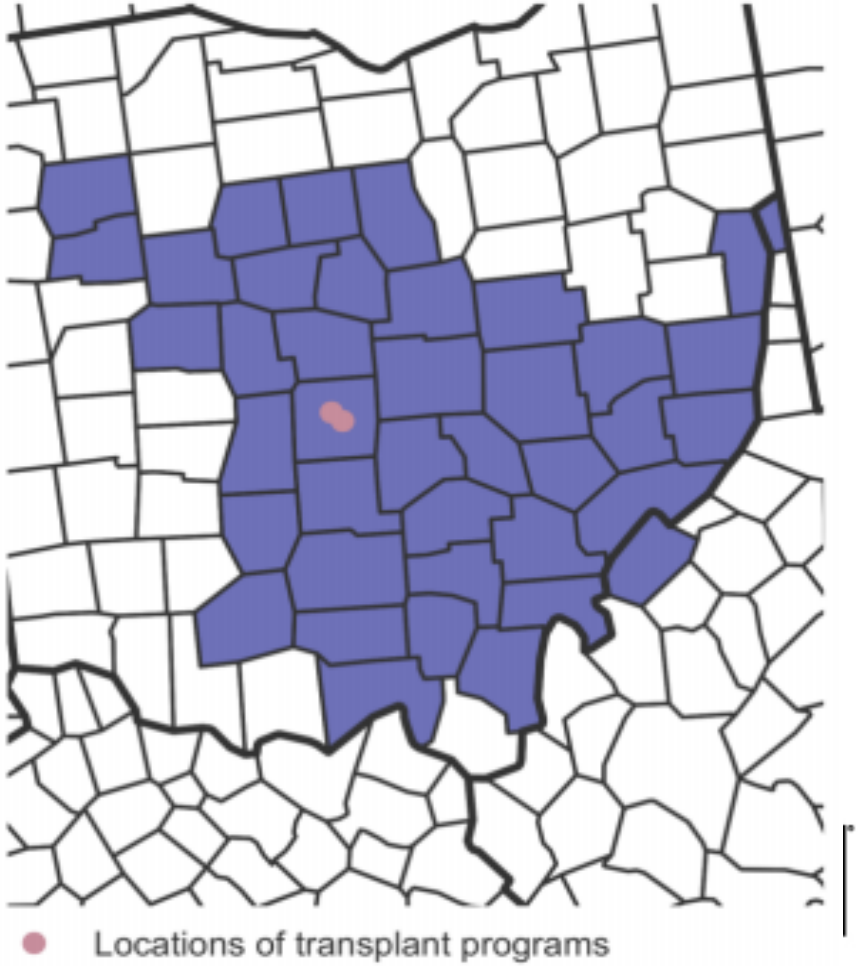
The Alliance

Advancements in DCD: A reflection on the first DCD heart donor in the U.S.

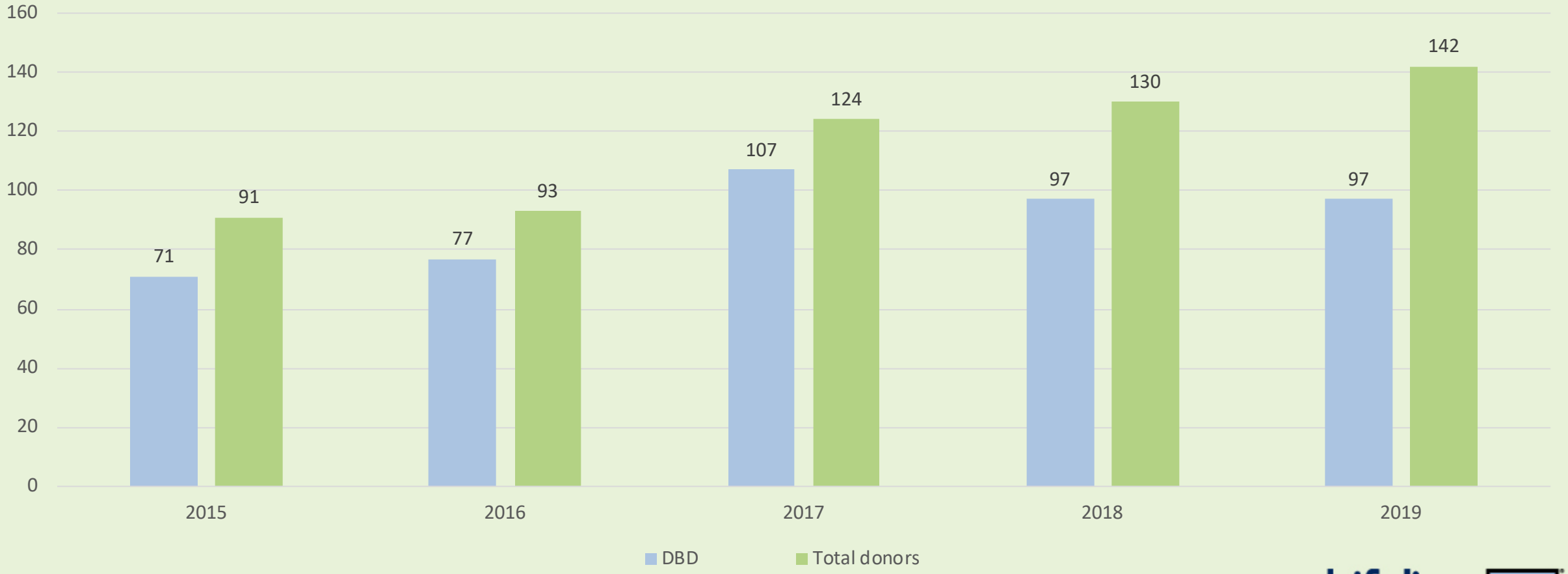
Andrew S. Mullins, MBA, FACHE
Chief Operating Officer

Lifeline of Ohio's Donation Service Area

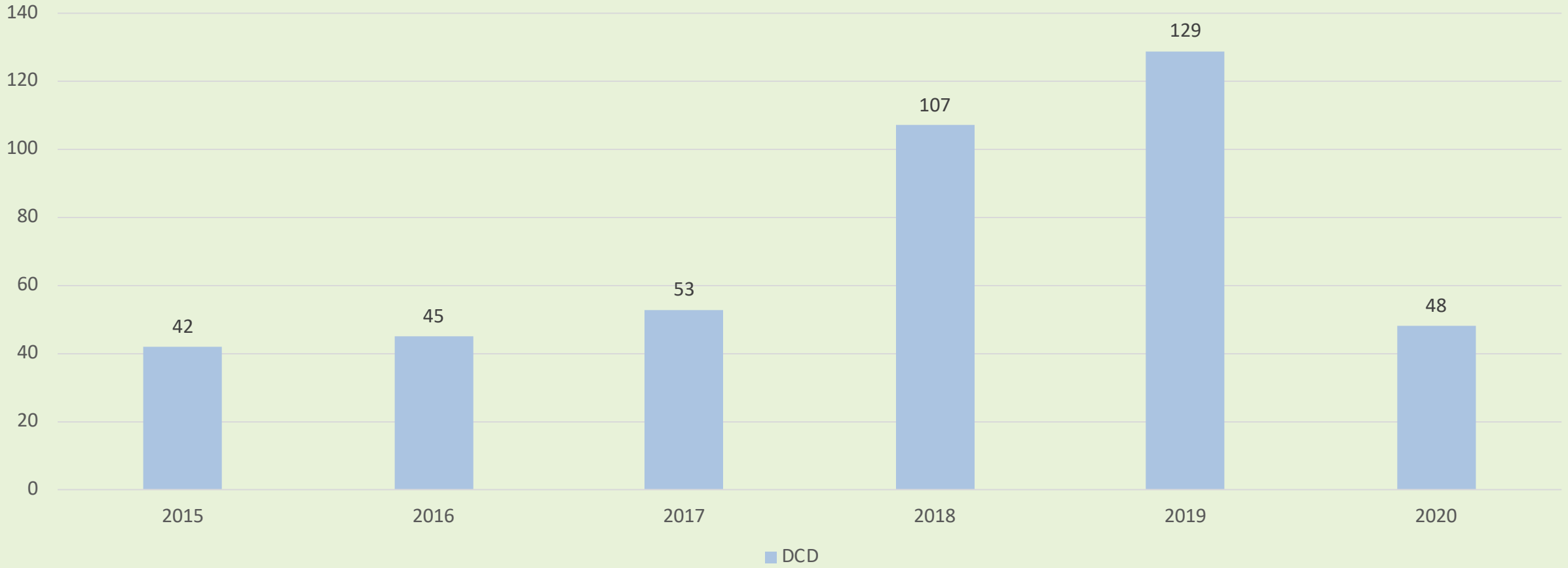
- 37 counties in Ohio & 2 counties in WV
- 78 hospitals
- 2 transplant centers
- 3.4 million people
- Facilitates organ, eye, tissue donation including birth tissue



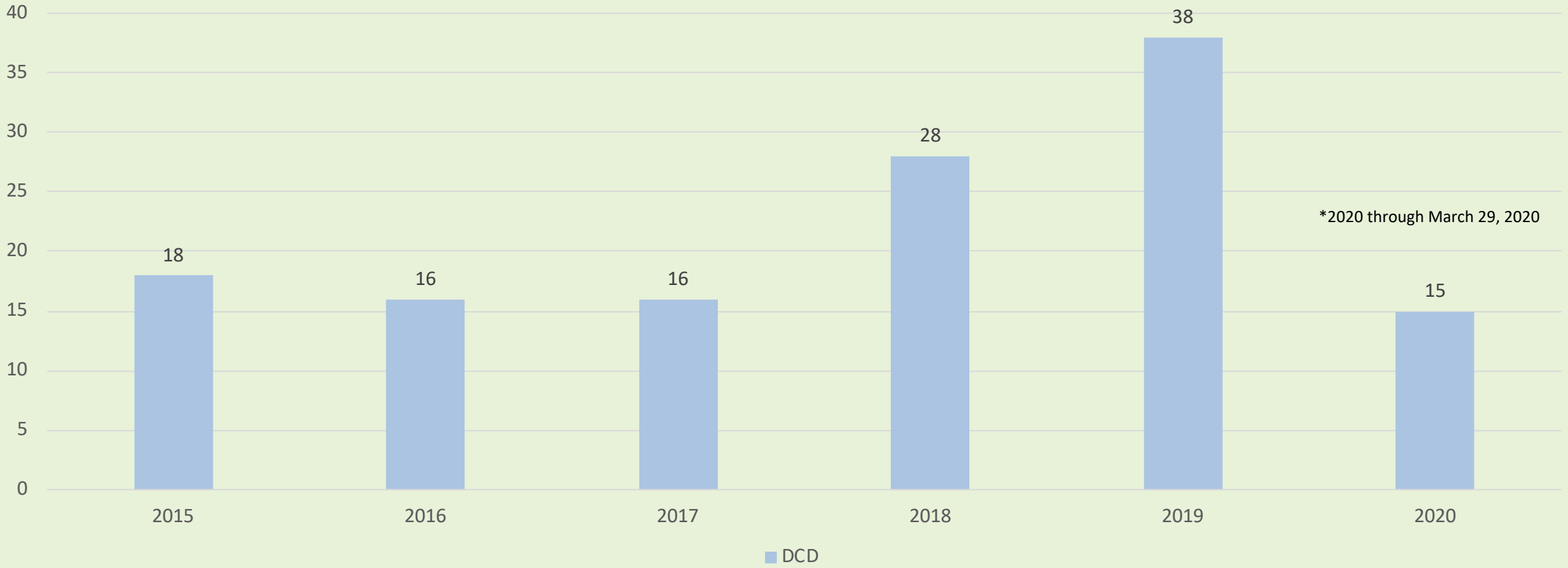
Lifeline of Ohio organ donors



DCD Approach volume



DCD donors


40
35
30
25
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18
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16
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38
15
2015
2016
2017
2018
2019
2020
*2020 through March 29, 2020
DCD

Our Hero of donation

"Giving in life and in death. You are a true hero."

“On Monday, November 25, 2019, I went into a sudden cardiac arrest in my home. I spent until December 1, 2019 at The OSU Medical Center. My parents knew that I loved helping other people. They knew that I would want to be an organ donor. As an organ donor I was able to give a gift to those that would carry on a part of me. With my donation, I saved six lives. Isn't that amazing! **I am also the first person to donate a heart of a circulatory death in the United States. So not only am I a hero, I made medical history**”

Case review

- Registered, 26/M
- Admitted to outlying hospital and transferred to Level 1 trauma center
- Family brought up donation
- LOPA tool showing “strong candidate for DCD”
- Heart, lungs, liver, and kidneys accepted
- WD occurred at 0104, pronounced at 0113, incision at 0119, cross-clamp 0122
- Duke successfully transplanted the DCD heart

What was different in the DCD process?

Transmedics OCS clinical trial

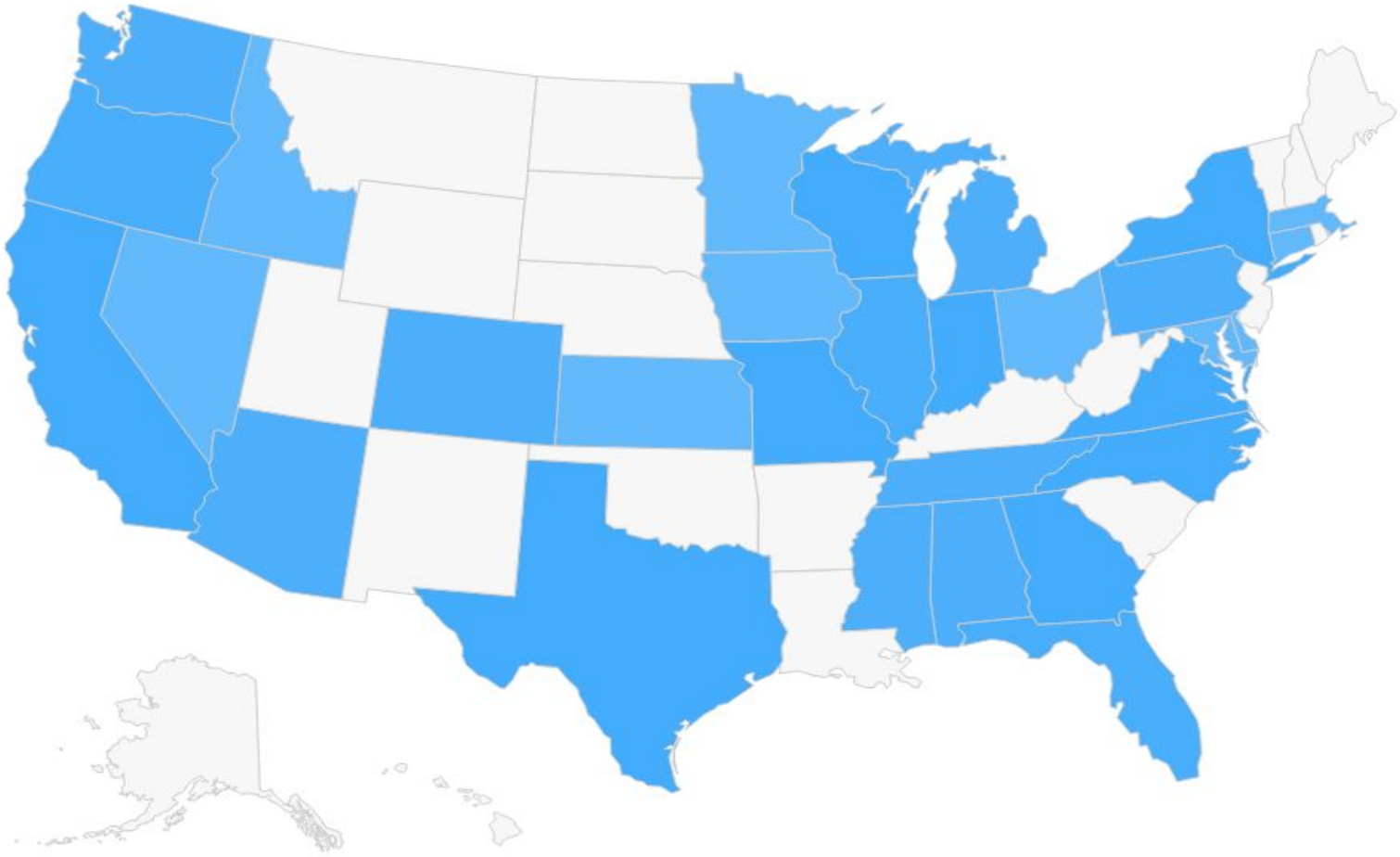
- 10 centers currently recruiting or in-process
- Estimated enrollment: 212 participants
- Start date: December 1, 2019
- Estimated completion date: December 31, 2021
- Study criteria:
  - Donor 18-49 years
  - WIT: ≤ 30 min (defined as mean SBP is < 50 mmHg or peripheral saturation < 70% to aortic cross-clamp and administration of cold cardioplegia in the donor)
  - Exclusionary criteria:
    - Previous cardiac surgery
    - Known CAD
    - Cardiogenic shock or MI, or
    - Sustained terminal EF of ≤ 50%, or
    - Significant valve disease except for competent bicuspid aortic valve

Reference: https://clinicaltrials.gov/ct2/show/study/NCT03831048

DCD Heart journey

- All starts with a “Yes”
- Power of information
- Why wouldn’t we try attitude
- Takes a team
- Lives saved

The Ripple Effect



185 stories

Highest volume: Georgia, California, New York, Wisconsin, Texas

519 M potential reach

Thanks to the heroic donors, their families, each of you, and this new technology, it is predicted there will be a 30% increase in available hearts for transplant!

Questions

Andrew S. Mullins, MBA, FACHE
Chief Operating Officer
amullins@lifelineofohio.org
614-384-7370

DCD Heart: Normothermic Regional Perfusion

Presented by:

Jessica Demchak BSN, RN, CPTC. Asst Director of Clinical and Hospital Relations
Amy L. Friedman MD. Chief Medical Officer

LiveOnNY

LiveOnNY Data

	2019
Organ Donors	341
DCD Donors	65
DCD Donors < 60 YEARS OLD	56
DCD Heart Donors	0

LiveOnNY | Caring for New Yorkers through Organ Donation

CURRENT DCD ENVIRONMENT

- Typically 1 to 2 hours wait period
- Rushed procurement post cardiac arrest
- Limited time for additional assessments
- Donor in acidotic state
- Liver usually limited to 30 minutes

LiveOnNY | Caring for New Yorkers through Organ Donation

Goals

- Limit the chaos
- Control the pace
- Recreate homeostasis
- Extend assessment time
- Expand organ utilization

Normothermic Regional Perfusion

- Isolate the body below the brain
- Restore warm, oxygenated perfusion to the organs
- Two options:
    - ECMO- Extracorporeal membrane oxygenation
    - Cardiopulmonary Bypass

Normothermic Regional Perfusion

ECMO	Cardio-Pulmonary Bypass
Warm, oxygenated blood	Warm, oxygenated blood
NA	Metabolic therapy feasible
NA	Cardiac volume control feasible
Perfusionist required	Perfusionist required
Portable	Not portable
$2000	$500

American Journal of Transplantation
AST | AMERICAN SOCIETY OF TRANSPLANTATION
ASTS

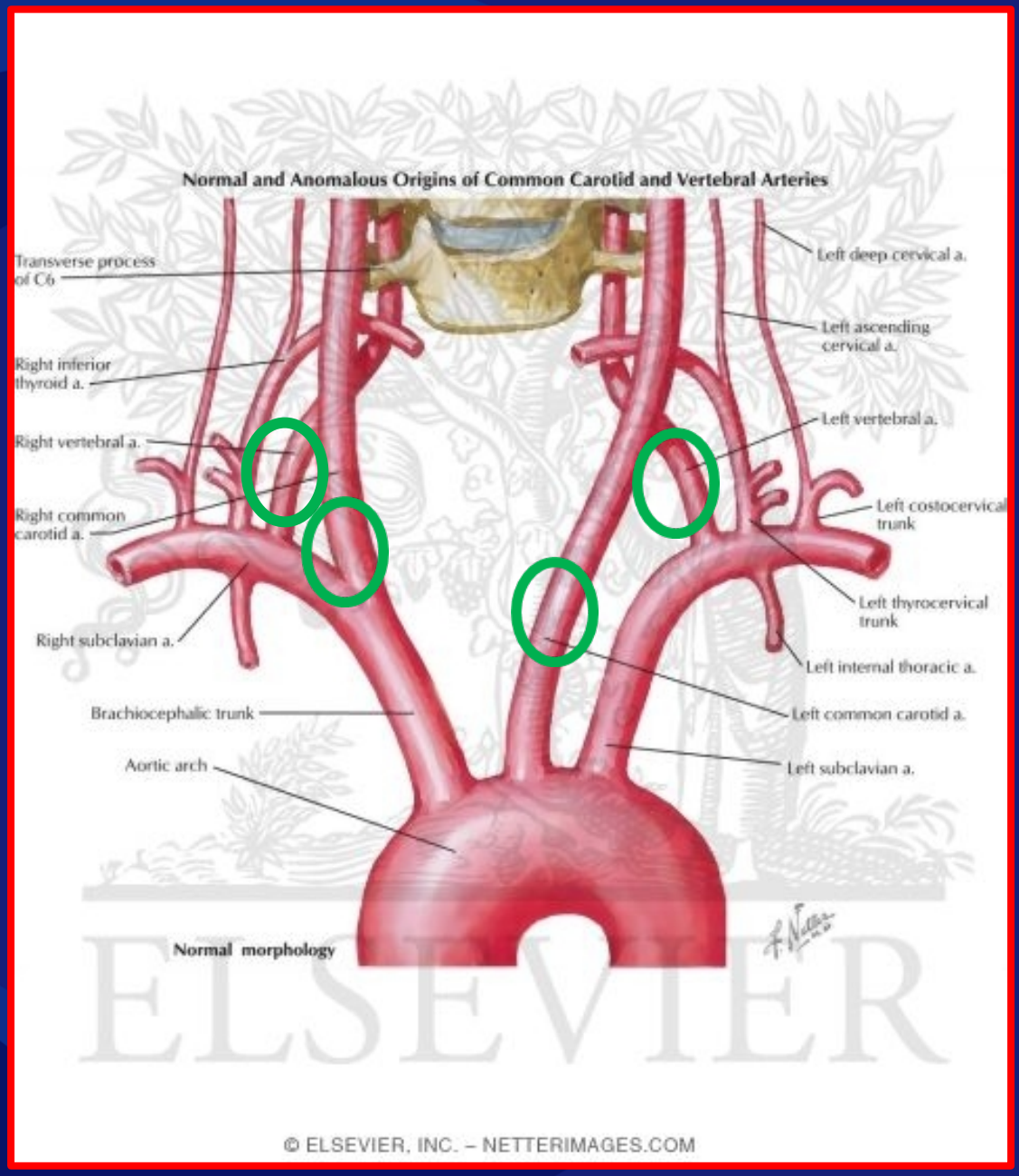
PERSONAL VIEWPOINT

Ethical and logistical concerns for establishing NRP-cDCD heart transplantation in the United States

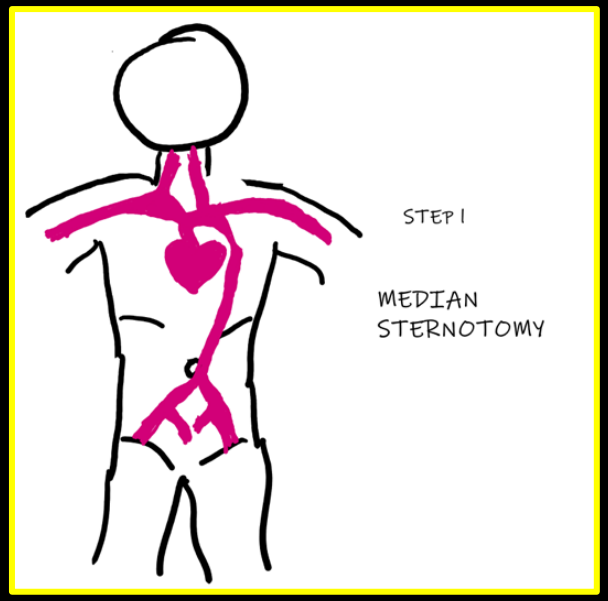
Brendan Parent, Nader Moazami, Stephen Wall, Julius Carillo, Zachary Kon, Deane Smith, B. Corbett Walsh, Arthur Caplan

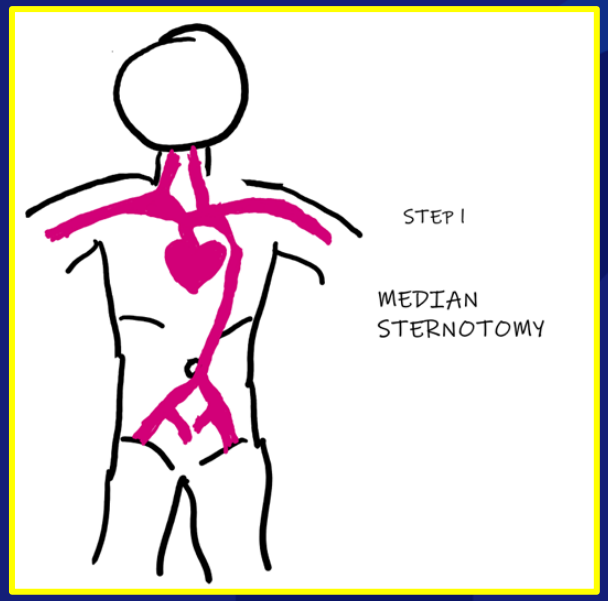
First published:08 January 2020 | https://doi.org/10.1111/ajt.15772

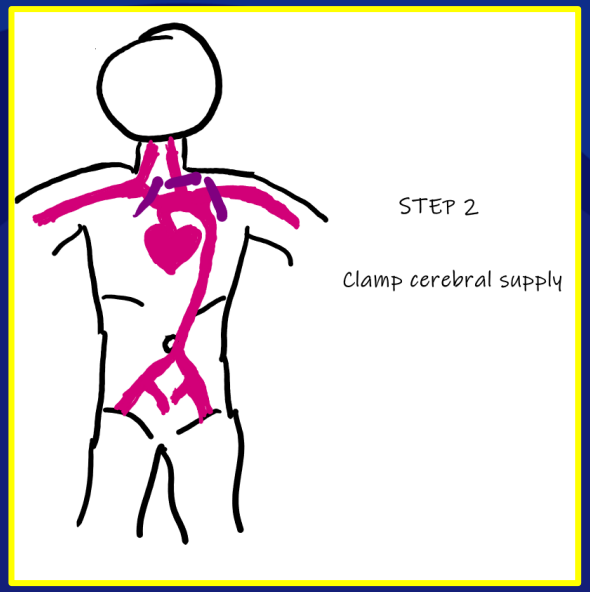
Permanent cessation for life-saving efforts must be achieved to assuage this concern and ligating principal vessels maintains no blood flow to the brain, which ensures natural progression to cessation of brain function.

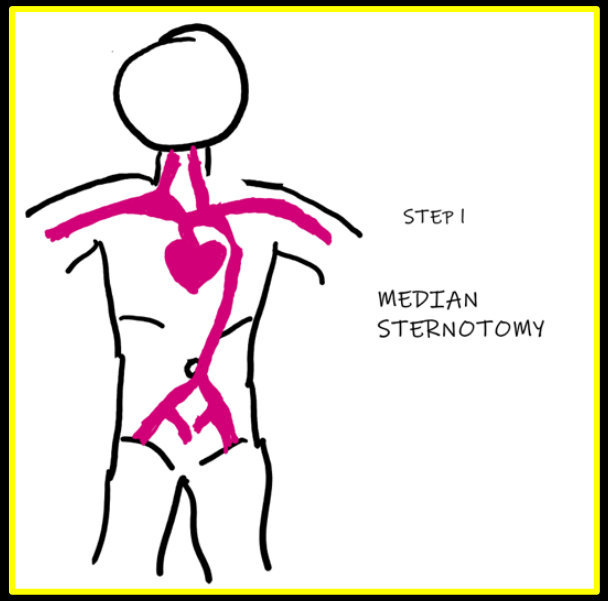


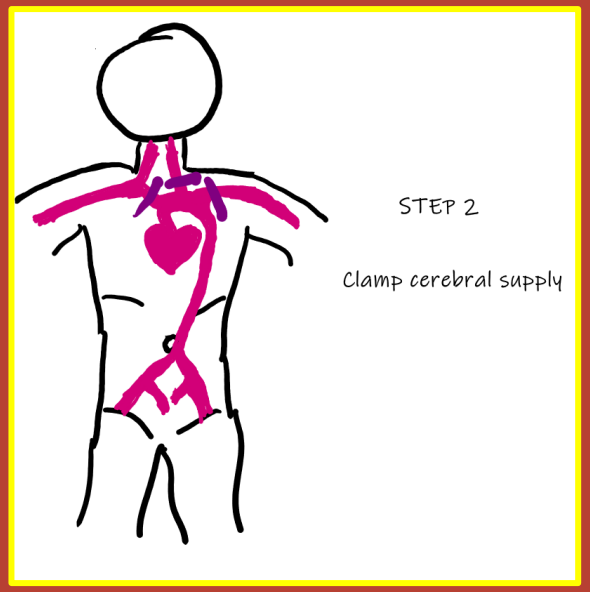
LiveOnNY

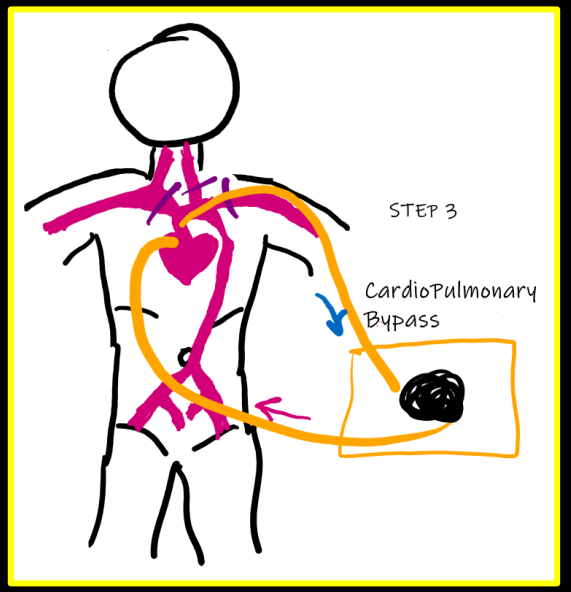

STEP I
MEDIAN
STERNOTOMY





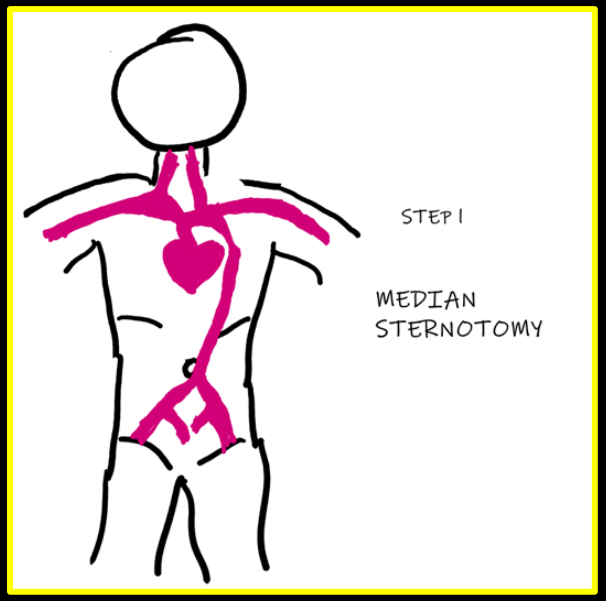






Warm Time Elapsed After Declaration

13 minutes


STEP 1
MEDIAN
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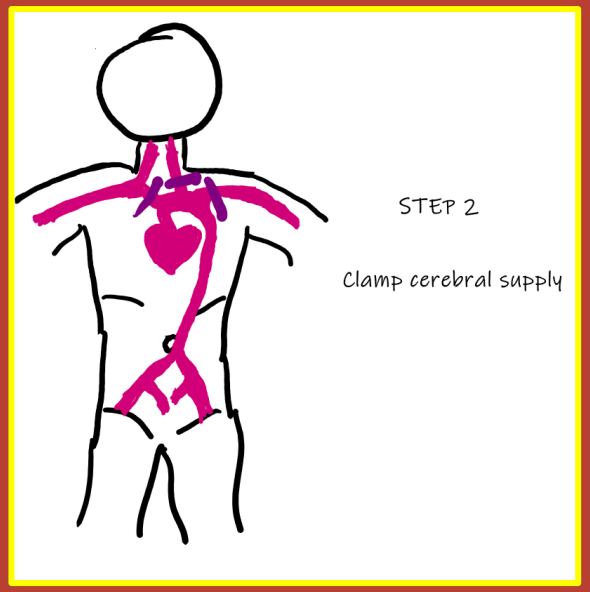
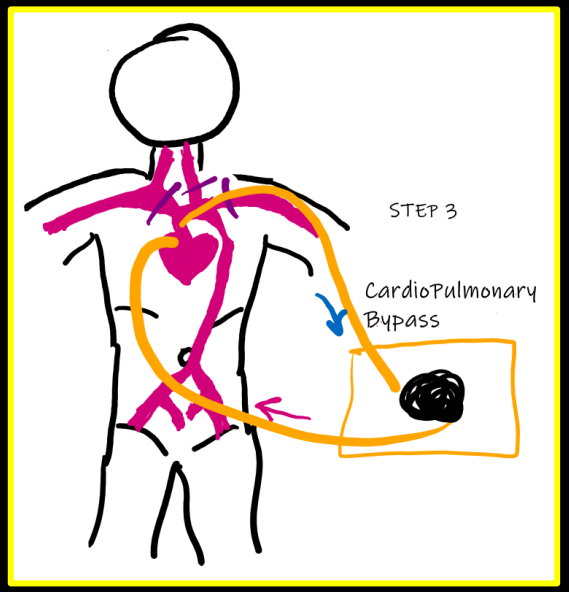
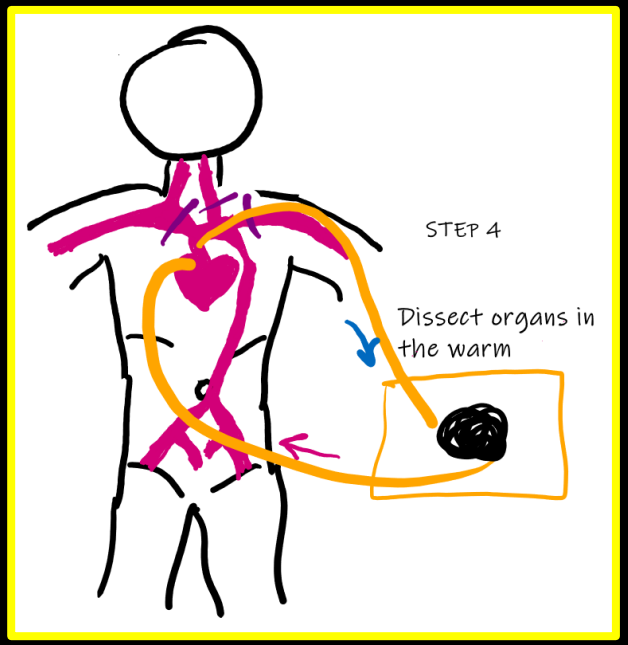
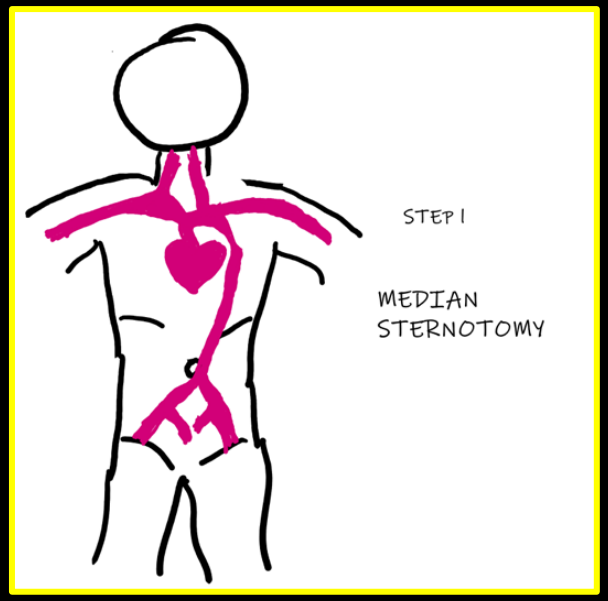
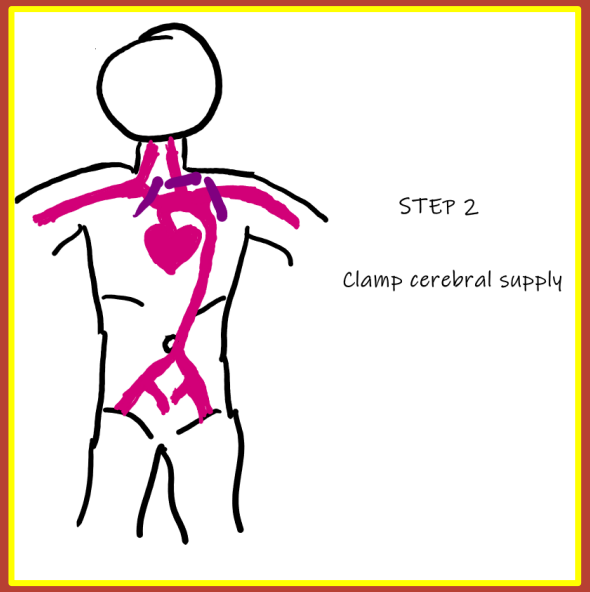
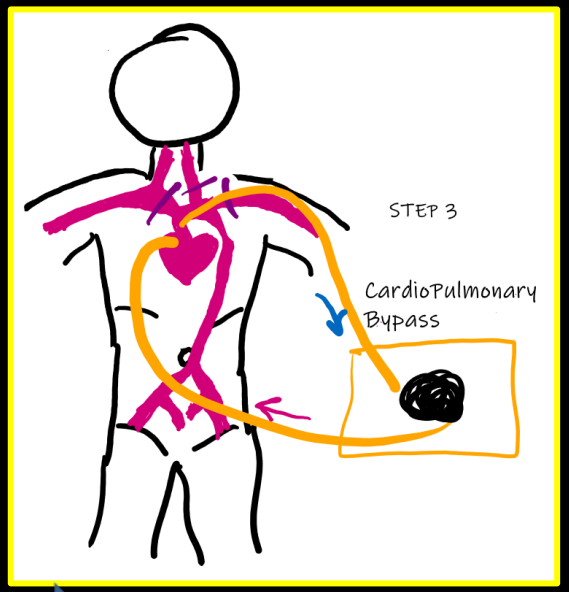

STEP 2
Clamp cerebral supply


STEP 3
CardioPulmonary
Bypass


STEP 4
Dissect organs in
the warm


STEP 1
MEDIAN STERNOTOMY


STEP 2
Clamp cerebral supply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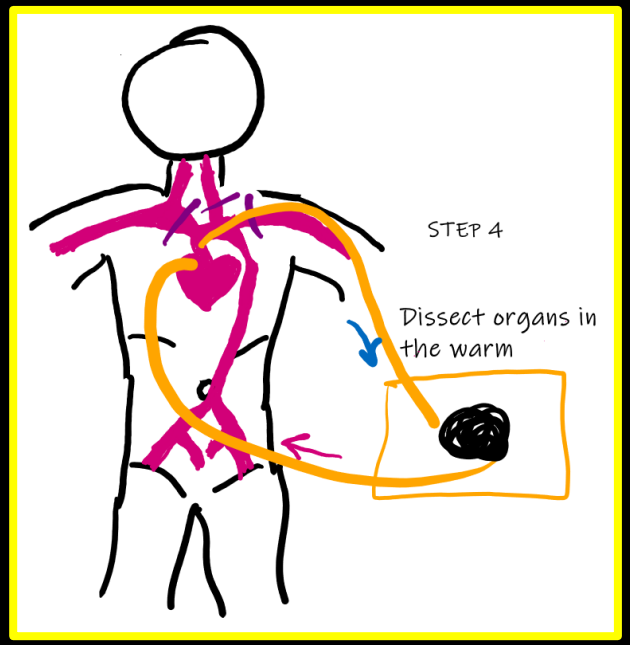
CardioPulmonary Bypass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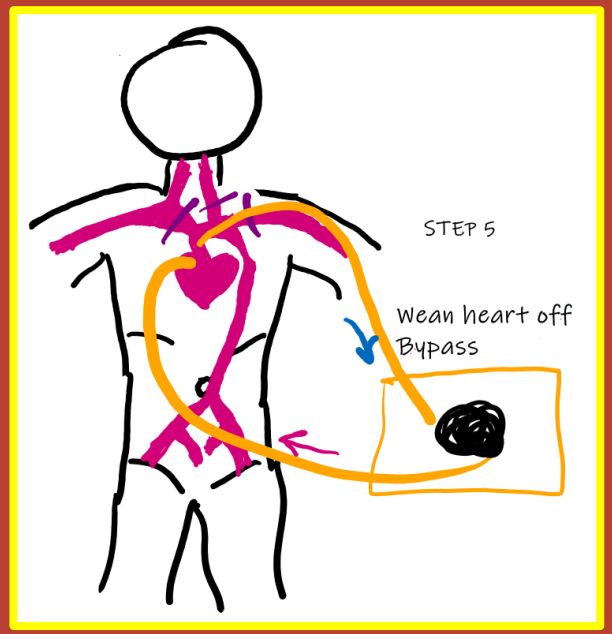
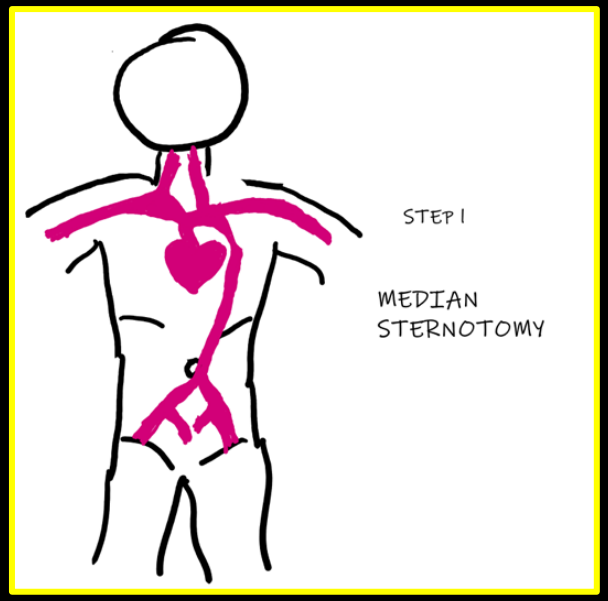
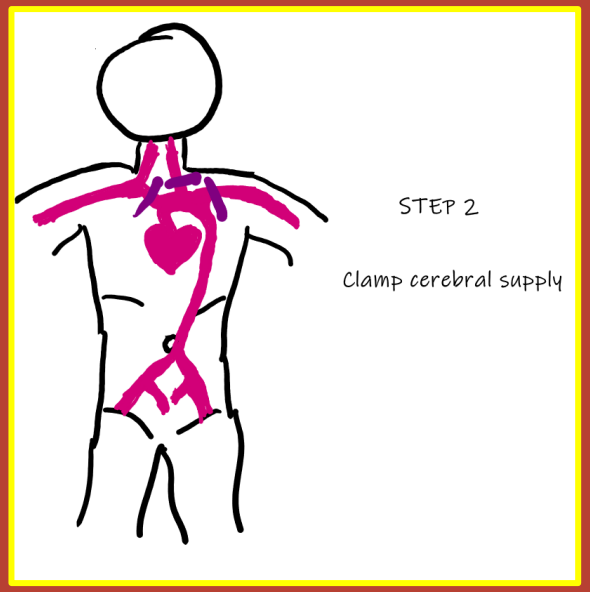
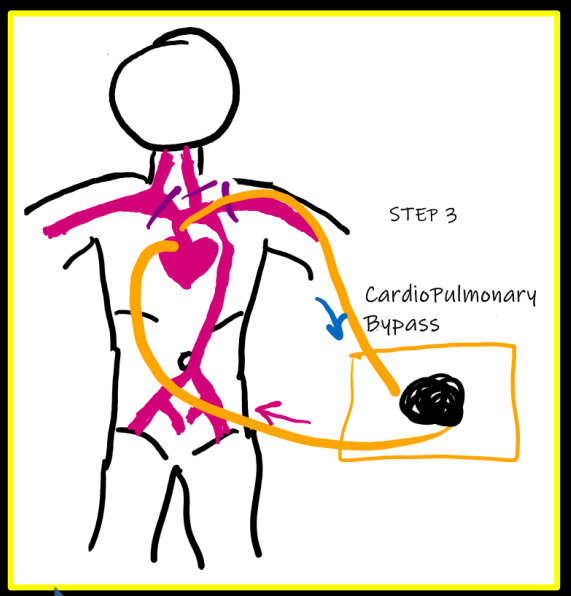
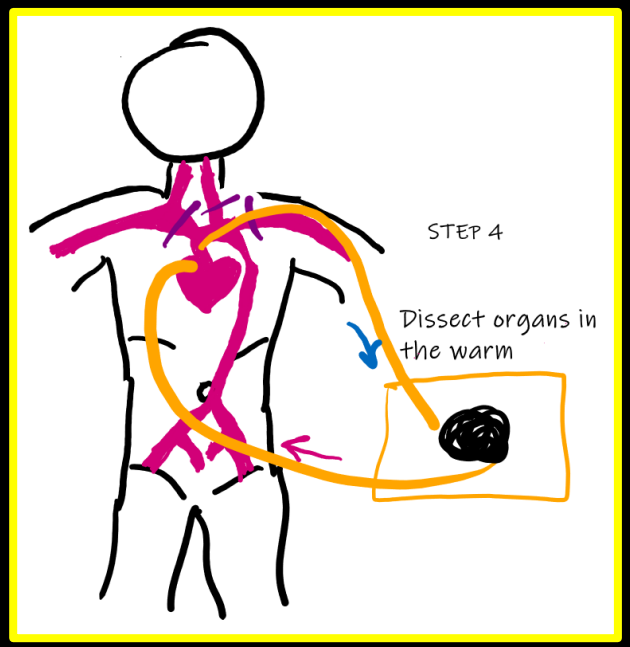
Dissect organs in the warm

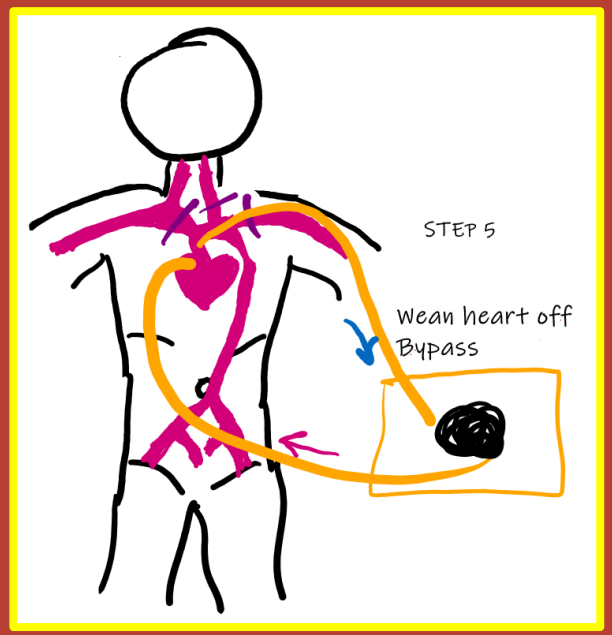

STEP 5
Wean heart off Bypass


STEP 1
MEDIAN STERNOTOMY


STEP 2
Clamp cerebral supply


STEP 3
CardioPulmonary Bypass


STEP 4
Dissect organs in the warm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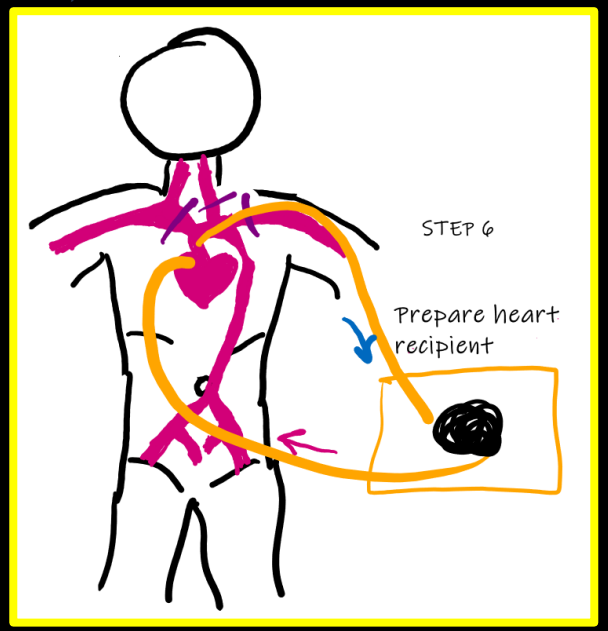
Wean heart off Bypass


STEP 6
Prepare heart recipient

Crossclamp + initiate cold ischemia for all organs within 180 minutes of declaration

Experience to date (3/30/20)

- 4 DCD heart donors (4 hearts, 3 liver, 6 kidneys)
- All patients arrested < 60 minutes
- UNOS allocation policy followed

Transplant Coordinator Considerations

What stays the same:

- Securing authorization
- Donor management: hemodynamic stability
- Securing nurse for comfort measures
- Securing pronouncing physician
- Education of all participants
- Preparation of the family with a waiting area

Transplant Coordinator Considerations

What has changed:

- Authorization must include transfer to NYU, family must be aware of wait times
- New lines placed at NYU: clean lines
- Coordination with NYU cardiothoracic team
- OR Process

OR Process

- Maintain a quiet, respectful environment: more difficult due to the quantity of participants and equipment.

- Monitoring of ischemic times:
  - Current measure: sat 80% or SBP < 80
  - With DCD heart (both Transmedic and NRP) sat of 70% or SBP < 50 (FDA regulation for trial study).

- Monitoring of new time windows:
  - Extubation to pronouncement of death
  - Incision wait period
  - Incision to ligation of neck vessels/ bypass
  - Bypass time of 30 mins (assess heart function and lab values)
  - Repeat bypass as needed (total time not to exceed 180 mins)

OR Process

- The donor will be re-intubated after the initiation of bypass.
- Heart Perfusionist monitors the donor lab values
  - TC should be aware of the lab values for other organ sharing.
  - TC is responsible for hepatic panel blood draws (**LiveOnNY based for assess organ function during this new process**). 3 draws: 1 before the initiation of bypass, 1 prior to the 30 min reassessment of the donor, 30 mins after the completion of bypass..
- Once bypass is successfully completed all teams will determine acceptance or decline (reallocate if needed) and prepare for xclamp.
- Procurement then continues as normal and all DCD policies are followed.

DCD Heart with Normothermic Regional Perfusion – Key Points

- IRB approval
- OPO medical advisory board approval
- Local transplant community engaged
- Protocol conducted at 1 cardiac transplant center
- Live DCD candidate transferred
- **TRANSPARENCY** (family, hospital personnel, transplant community)

LiveOnNY

Learning Together

We are very honored to be a part of this amazing process. Working in effort to increase DCD organ viability. Thank you for letting us share our experience with you……

LiveOnNY