Preparing for Implementation of Continuous Distribution of Lungs

Welcome to the webinar!

Agenda

- Overview of lung composite allocation scoring
- Q&A
- Implementation timeline
- Q&A

Speakers (1 of 2)



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Chair, OPTN Lung Transplantation Committee

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Division of Thoracic Surgery

Duke University Health System

Speakers (2 of 2)



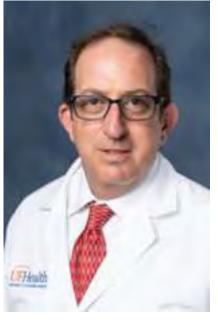
Erika D. Lease, MD, FCCP

Immediate Past Chair, OPTN Lung Transplantation Committee

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Director of Pediatric Lung Transplant

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Overview of Lung Composite Allocation Scoring

Changes to Lung Allocation

Current system:

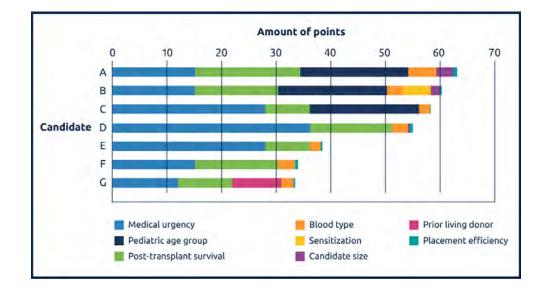
- Candidates are grouped into classifications
- Within each classification:
 - Candidates age 12+ sorted by lung allocation score (LAS)
 - Candidates <12 sorted by pediatric priority waiting time

Continuous distribution:

- No classifications or distance cut-offs
- <u>All</u> candidates sorted based on lung composite allocation score (lung CAS)
- LAS will no longer be used

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are	And registered at a transplant hospital that is at or within this distance from the donor hospital
1	At least 12 years old, blood type identical to the donor	250NM
2	At least 12 years old, blood type compatible with the donor	250NM



LAS and CAS are not directly comparable (1 of 2)

Lung Allocation Score (LAS)

Attribute	Maximum Points							
Waiting list Survival (1 year)								
Post-Transplant Survival (1 year)								
Total 100								

WL survival rated more heavily than PT survival (2:1 ratio)

Lung Composite Allocation Score (CAS)

Attribute	Maximum Points
Waiting list Survival (1 year)	25
Post-Transplant Survival (5 year)	25
Candidate Biology	15
ABO	5
CPRA	5
Height	5
Patient Access	25
Pediatric	20
Prior Living Donor	5
Placement Efficiency	10
Travel Efficiency	5
Proximity Efficiency	5
Total	100

LAS and CAS are not directly comparable (2 of 2)

- Difference in possible points assigned
 - LAS: Up to 100 points for waitlist and post-transplant survival
 - Lung CAS: Up to 50 points for waitlist and post-transplant survival
- Different relative weights between waitlist and post-transplant survival
 - LAS uses 2:1 ratio
 - Lung CAS uses 1:1 ratio
- Scores are calculated differently
 - Waitlist survival score uses the same variables for LAS but rating scale in lung CAS is nonlinear
 - Lung CAS uses 5-year post-transplant survival rather than one-year \rightarrow changes to variables

Not possible to have a lung CAS of 100

- To get maximum points, patient would need to be:
 - Pediatric (20 points)
 - A prior living donor (5 points)
 - 100% sensitized (5 points)
 - Blood type O (0.4550 points)
 - Either very short or very tall (~1 point)
 - Extremely medically urgent with excellent post-transplant outcomes (up to 25 points each)
 - Co-located at the donor hospital (10 points)
- Rare to see lung CAS higher than ~55

Score distributions are different – LAS:

<u>https://unos.org/news/submitting-las-exception-requests-for-candidates-</u> <u>diagnosed-with-ph/</u>

The LAS for all active candidates greater than or equal to 12 years of age waiting for

lung transplants **as of August 19, 2022** are as follows:

Number	25 [≞]	Median	75 th	90 th	95 [™]	99 [™]
waiting	percentile		percentile	percentile	percentile	percentile
819	33.9	37.3	41.7	49.6	57.5	90.0

Score distributions are different – lung CAS:

https://unos.org/news/lung-cas-score-summary/

Number waiting	25 th percentile	Median Median		95 th percentile	99 th percentile				
1076	1076 19.8320		21.5280	23.1060	29.9269	44.2272			
CAS subscore – does not include points for placement efficiency or prior living donor									

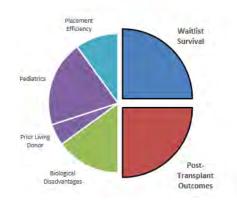
CAS subscore – does not include points for placement efficiency or prior living donor

As of September 16, 2022

Waitlist scores in lung CAS are lower

Number	25 th	Median	75 th	90 th	95 th	99 th	
waiting	percentile		percentile	percentile	percentile	percentile	
1076	0.1050	0.2925	0.6050	1.3250	2.2075	18.4250	

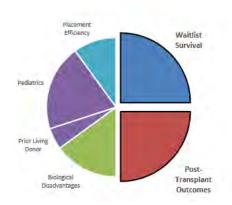
This is due to the nonlinear shape of the waiting list survival rating scale



As of September 16, 2022

Post-transplant scores in lung CAS

Number	25 th	Median	75 th	90 th	95 th	99 th	
waiting	percentile		percentile	percentile	percentile	percentile	
1076	18.7150	19.7700	20.4675	20.9600	21.3300	21.9600	



As of September 16, 2022

Composite allocation scoring

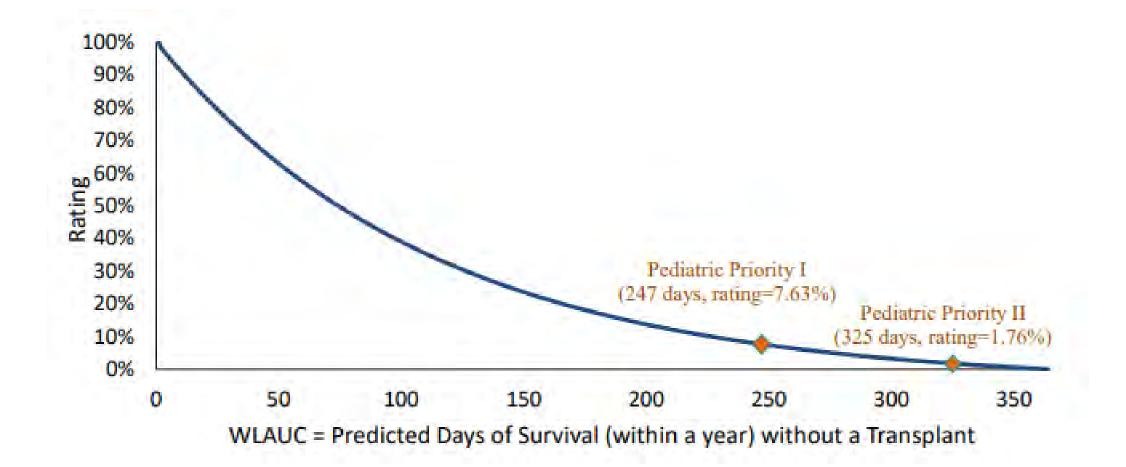
- Each attribute has a rating scale
- The rating scale is multiplied by the attribute weight

• Example:

- A candidate is assigned a waiting list survival rating based on clinical data entered
- The rating is multiplied by the weight assigned to waiting list survival, which is 25, to get the waiting list points

Attribute	Maximum Points
Waiting list Survival (1 year)	25
Post-Transplant Survival (5 year)	25
Candidate Biology	15
ABO	5
CPRA	5
Height	5
Patient Access	25
Pediatric	20
Prior Living Donor	5
Placement Efficiency	10
Travel Efficiency	5
Proximity Efficiency	5
Total	100

Waiting list survival rating scale



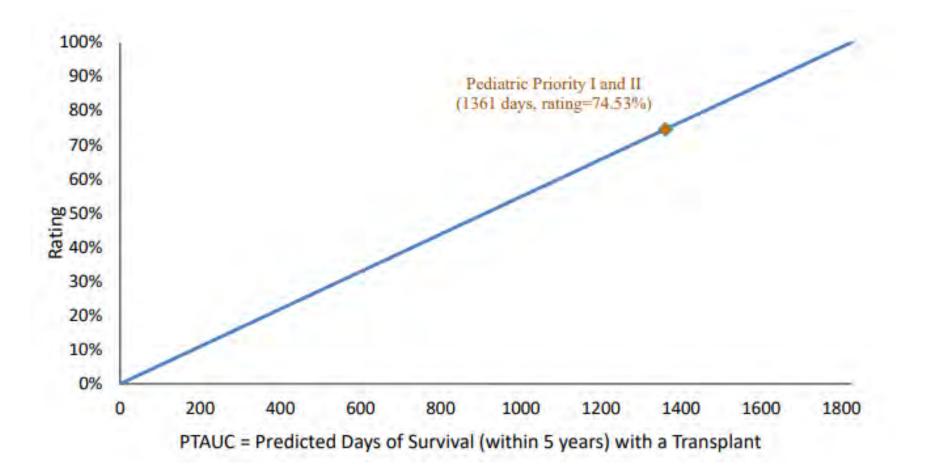
Pediatric scoring

• Candidates under age 12 assigned to pediatric priority 1 or 2

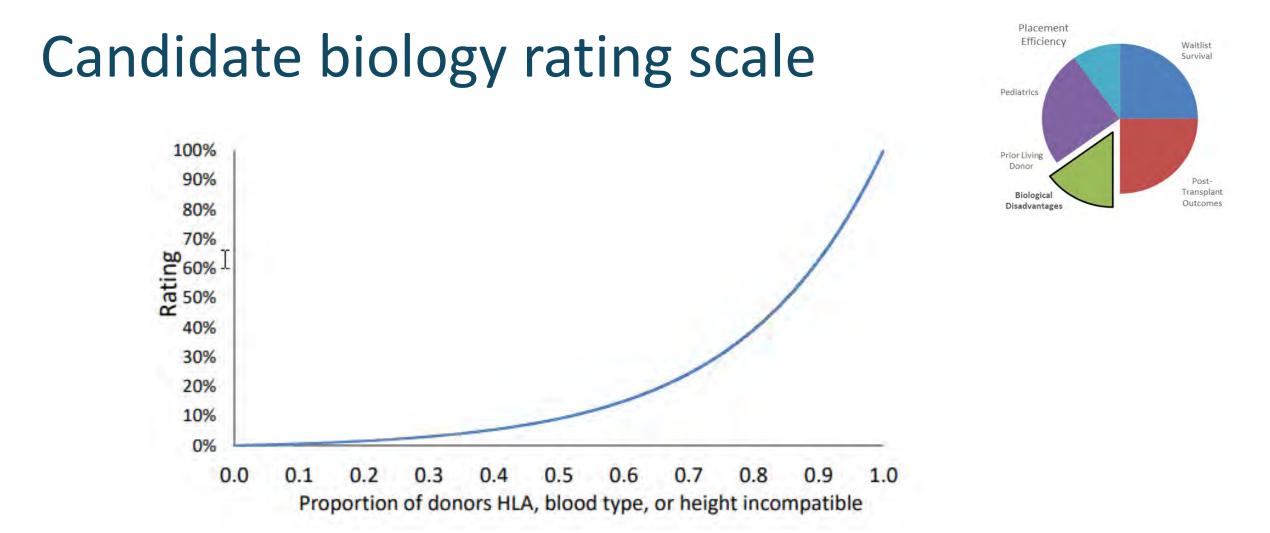
Pediatric priority	Waiting list survival score	Post-transplant survival score
1	1.9073 points	18.6336 points
2	0.4406 points	18.6336 points

- Pediatric candidates (registered before age 18) receive 20 points for patient access
- Candidates of small stature also receive points for height

Post-transplant survival rating scale



Extended from one-year to five-year post-transplant survival

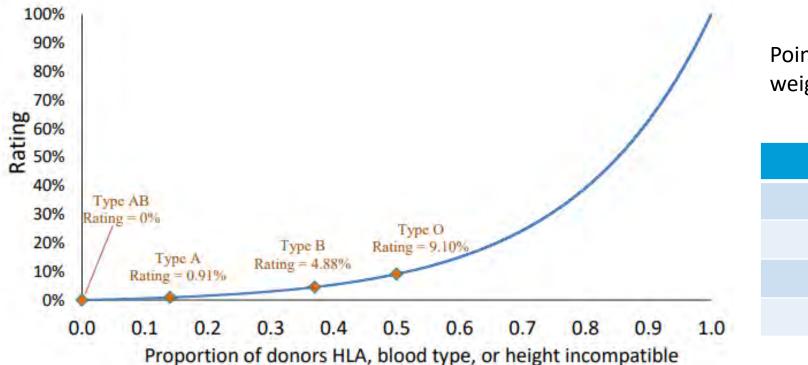


CPRA, blood type, and height aligned on same scale based on proportion of incompatible donors: Rating = $(100^{(proportion incompatible)} - 1)/99$



- CPRA will now factor into lung allocation
- Candidates will be screened off match run for unacceptable antigens
- Candidates will receive more CPRA points if more unacceptable antigens are entered
- Updated CPRA calculation slated for implementation in November 2022
 - https://optn.transplant.hrsa.gov/media/nlqdyd1o/policy-notice_change-cpra-calculation_histo.pdf
- Learn more: Review the "Unacceptable Antigens & CPRA in Lung Continuous Distribution" offering in UNOS Connect

Blood type

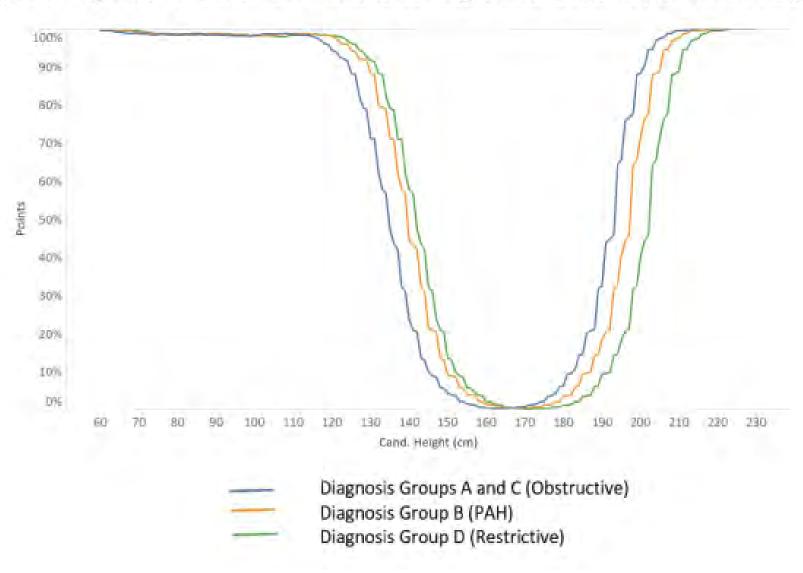


Points = Rating * attribute weight, where weight = 5

Blood Type	Points
AB	0
А	0.0455
В	0.2439
0	0.4550

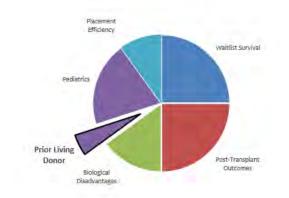
Height

Figure 8. Proportion of Donors Estimated to be Height-Incompatible by Candidate Height



Prior living donor

- Prior living donors receive 5 points
- Must have donated at least one organ for transplantation within the U.S. or its territories
- Beginning Nov. 8 transplant programs may begin submitting information to the OPTN so candidates will receive points upon implementation
 - Name of recipient or intended recipient
 - Recipient's or intended recipient's transplant hospital
 - Date the donated organ was procured



Placement efficiency

- Candidates will receive up to 10 points
 - Up to 5 points for travel efficiency
 - Up to 5 points for proximity efficiency
- Placement efficiency scores are calculated for each match run



Example: Patient profile

- Very urgent adult candidate with COVID-19 ARDS, blood type A, average height, CPRA of 62%
- LAS: 94.0072
- Lung CAS subscore: 37.9075
 - Waiting list survival points: 21.7725
 - Post-transplant outcomes points: 15.2525
 - Blood type: 0.0455
 - CPRA: 0.835
 - Height: 0.0020
 - Pediatric: 0
 - Prior living donor: 0
 - Placement efficiency: determined on match run

Requesting score exceptions

- LAS exceptions will go away with implementation
- Transplant programs will be able to request CAS exceptions prior to implementation
- Exceptions may be requested for a percentage of a goal
 - Waiting list survival, post-transplant outcomes, candidate biology, patient access
- Learn more: Review the "Scoring and Exceptions Under Lung Continuous Distribution" offering in UNOS Connect
 - Contains several patient examples

Expected impact based on modeling

Reduced waitlist deaths and slight decrease in % flying

	Current	Expected
1 Year Waitlist Mortality Count	435	260
Percent Died by 2 Years Post-transplant	23.38	23.44
Percent Expected to Fly (>75NM)	81.32	79.02
Median Donor-Recipient Distance (NM)	195	353

Expected impact by region based on modeling

- Decrease in variation of transplant rates across regions
- Decline or no change in waitlist deaths for each region
- Similar estimates for post-transplant survival across regions
- Regional differences in travel remain

Resources (1 of 3)

- Lung CAS Data Report for transplant programs in Data Services Portal
 - Shows calculated CAS subscore for currently registered patients
 - Does not include points for placement efficiency
 - Prior living donor status and CPRA points will be updated in the coming months

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Lung CAS Report for AAAA-TX1

					C)emographics					Medical	Urgency
Waitlist Id	Last Name	First Name	Waitlist Organ	Date Of Birth	Diagnosis Group	Diagnosis Description	Age In Years	Pediatric Priority (1, 2)	Calculated LAS Value	Match LAS Value	1Year Waitlist Measure In Days	Waitlist Measure Attribute Points (0-25)
******	Xxxx	Xxxxx	LU	1/1/1900	D	IIP: BOOP/COP	40		39.7880	39.7880	319	0.5075
******	Xxxx	Xxxxx	LU	1/1/1900	D	COVID-19: ARDS	51		94.0072	94.0072	15	21.7725
******	Xxxx	Xxxxx	LU	1/1/1900	D	MIXED CONNECTIVE TISSUE DISEASE	60		35.8339	35.8339	343	0.2125
******	Xxxx	Xxxxx	LU	1/1/1900	D	MIXED CONNECTIVE TISSUE DISEASE	10	1	34.5801	34.5801	347	1.9073
******	Xxxx	Xxxxx	LU	1/1/1900	D	PULMONARY FIBROSIS OTHER SPECIFY CAUSE	8	2	41.8119	41.8119	314	0.4406
******	Xxxx	Xxxxx	LU	1/1/1900	D	COVID-19: PULMONARY FIBROSIS	70		49.5440	49.5440	263	1.4975
******	Xxxx	Xxxxx	LU	1/1/1900	D	IIP: IDIOPATHIC PULMONARY FIBROSIS (IPF)	52		37.7279	37.7279	329	0.3775
******	Xxxx	Xxxxx	LU	1/1/1900	А	ALPHA - 1 - ANTITRYPSIN DEFICIENCY	45		32.8410	32.8410	357	0.0750
******	Xxxx	Xxxxx	HL	1/1/1900	D	COVID-19: ARDS	22		94.0072	94.0072	15	21.7725
******	Xxxx	Ххххх	LU	1/1/1900	D	COVID-19: ARDS	16		90.8169	90.8169	37	17.5850
******	Xxxx	Xxxxx	LU	1/1/1900	А	COPD/EMPHYSEMA	43		32.3075	32.3075	362	0.0175

Data as of: 3/20/2022 1:00:35 AM - Report Run Date Time: 3/21/2022 1:03:00 FM

Resources (2 of 3)

- Educational offerings: Lung Continuous Distribution playlist in UNOS Connect
 - LUN102 Basic Principles of Continuous Distribution of Lungs
 - LUN103 Unacceptable Antigens & CPRA in Lung Continuous Distribution
 - SYS 183 Using the Lung CAS Report
 - LUN 104 Scoring and Exceptions Under Lung Continuous Distribution
- Guide to Calculating the Lung Composite Allocation Score

Resources (3 of 3)

Upon implementation - Lung Composite Allocation Score (CAS) calculator will replace the Lung Allocation Score (LAS) calculator on the OPTN website

LAS calculator

This is a sample calculator to show how the lung allocation score (LAS) is established. It uses the same formula as the one transplant hospitals use to enter data on patients on the waiting list for a lung transplant.

Learn about LAS

• LAS results should not be considered definitive; they are merely a snapshot based upon the values entered and can vary daily.	
Date of birth *(mm/dd/yyyy)	
Height *	Weight *
ft in	lbs
cm	kg
Lung diagnosis code *	~

Questions about scoring

- Will we have access to estimated waitlist urgency and post-transplant survival scores?
 - Yes available now in Data Services Portal; will be available in OPTN Waiting List post-implementation
- Will patients receive both LAS and CAS?
 - No. LAS is going away and patients will receive a CAS instead
- Does CAS use the same variables for LAS?
 - The CAS uses most of the same variables as LAS but also accounts for CPRA, height, blood type, pediatric status, prior living donor status, and placement efficiency
- What is the difference between distance cutoff for LAS vs CAS?
 - No distance cutoff for CAS; candidates get more points if they are closer to the donor hospital.

Questions about impact (1 of 2)

- What is the biggest impact members will see as a result of policy change?
 - Composite allocation score no more classifications in allocation
 - Exceptions process is different
 - Modeling showed reduced waitlist deaths and slight decrease in % flying, but increase in median distance between donor and recipient
- Impact for coordinators doing the listing?
 - Will need to indicate if candidates are on high flow nasal cannula or ECMO
 - May need to submit information on prior living donor status and unacceptable antigens
- Do you expect to see changes in who is selected for listing?
 - Remains at discretion of transplant programs

Questions about impact (2 of 2)

- How will this effect local distribution, especially for Midwest states?
 - Modeling showed that regions with higher median distances/more organs flown under current allocation tend to have higher median distances/more organs flown in continuous distribution
- In general, what do transplant programs need to do to prepare?
 - Familiarize staff with new composite allocation score and exceptions process
 - Review candidates who currently hold exceptions and determine if a CAS exception request should be submitted for them (LAS exceptions will go away upon implementation)
 - Enter unacceptable antigens if you want your candidates to get more points based on CPRA (those candidates will be screened off the match for donor lungs with those antigens)
 - Notify OPTN of prior living donor status for your candidates

Phase 1 implementation: 11/8/2022

- Implementing two new data fields:
 - Prior living donor
 - Will require documentation be submitted to Organ Center for lung candidates who previously donated an organ
 - High flow nasal cannula
 - Will display when candidate requires supplemental oxygen at rest, at night or with exercise
 - This field will become required for all lung candidates receiving supplemental oxygen at rest, at night, or with exercise when lung continuous distribution is implemented
- Implementing Lung Composite Allocation Score: 28 day report
 - Will help members comply with policy to update clinical values every 28 days for certain candidates
 - Will include transition section to identify candidates on high flow nasal cannula

Implementation

- After 11/8, Lung CAS Data Report in Data Services Portal will be updated periodically to reflect submitted data for prior living donor status
- Prior to implementation, transplant programs will be able to submit exception requests for lung CAS (slated for early January)
- Early 2023: Continuous distribution of lungs will go into effect

Additional resources coming soon

- Educational offerings
 - Lung Review Board orientation
 - Continuous Distribution for OPOs
 - Lung Continuous Distribution Systems Training for Transplant Hospitals
 - Lung Review Board Submission Checklist
- Patient webinar
- Policy toolkit with member and patient FAQs: <u>https://optn.transplant.hrsa.gov/professionals/by-organ/heart-lung/lung-continuous-distribution-policy/</u>

Thank You!