

Navigating the Future of Lung Allocation: The Impact and Evolution of the New CAS Framework

TODAY'S PRESENTER



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Meet Our Presenter



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Navigating the Future of Lung Allocation

The Impact and Evolution of the New CAS Framework

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Disclosure Slide

- Advisory board for Paragonix, Biomedinnovations, Transmedics, and CSL Behring on topics related to lung transplantation
- Research funding from Biomedinnovations, Cystic Fibrosis Foundation, NHLBI and Transmedics
- None of those are directly related to this talk
- Vice-chair Organ Procurement and Transplant Network (OPTN) Lung Committee



Discussion Aims

- Provide a review of the historical evolution of lung allocation system in the US.
- Review adoption of Continuous Distribution Framework for all solid organ allocation by the Organ Procurement and Transplant Network (OPTN).
- Review Composite Allocation Score (CAS) and its goals.
- Provide an overview of 1-year post CAS implementation report findings.



Special Contribution

This patient, satisfying stringent preset technical and moral criteria for the procedure, is believed to be the first recipient of a successful lung transplant. Although the patient died of renal failure on the 18th postoperative day, the lung was demonstrated to have functioned and immunologic rejection did not occur.

Lung Homotransplantation in Man

Report of the Initial Case

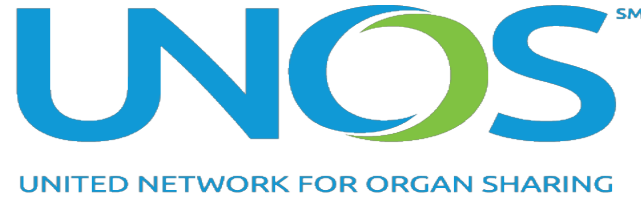
*James D. Hardy, MD, Watts R. Webb, MD, Martin L. Dalton, Jr., MD,
and George R. Walker, Jr., MD, Jackson, Miss*



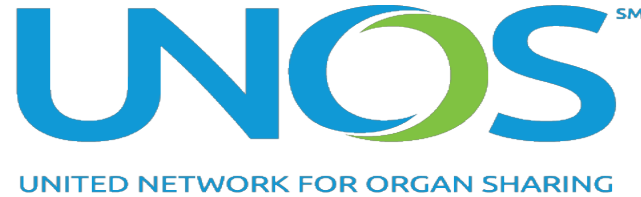
Organ Demand Exceeds Supply = Limited Societal Resource

Ethical Principles Used for the Allocation of Donor Organs

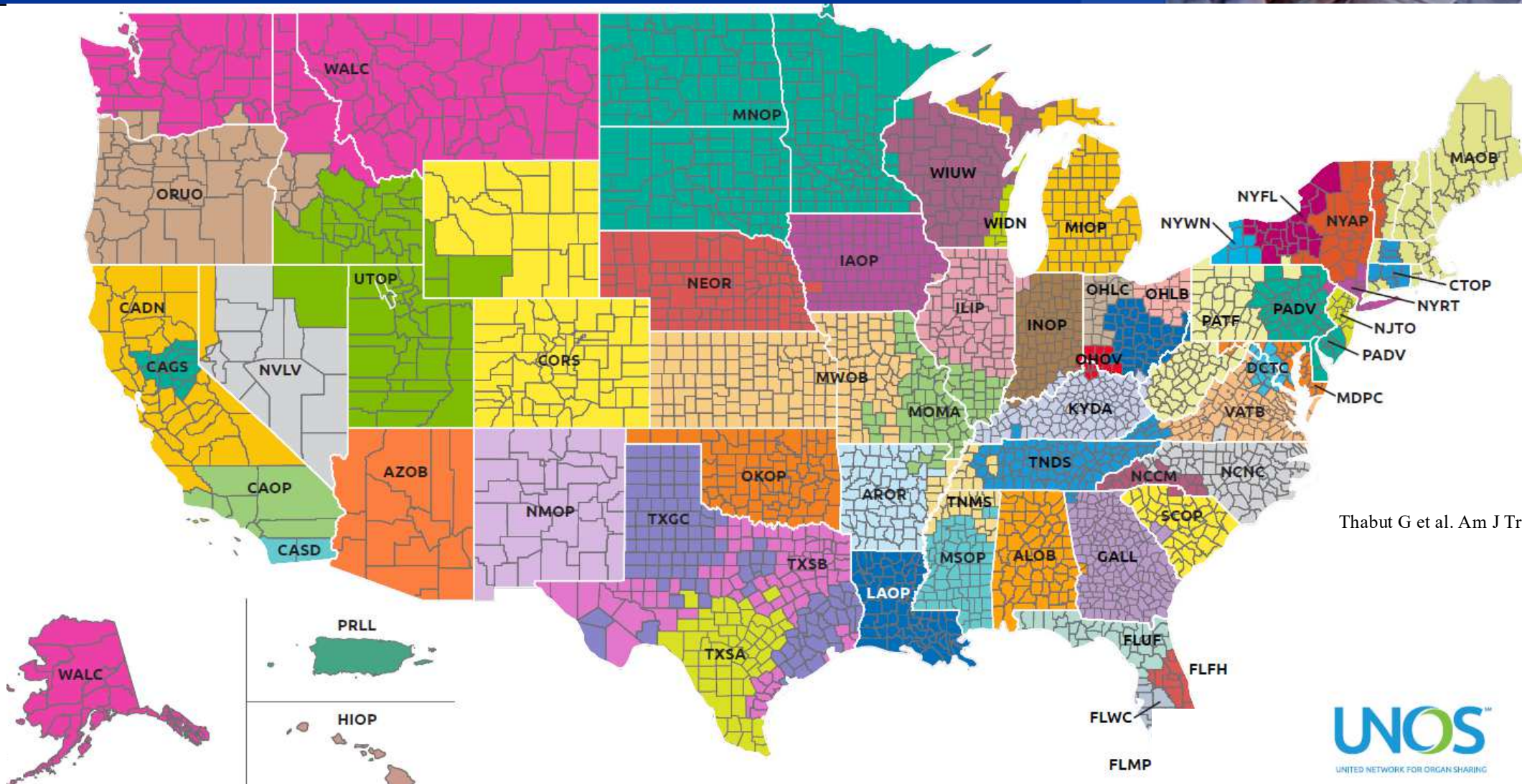
Principle	Application to Organ Allocation
Utility	To maximize net benefit Using years of <u>survival gained</u> to prioritize allocation
Justice/ Equity	To distribute the benefits and burdens of allocation system in a fair manner - Using <u>medical urgency</u> to prioritize allocation - To allow special consideration for candidates for whom it is harder to find a suitable organ - Geographical fairness - Age
Respect for Persons	To treat persons as autonomous with right for self determination The right to give or withhold informed consent for lung transplant



- 1984 National Organ Transplant Act (NOTA)
 - U.S. Congress passed the NOTA
 - Created framework for how solid organ transplant system
 - Established a public-private partnership, the Organ Procurement and Transplant Network (OPTN) that oversees the U.S. transplant system.



- National Organ Transplant Act (NOTA)
 - 1984 U.S. Congress passed the NOTA
 - Created framework for how solid organ transplant system
 - Established a public-private partnership, the Organ Procurement and Transplant Network (OPTN) that oversees the U.S. transplant system.
- 1986 developed allocation system for heart and heart-lung allocation based on donor service area (DSA), waitlist time and ABO compatibility
- 1990 same allocation for isolated lung transplantation



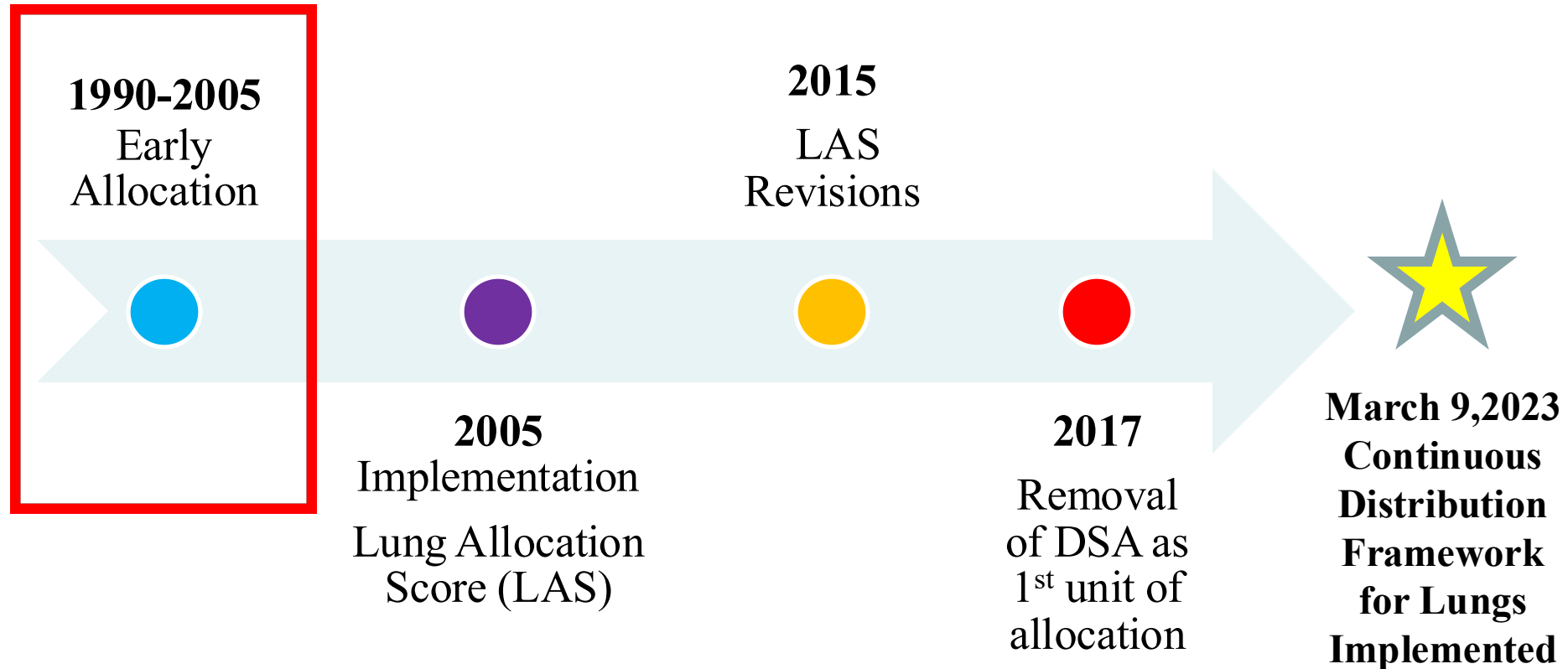
Thabut G et al. Am J Transplant 2012;11:3085-3093.

58 Donor Service Areas (DSA) were first unit of allocation

- Areas designated by CMS with unequal population size, land mass and arbitrary boundaries



Timeline of US Lung Allocation Policies





Lung Allocation Policies 1990-2005

- Policy impact:

 Waitlist Mortality (WL) and WL size

 Higher WL Mortality IPF Diagnosis

- Reasons:

- For patients with rapidly progressive disease, no method for adjustment to score
- Practice to list early in disease course to accrue waitlist points
- 1995 Amendment
 - 90-day credit for IPF diagnosis
 - Impact of the amendment never studied

Tsuang WM, Lease EL, Budev MM. Clin Chest Med 2023;44:59-68.

Hosenpud JD et al. Lancet 1998;351:24-7.

Egan TM. Respir Crit Care Med 2018;39:126-137.



The “Final Rule”

- 1998 U.S. Department of Health and Human Services (HHS) publishes the “Final Rule on Organ Transplantation”
 - Reduce reliance on waiting time and prioritize based on medical severity of illness while avoiding futility
 - Broader geographic distribution of organs
 - Seek the best use of donated organs
 - Promote efficient management of organ placement



The “Final Rule”

- 1999 Thoracic Committee tackles lung allocation
- 6 years later, May, 2005 LAS implemented
 - Priority based on predicted waitlist mortality within 1-year and posttransplant survival within 1-year.
 - DSA remained initial geographic distribution area



Lung Allocation Score (LAS)

Calculation of LAS

Waitlist urgency measure =

Expected # of days lived without transplant during the next year

Posttransplant survival measure =

Expected # of days lived during **1st year** after transplant

Raw allocation score =

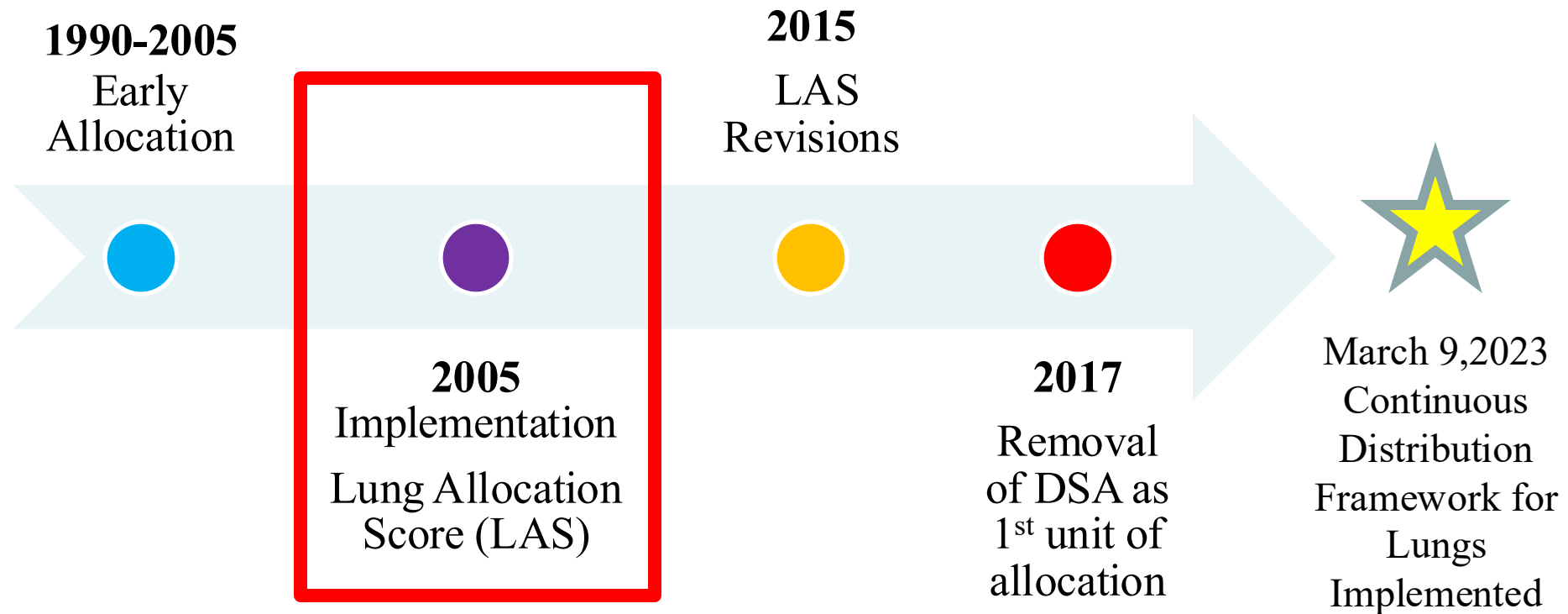
Posttransplant survival measure – **2x** (waitlist urgency measure)

Normalized LAS =

$100 \times (\text{raw score} + 2 \times 365) / 3 \times 365$

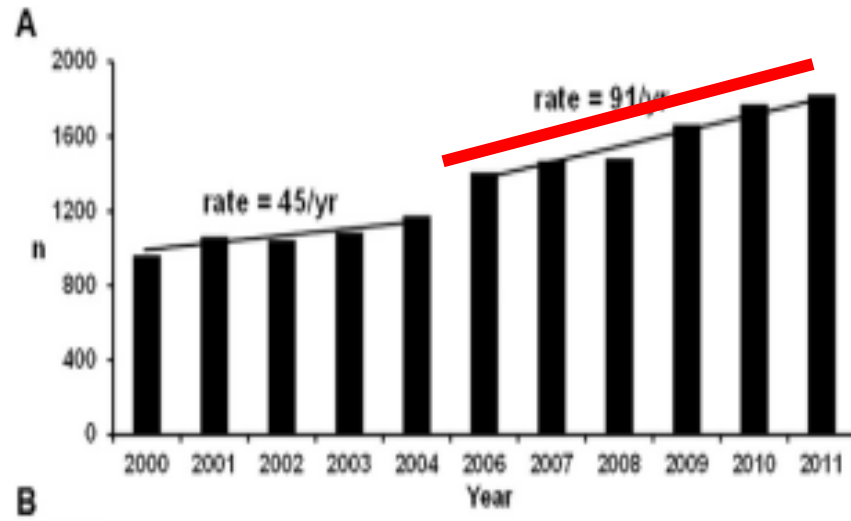


Timeline of US Lung Allocation Policies

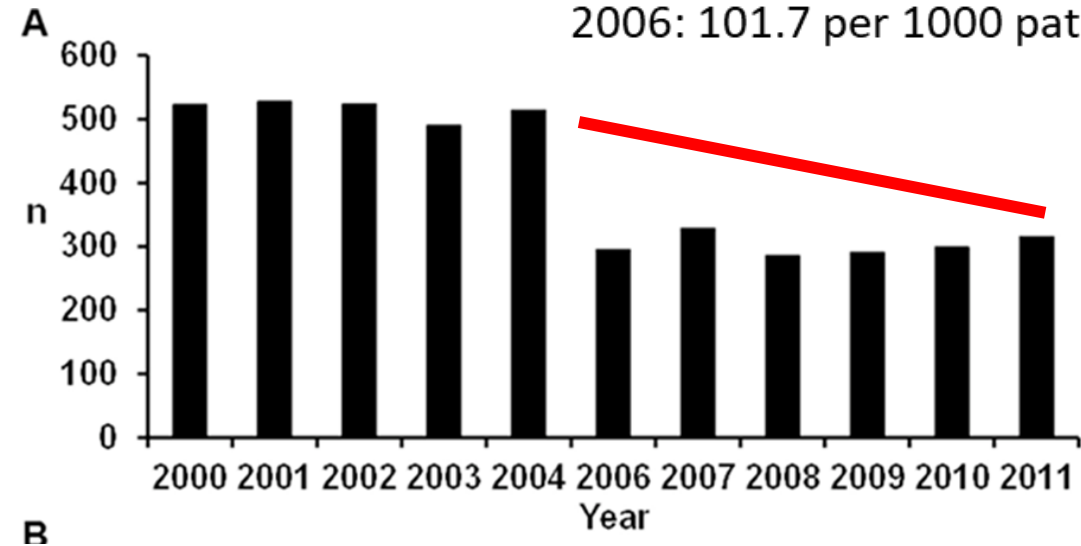




Positive Results of LAS



Increase Rates of Lung Transplants 2006-2011



Decreased Waitlist Mortality 2005-2011

Wait list deaths decreased
1999: 190.5 per 1000 patient years
2006: 101.7 per 1000 patient years



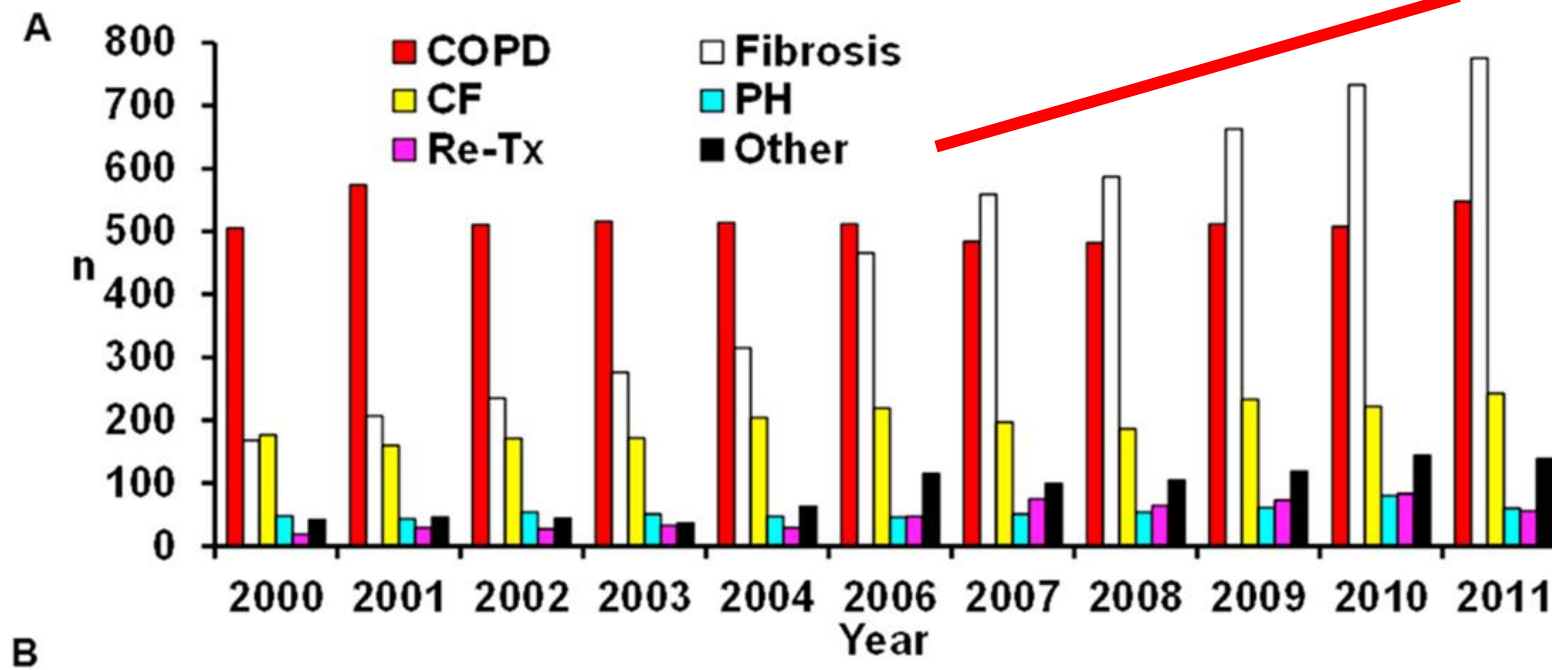
Effects of Lung Allocation Score (LAS)

	Pre-LAS (n=122)	Post-LAS (n=122)
	4/26/03-4/26/05	5/5/05-6/30/07
Days on Wait List, Median	239	11
Wait List Survival [†]	88% (296/337)	97% (212/217)
Native Lung Disease		
Restrictive	30% (37)	50% (61)
Obstructive	45% (54)	32% (32)
Cystic Fibrosis	21% (26)	15% (18)
Congenital/Vascular	4% (5)	3% (4)
Recipient Age, Mean (SD)	49 (14.3)	51 (13.7)
Male Gender	53% (64)	59% (72)
Ventilatory Dependent at Time of Transplant	1.6% (2)	2% (3)



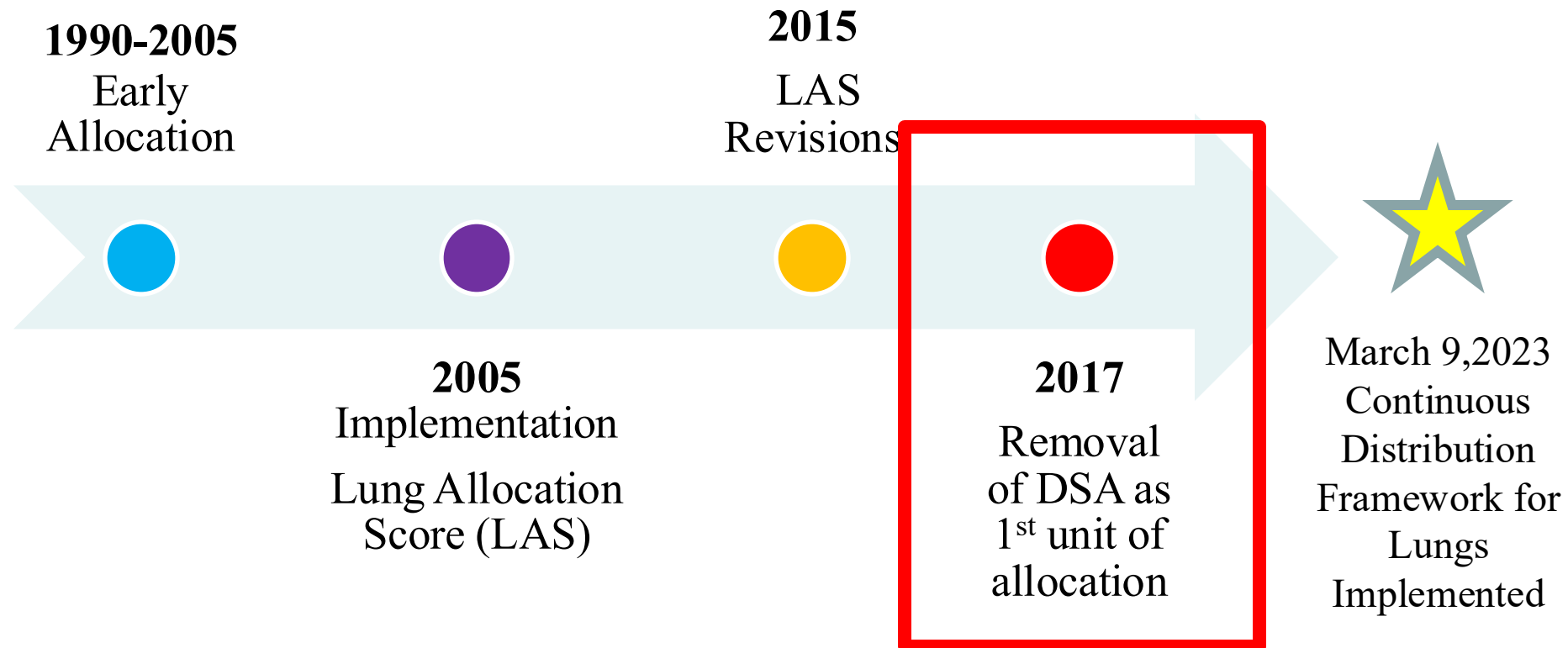
Results of LAS Implementation

Pulmonary Fibrosis (Group D) Most Common Indication For Transplantation in US Overtaking COPD (Group A)





Timeline of US Lung Allocation Policies





**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

MIRIAM HOLMAN,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES through ERIC
HARGAN in his official capacity as Acting
Secretary of the United States Department of
Health and Human Services,

Defendant.

Civil Action No.:

**VERIFIED COMPLAINT FOR A TEMPORARY RESTRAINING ORDER
AND PRELIMINARY AND PERMANENT INJUNCTIVE RELIEF**



The Plaintiff

21 y/o woman with rare form of pulmonary hypertension

Listed for lung transplant in NYC on October 6, 2017

On ECMO for an extended period of time without transplantation





The Lawsuit: Holman v HHS

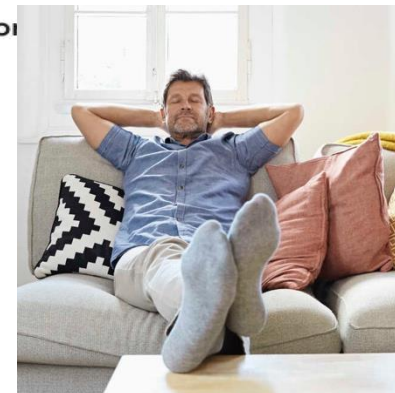
- Argued that DSA's were “antiquated and arbitrary” geographic administrative areas.
- Current allocation policy does not comply with Final Rule.

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

- Requested removal of DSA as primary geographic distribution area, and instead use 500 concentric miles as initial allocation area.



Who Should Get These Lungs? :





The Lawsuit: Holman v HHS

- OPTN Thoracic Committee met emergently on Thanksgiving and provided recommendations to the OPTN Executive Committee
- Nov 24, 2017, the Executive Committee concluded
 - “a policy that does not depend on DSA[s] as the primary unit of allocation of lungs is more consistent with the OPTN Final Rule than a policy that shares first exclusively within the DSA.”
 - 250 nautical mile concentric circles as the first distribution area was suggested



The Lawsuit: Holman v HHS

- The Executive Committee action avoided a court-ordered lung allocation policy.
- The lawsuit forced a change in lung allocation that was unlikely to occur on its own volition.
- Ad Hoc Geographic Committee was formed, and recommendations made on allocation for all organs.



Ad Hoc Committee on Geography

Principles of Organ Distribution

Deceased donor organs are a national resource to be distributed as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.

Geographic distribution may be constrained in order to:

1. Reduce inherent differences in the ratio of donor supply and demand across the country
2. Reduce travel time expected to have a clinically significant effect on ischemic time and organ quality
3. Increase organ utilization and prevent organ wastage
4. Increase efficiencies of donation and transplant system resources

FURTHER RESOLVED, that further recommendations from the Ad Hoc Geography Committee, as set forth below, are hereby accepted, effective June 12, 2018.

1. Request community feedback on the recommended distribution frameworks with a goal of identifying a single, preferred distribution framework to be used across organ types.
2. Perform a policy analysis of current organ distribution policies in reference to the proposed principles of organ distribution.
3. Maintain the Ad Hoc Geography Committee through the remainder of 2018 to receive and respond to community feedback and to facilitate conversations among organ-specific committee leadership about policy analysis.



Impact of Lawsuit

NEWSFEED

How One Lawsuit Could Change Organ Donation Waiting Lists Forever

An emergency order in a case debating the current transplant system threatens to upend decades of organ allocation policies.

January 12, 2018 • By Casey Halter

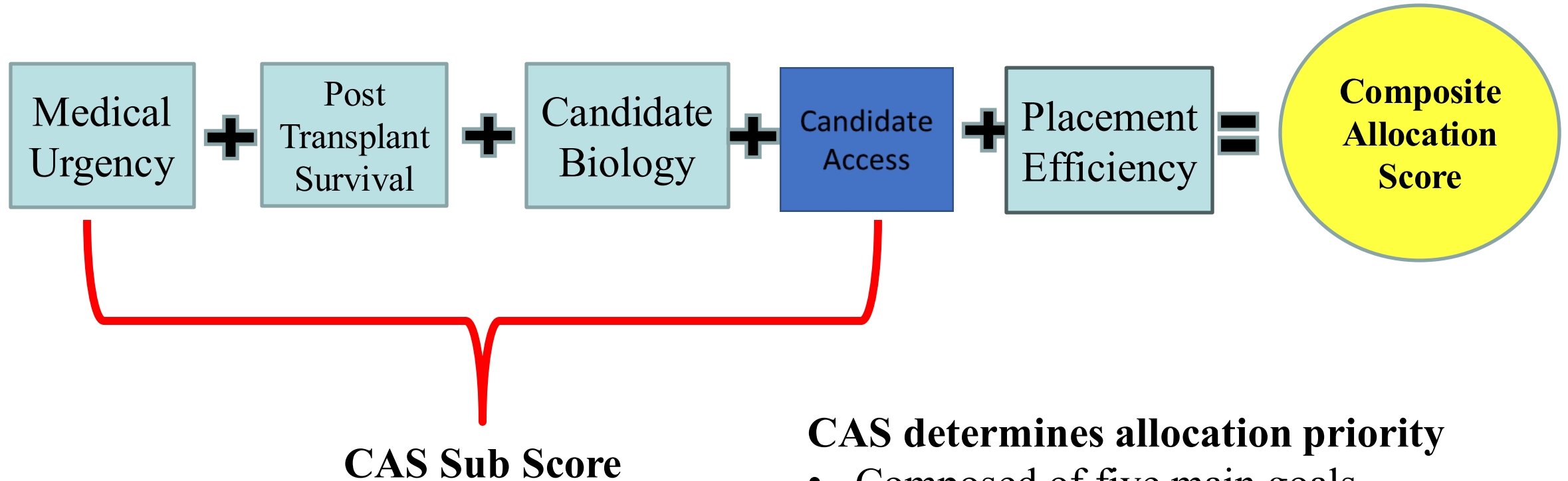


Continuous Distribution (CD)

- **Selected as the future framework for allocation for all organs**
- Replaces previous **classification-based** system with a **points-based system**
- Eliminated hard boundaries geography, flexible and specific for all organ types
- **Lungs Selected First** because 2 parts of LAS included **waitlist urgency measure (WLAUC)** and **post transplant survival measure (PTACU)** already



Lung Composite Allocation Score (CAS)



CAS determines allocation priority

- Composed of five main goals
- Weight of each goal is determined by LTx “stakeholders” (i.e. patients, doctors, etc.)



Continuous Allocation Score (CAS)

**CAS
SubScore**

Attribute	Definition	% of Available Points
Waiting list Survival	Expected 1-year waiting list survival	25
Post-Transplant Outcomes	Expected 5 year post-transplant survival	25
Candidate Biology	Total of ABO, CPRA, and height points	15
ABO	Based on percentage of compatible donors by blood type	5
CPRA	Based on percentage of compatible donors by CPRA	5
Height	Based on percentage of compatible donors by height	5
Patient Access	Total of pediatric and prior living donor points	25
Pediatric	For candidates under 18 years old	20
Prior Living Donor	For candidates who donated any organ	5
Placement Efficiency	Total of travel and proximity efficiency points	10
Travel Efficiency	Based on impact of distance on costs of travel	5
Proximity Efficiency	Based on impact of distance on other efficiency (time, availability, etc.)	5

Total Score **Waiting list Survival** + **Post-Transplant Outcomes** + **Candidate Biology** + **Patient Access** + **Placement Efficiency** **100**



1-year Monitoring Cohorts for Lung CAS

One year of pre- and post-CD implementation

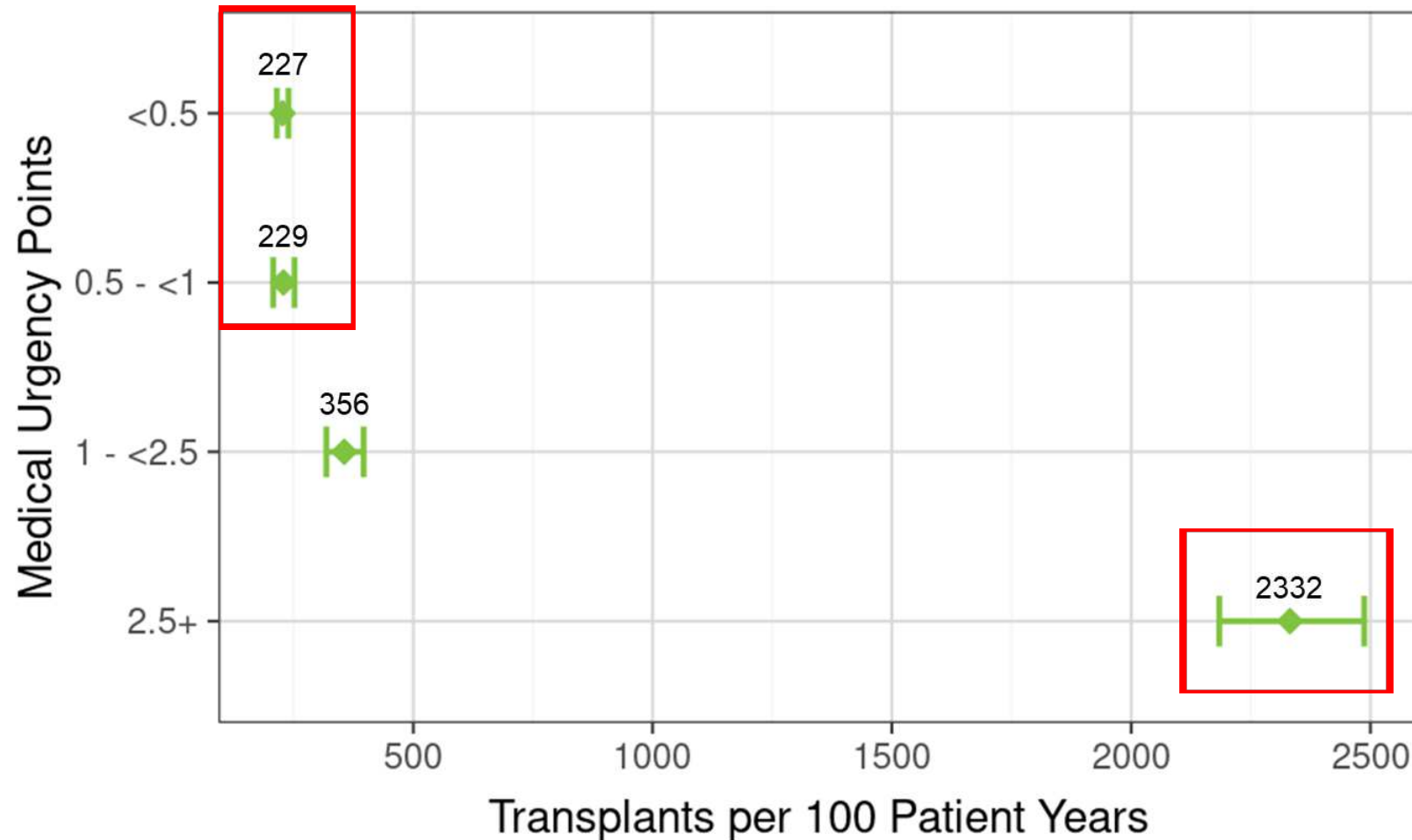
- **Pre-CD:** March 9, 2022 – March 8, 2023
- **Post-CD:** March 9, 2023 – March 8, 2024

Analysis based on OPTN data as of April 12th, 2024

Data are subject to change based on future data submission or correction



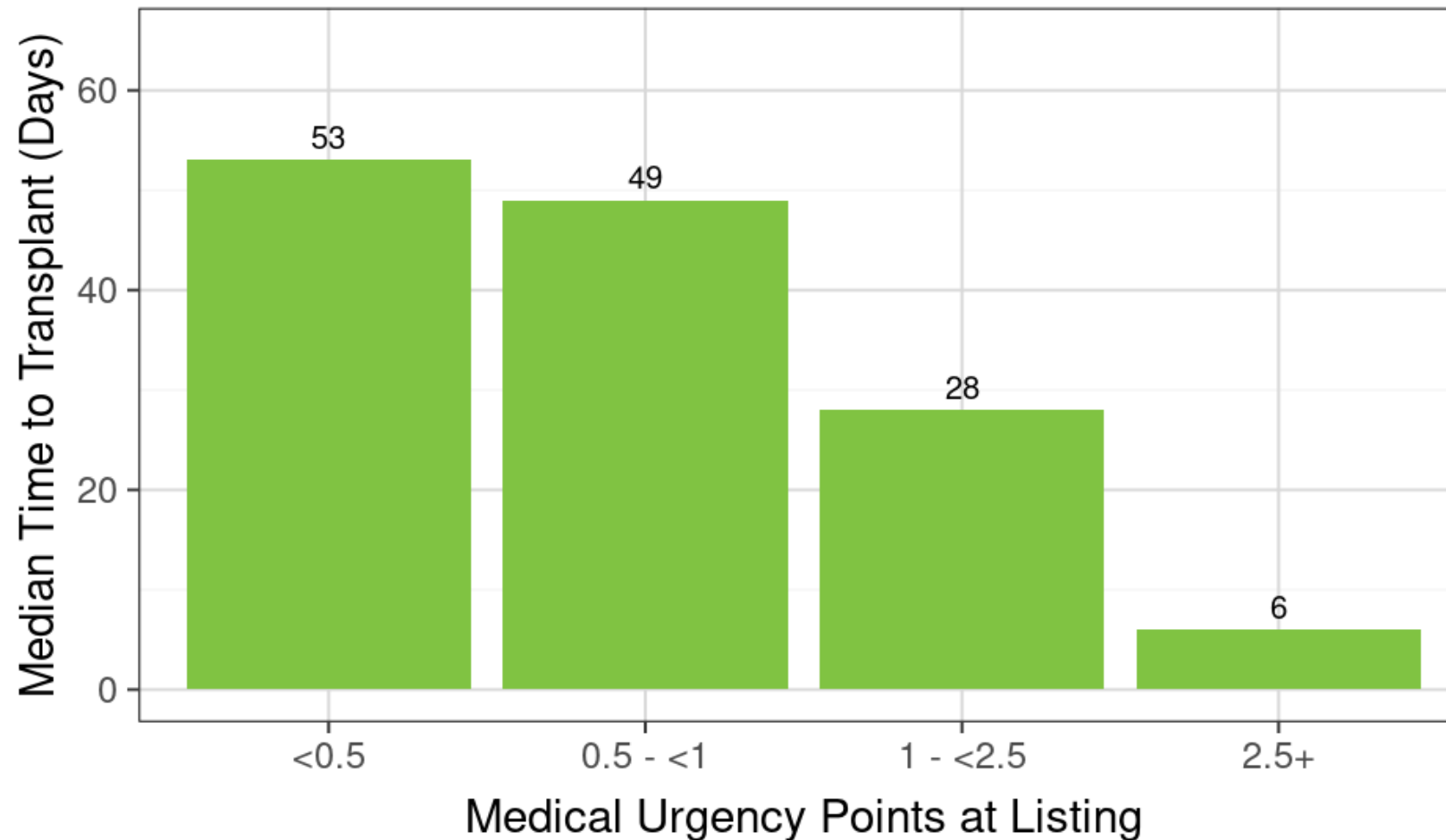
In the post-CD era, the most medically urgent candidates had the highest transplant rates



*Based on OPTN data as of April 12th, 2024. Data are subject to change based on future data submission or correction.



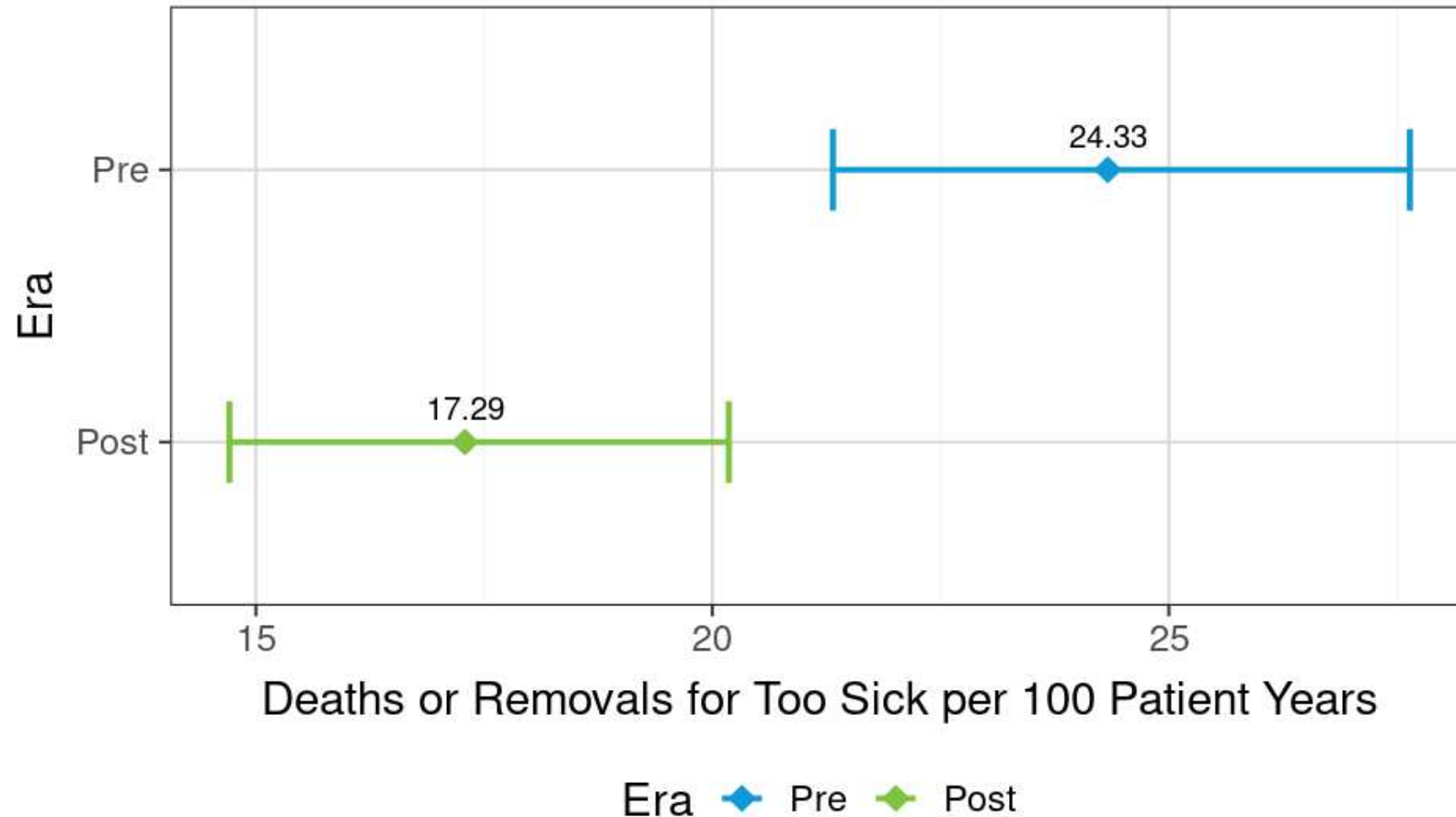
In the post-CD era, median time to transplant was shortest for the most medically urgent candidates



*Based on OPTN data as of April 12th, 2024. Data are subject to change based on future data submission or correction.



The number of deaths or removals for too sick per 100 patient years decreased by 29% from the pre-CD to post-CD era



*Based on OPTN data as of April 12th, 2024. Data are subject to change based on future data submission or correction.

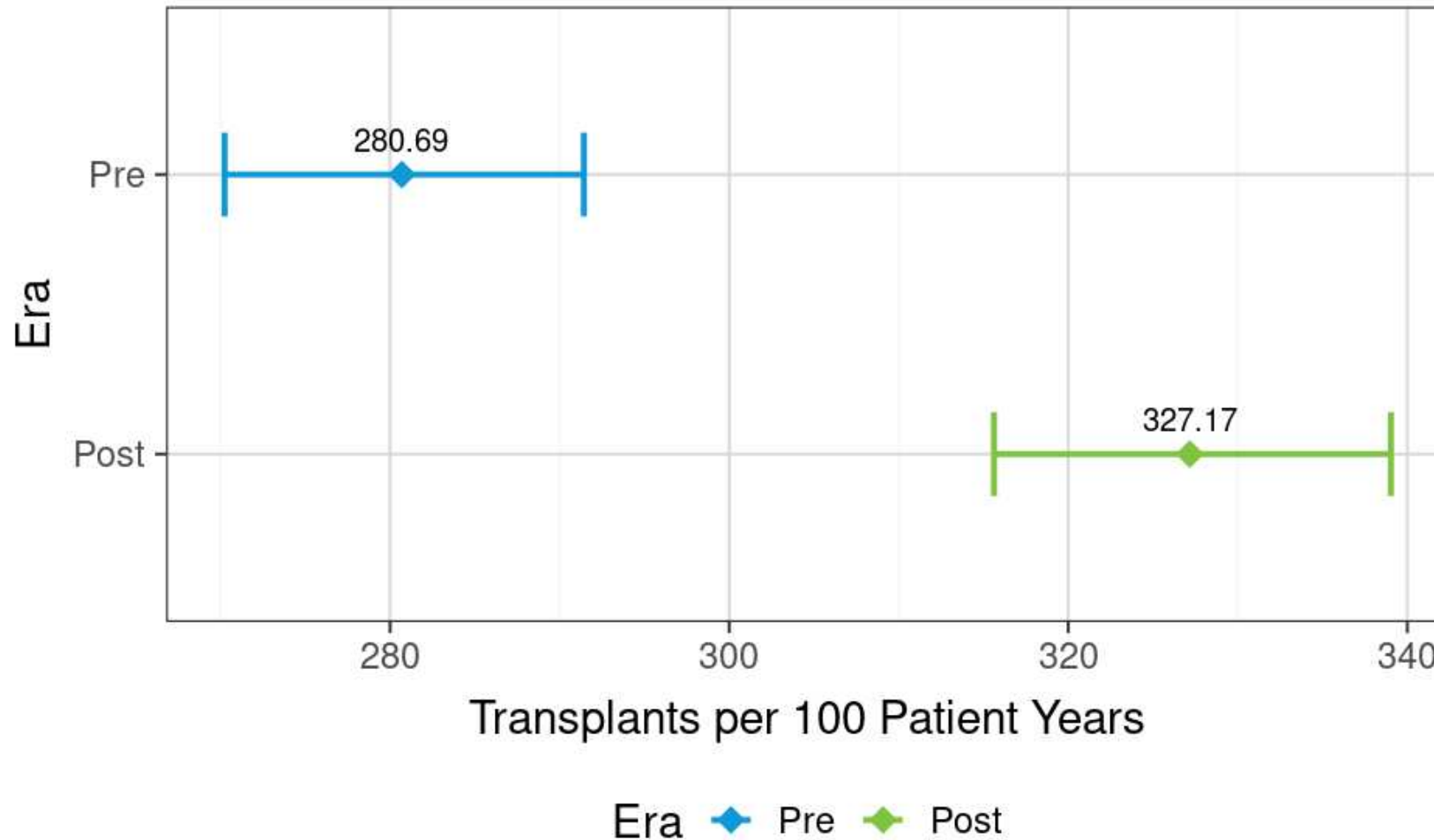


Waitlist Mortality Rate: Jan 1, 2016 – April 2, 2024





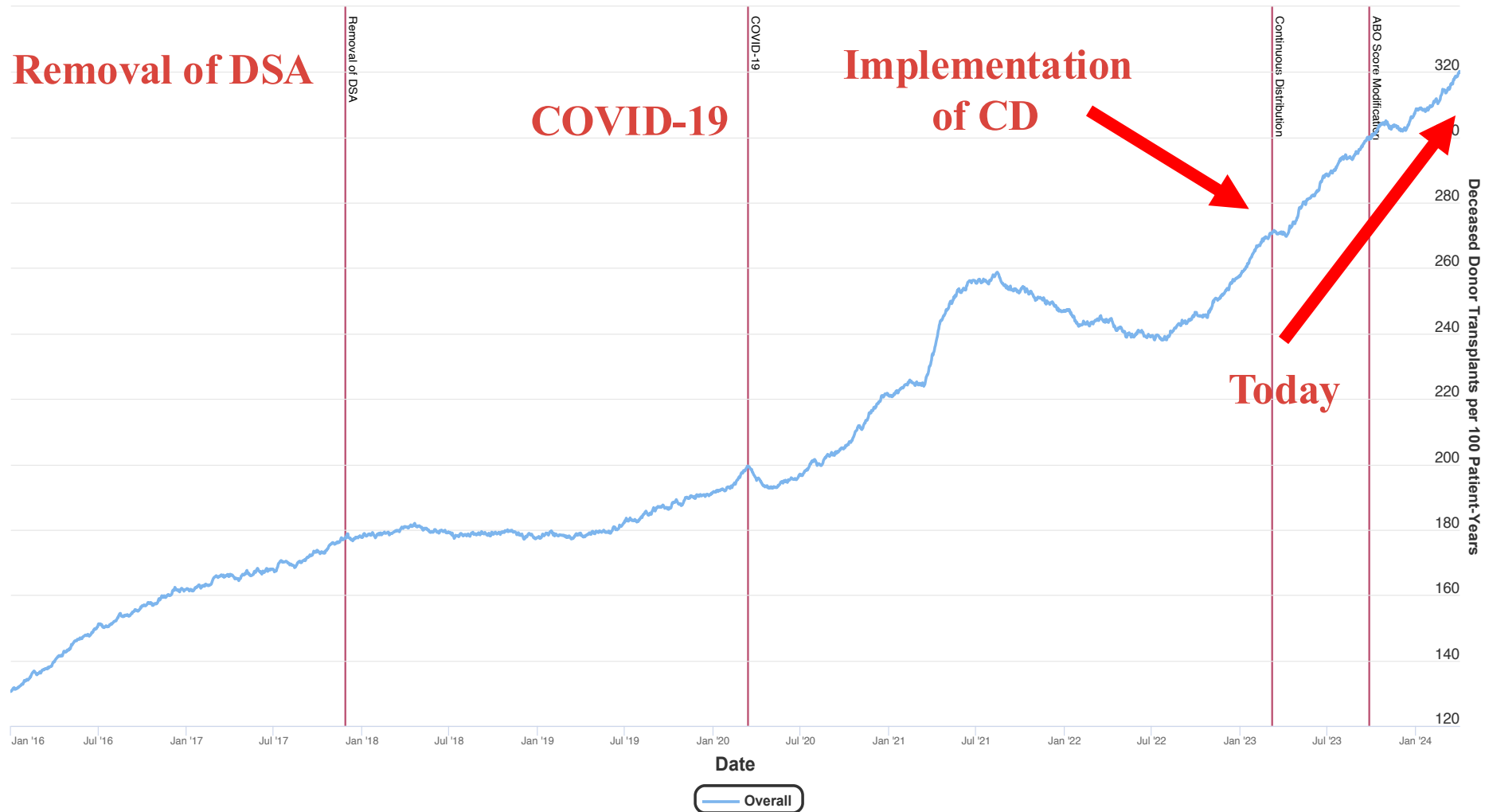
The number of lung transplants per 100 patient years increased by 16.6% from the pre-CD to post-CD era



*Based on OPTN data as of April 12th, 2024. Data are subject to change based on future data submission or correction.

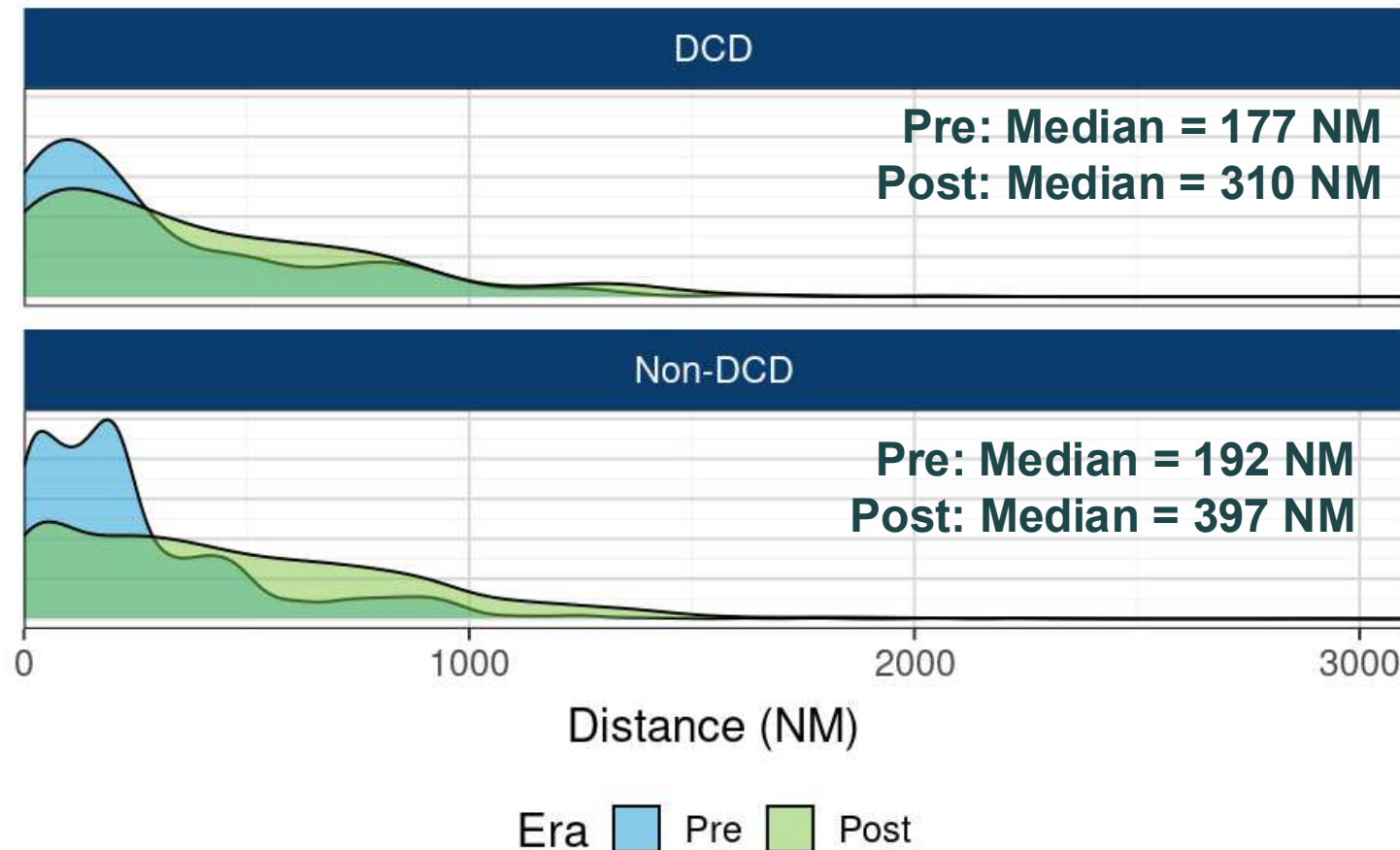


Lung Transplant Rate: Jan 1, 2016 – April 2, 2024





The median distance from the donor to transplant program doubled pre-CD to post-CD (from 192 NM to 385 NM)

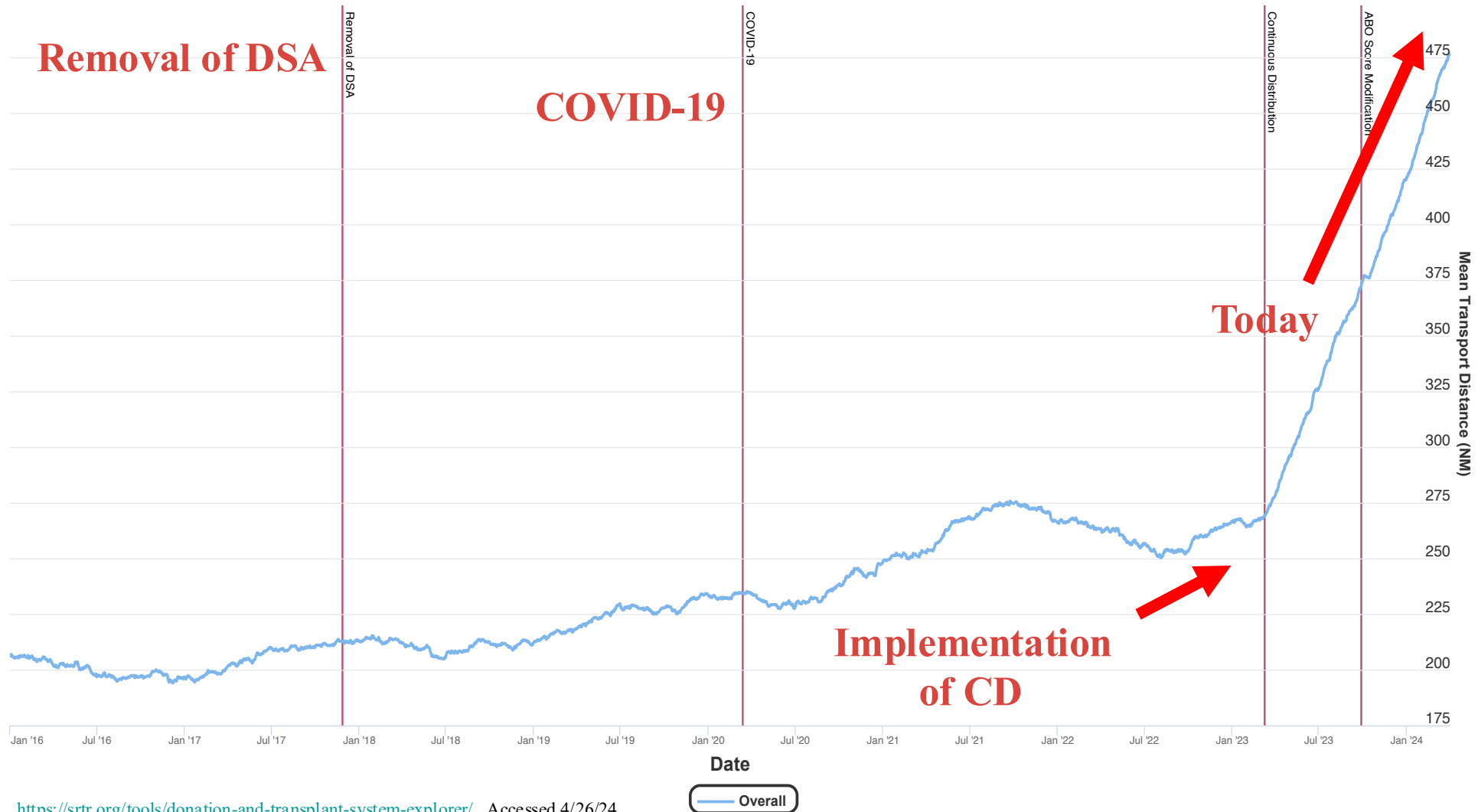


Overall Median
Pre: 192 NM
Post: 385 NM

*Based on OPTN data as of April 12th, 2024. Data are subject to change based on future data submission or correction.

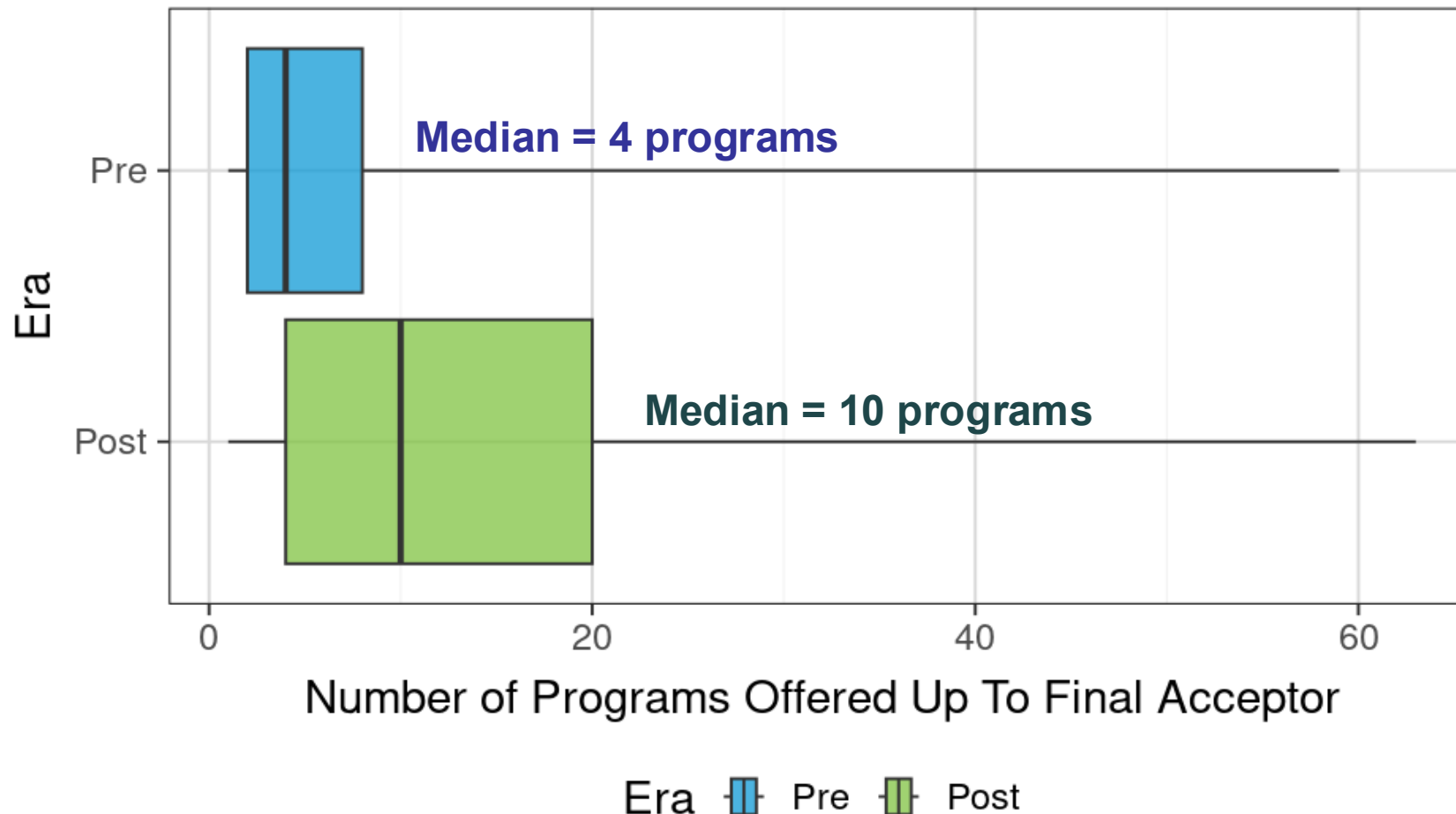


Transport Distance: Jan 1, 2016 – April 2, 2024





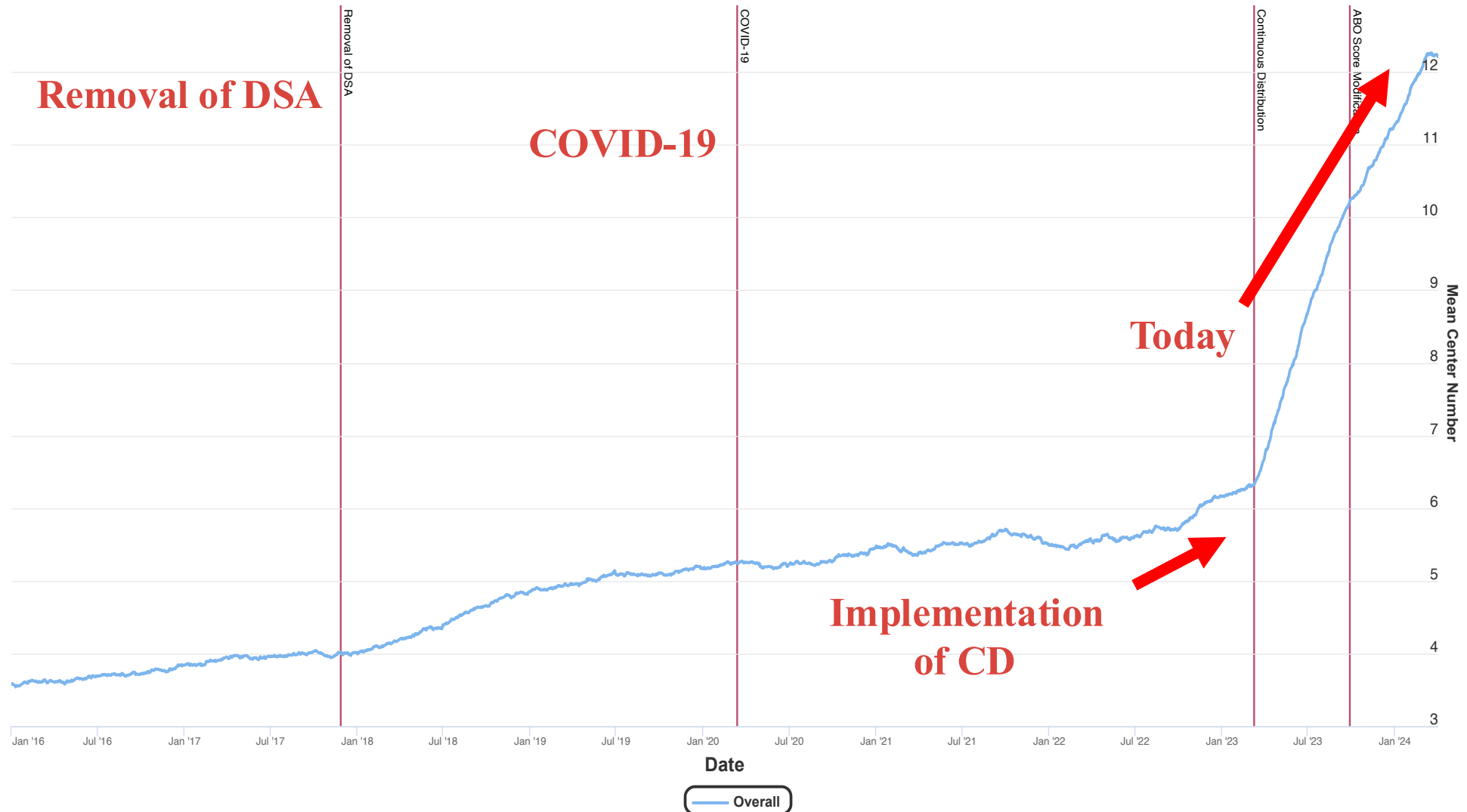
The median number of programs receiving offers each match run increased from 4 to 10 from the pre-CD to post-CD era



*Based on OPTN data as of April 12th, 2024. Data are subject to change based on future data submission or correction.

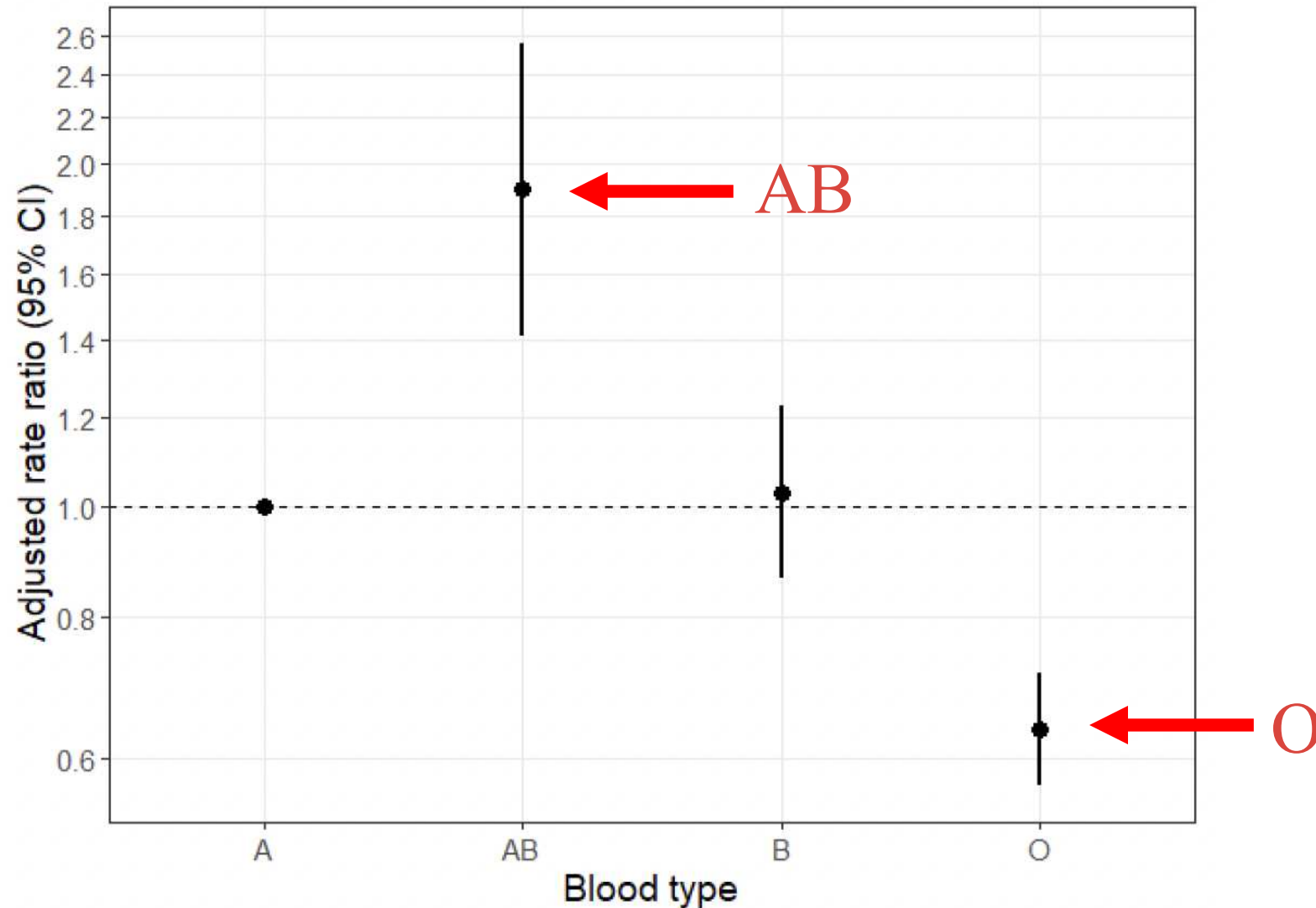


Mean Center Number: Jan 1, 2016 – April 2, 2024



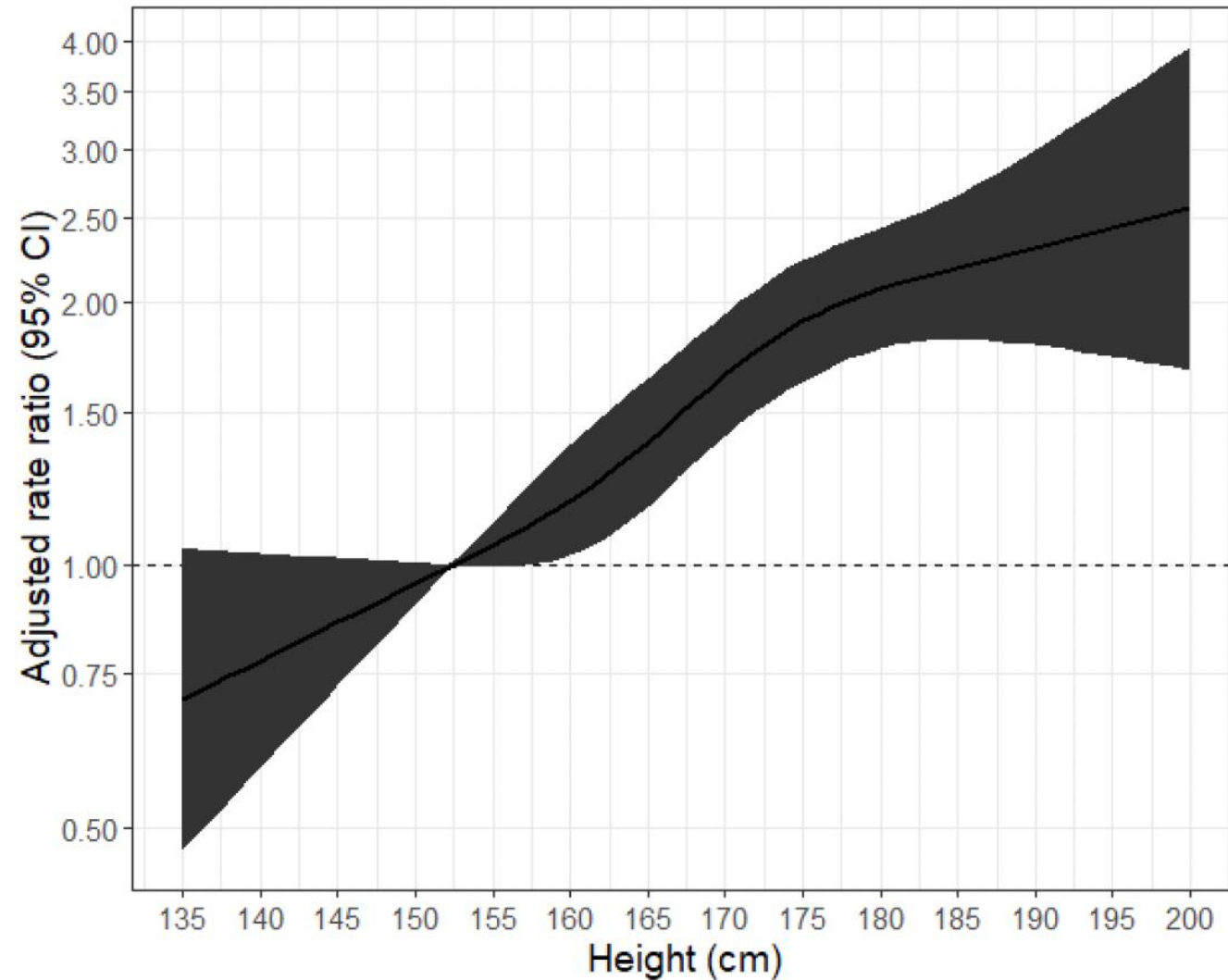


Adjusted Transplant Rate Ratios for Blood Type (ABO)



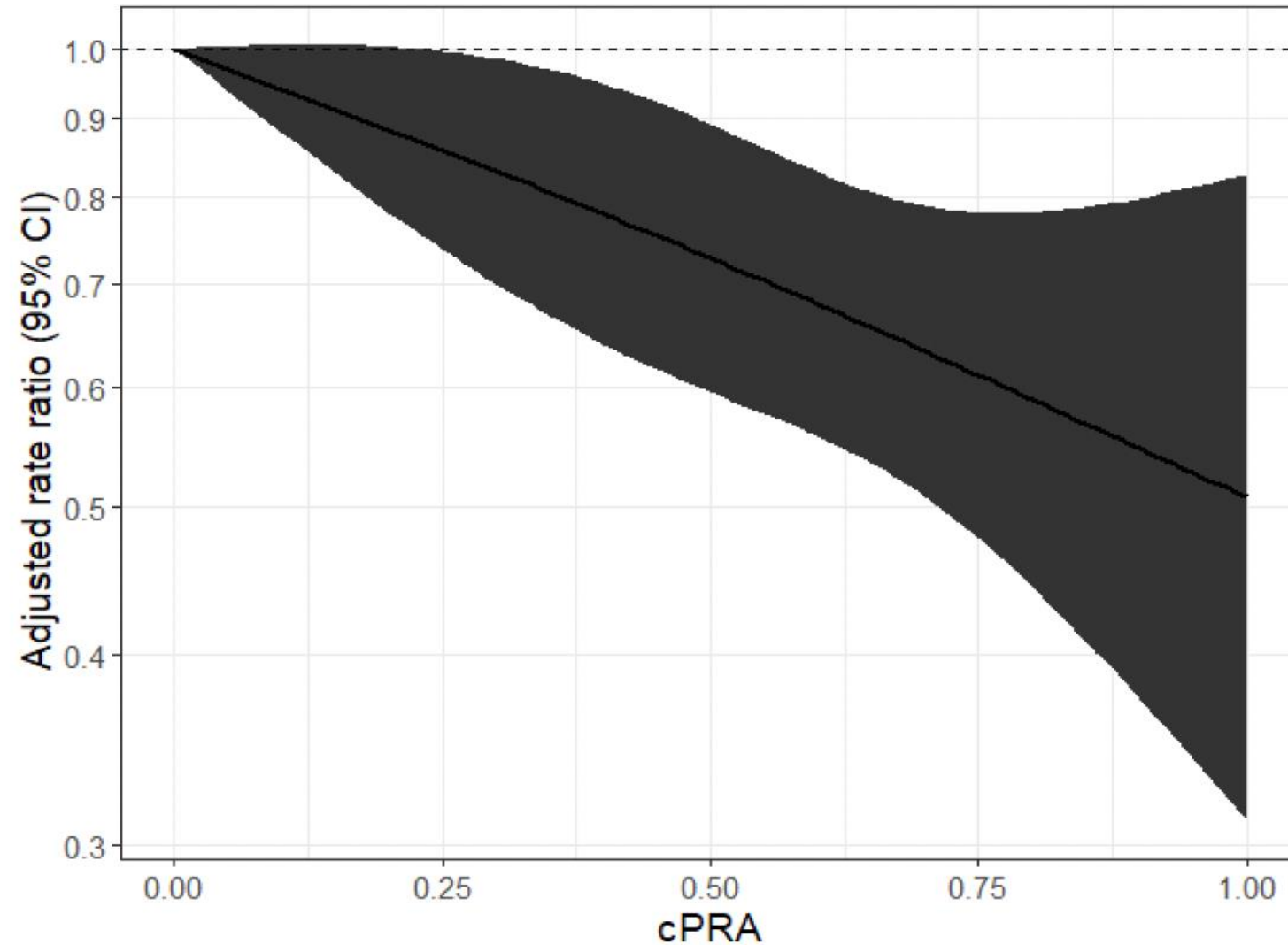


Adjusted Transplant Rate Ratios for Height





Adjusted Transplant Rate Ratios for cPRA





Put in some updates from ABO and biologic factors



Conclusions

- Public policy can dramatically impact organ donation and the well-being of our patients
- Long-term impact of continuous distribution remains to be determined
- Utilizing the CAS may allow for greater flexibility and efficiency in “tweaks” to the system
- The optimal allocation system will need to balance multiple factors of the final rule with the ultimate goal of increasing organ donation, enhancing efficiency, and reducing disparities



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QA

QUESTIONS & ANSWERS