

OPTN/UNOS Thoracic Organ Transplantation Committee

Proposal to Modify Pediatric Lung Allocation Policy

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Proposal to Modify Pediatric Lung Allocation Policy

Executive Summary

On May 31, 2013, former Secretary of Health and Human Services, Kathleen Sebelius, requested that the OPTN review lung allocation policy, with “particular attention to the age categories used in allocation” and the “intent of identifying any potential improvements to this policy that would make more transplants available to children, consistent with the requirements of the OPTN final rule.”¹ As an immediate measure, the OPTN/UNOS Board of Directors approved the Adolescent Classification Exception for Pediatric Candidates, which allowed lung candidates less than 12 years old to request an exception from the Lung Review Board to be classified as an adolescent candidate for the purposes of prioritization by Lung Allocation Score (LAS).² Following its passage, the Thoracic Organ Transplantation Committee conducted a more comprehensive review of lung allocation policy and identified two additional opportunities for improving access to transplant for all pediatric candidates less than 18 years old.

The Committee proposes broader geographic sharing of pediatric donor lungs. This will give candidates less than 18 years old better access to properly sized donors, which aligns with Goal 2 of the OPTN Strategic Plan. The Committee also proposes establishing eligibility criteria for candidates registered prior to their second birthday to receive a deceased donor lung of any blood type. This will increase utilization of the smallest donor lungs and decrease waiting list mortality among infants, which supports Goals 1 and 3 of the OPTN Strategic Plan.³

¹ May 31, 2013, Letter from U.S. Department of Health and Human Services Secretary Kathleen Sebelius to Dr. John Roberts, President of the OPTN Board of Directors.

² http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policy_Notice_07-01-2014.pdf

³ <http://optn.transplant.hrsa.gov/governance/strategic-plan/>

Proposal to Modify Pediatric Lung Allocation Policy

Affected Policies: Policy 10.4.B: Allocation of Lungs by Blood Type; 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old; 10.4.D: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old; and 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old

Sponsoring Committee: Thoracic Organ Transplantation Committee

Public Comment Period: August 14 – October 14, 2015

What problem will this proposal solve?

On May 31, 2013, former Secretary of Health and Human Services, Kathleen Sebelius, requested that the OPTN review lung allocation policy, with “particular attention to the age categories used in allocation” and the “intent of identifying any potential improvements to this policy that would make more transplants available to children, consistent with the requirements of the OPTN final rule.”⁴ As an immediate measure, the OPTN/UNOS Board of Directors approved the Adolescent Classification Exception for Pediatric Candidates, which allowed lung candidates less than 12 years old to request an exception from the Lung Review Board to be classified as an adolescent candidate for the purposes of prioritization by Lung Allocation Score (LAS).⁵ Following its passage, the Thoracic Organ Transplantation Committee began a more comprehensive review of lung allocation policy to identify additional opportunities for improving access to transplant for all pediatric candidates less than 18 years old.

On November 12, 2014, the Board approved the “Ethical Principles of Pediatric Organ Allocation,” which provides the ethical justification for pediatric priority in organ allocation. It states that, “children with end-stage organ failure have a time-limited opportunity for growth and development and may suffer lifelong consequences if not expeditiously transplanted.” Further, pediatric candidates, especially those waiting for thoracic organs, face barriers to transplantation due to their small size and developing anatomy and need to have ready access to appropriate size-matched organs.⁶ However, current policy only permits broader geographic sharing through Zone B of child (0-11 year old) donor lungs to child candidates (see diagram on page 5).⁷ This means that lungs from child deceased donors are not offered to adolescent (12-17 year old) candidates beyond Zone A before being offered to adult candidates. Lungs from adolescent deceased donors are not offered to either adolescent or child candidates, of the same age and medical urgency status, across a wider area before being offered to adult candidates.

Infant lung candidates are especially disadvantaged by a lack of appropriate size-matched organs. While current policy allows candidates registered prior to turning two years old to receive hearts from deceased donors of any blood type, alternative blood type transplants are not permitted for the 12-14 lung candidates registered prior to their 2nd birthday each year. Candidates less than one year old have the highest percentage of removal from the waiting list because of death or too sick to transplant (see table below). OPTN data also show that the percentage of donors for whom there are no candidates on the

⁴ May 31, 2013, Letter from U.S. Department of Health and Human Services Secretary Kathleen Sebelius to Dr. John Roberts, President of the OPTN Board of Directors.

⁵ http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policy_Notice_07-01-2014.pdf

⁶ Organ Procurement and Transplantation Network. *Ethical Principles of Pediatric Organ Allocation*. Richmond, VA, 2014, available at <http://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/>.

⁷ Policy 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old, Organ Procurement and Transplantation Network Policies.

match run, is substantially higher for donors 0-2 years old than any other age group (N=286, 23.6%, see Table 2). While at times this is because no size-matched candidates are currently waiting, it may also be due to the unavailability of an appropriate blood type match candidate.

Table 1. Waiting list removal reasons by age group for lung candidates added to the waiting list between January 1, 2008, and May 31, 2012

Candidate age at listing	All		Removal reason							
			Still waiting		Transplanted		Other		Died/too sick	
	N	%	N	%	N	%	N	%	N	%
All	10,018	100.0	487	4.9	7,352	73.4	696	6.9	1,483	14.8
0 years	37	100.0	1	2.7	20	54.1	4	10.8	12	32.4
1-2 years	23	100.0	4	17.4	13	56.5	2	8.7	4	17.4
3-11 years	74	100.0	5	6.8	43	58.1	6	8.1	20	27.0
12-17 years	188	100.0	5	2.7	142	75.5	12	6.4	29	15.4
18-35 years	1,238	100.0	60	4.8	861	69.5	109	8.8	208	16.8
36-65 years	6,815	100.0	388	5.7	4,950	72.6	468	6.9	1,009	14.8
66+ years	1,643	100.0	24	1.5	1,323	80.5	95	5.8	201	12.2

Why should you support this proposal?

This proposal improves access to transplantation for all pediatric candidates, including infants, children, and adolescents, without evidence of an adverse impact to adults. It accomplishes this through broader sharing of pediatric donor lungs, with prioritization of child and then adolescent candidates, and by establishing eligibility criteria for alternative blood type matching. These proposed policy changes are consistent with the “Ethical Principles of Pediatric Organ Allocation,” which affirms the need for policies that maximize transplant benefit to pediatric candidates as a most vulnerable population.⁸

How was this proposal developed?

The Lung Subcommittee investigated four potential solutions to improve access to lung transplantation for pediatric candidates, including:

- Matching donors to candidates by physical size, rather than age
- Use of the LAS in allocation for candidates less than 12 years old
- Broader sharing of child (0-11 years old) and adolescent (12-17 years old) donor lungs
- Alternative blood type matching for very young pediatric lung candidates

Early in the development process, the Lung Subcommittee eliminated allocating organs by physical size as a potential solution. Since adolescent donor lungs are appropriate size matches for adult candidates, allocation based on physical size would increase competition for adolescent donor lungs and disadvantage adolescent candidates (Exhibit A).

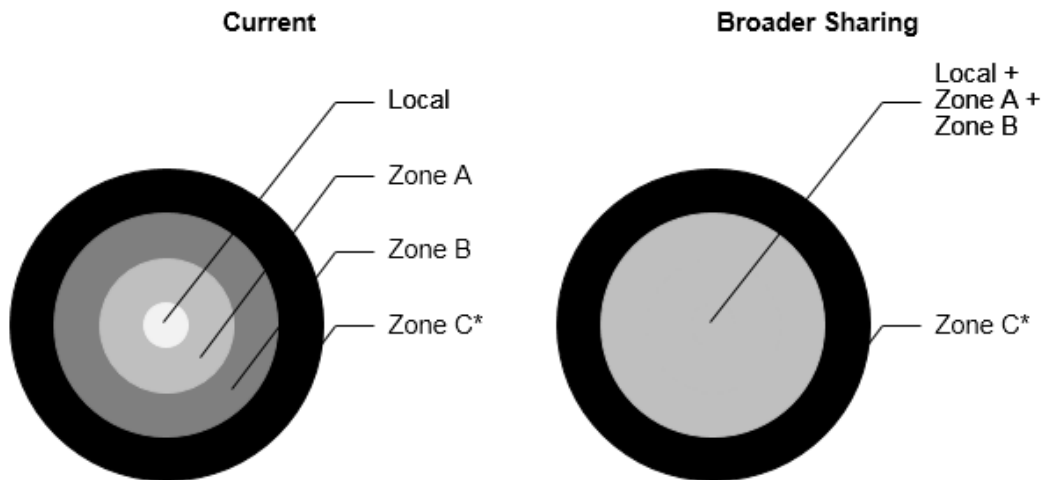
The Lung Subcommittee also does not believe it is appropriate to apply the LAS to candidates less than 12 years old. The LAS was developed using a mostly adult population. Child lung candidates suffer from

⁸ Organ Procurement and Transplantation Network. *Ethical Principles of Pediatric Organ Allocation*. Richmond, VA, 2014, available at <http://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/>.

different diseases than adults,⁹ meaning that the score may not accurately reflect the severity of their illness or its progression. Some variables used in the LAS are clinical tests that are not performed in pediatric candidates or, if performed, may have results that are difficult to interpret or not comparable to adults. For instance, it is difficult to perform a forced vital capacity (FVC) test on a toddler and impossible to acquire a six-minute walk distance for an infant. However, providers may still petition for an Adolescent Classification Exception on behalf of their patients less than 12 years old so that they may be allocated based on LAS when it is appropriate.¹⁰

Having eliminated the first two potential solutions, the Lung Subcommittee then explored the impact of broader sharing in promoting access for pediatric candidates. As illustrated in Figure 1 below, currently lungs are allocated first to candidates in an area local to the donor hospital and then to candidates within 500-mile concentric circles known as “zones.” Within each of these zones, candidates are classified by age group.¹¹ The order of the candidate age groups depends on the age of the donor. Currently, child candidates receive priority for child donor lungs (followed by adolescents, then adults), and adolescent candidates receive priority for adolescent donor lungs (followed by children, then adults). Broader sharing allows deceased donor lungs to be offered to pediatric candidates, of the same age and medical urgency status, across a much wider area before being offered to adult candidates.

Figure 1. Geographic Distribution in Deceased Donor Lung Allocation



*Continue to radiate in 500-mile concentric circles through Zone E

⁹ Kirkby, S. and D. Hayes, Jr. “Pediatric lung transplantation: indications and outcomes.” J Thorac Dis 6 (2014): 1024-1031.

¹⁰ Policy 10.2.B: Lung Candidates with Exceptional Cases, Organ Procurement and Transplantation Network Policies.

¹¹ In addition to age, patients are prioritized by blood type, medical urgency (Priority 1 or 2 for candidates less than 12 years old, LAS for candidates 12 years and older), and waiting time.

The Lung Subcommittee requested modeling for several concepts of broader sharing of pediatric donor lungs to pediatric candidates. While members quickly concluded that broader sharing among the local area, Zone A, and Zone B improved access for pediatric candidates, they spent several months deliberating between two allocation sequence options:

1. "Share Both": Broader sharing of both child and adolescent donor lungs, with children receiving priority for child donor lungs and adolescents receiving priority for adolescent donor lungs
2. "Child Priority": Broader sharing of both child and adolescent donor lungs, with children and then adolescents receiving priority for lungs from all donors less than 18 years old

Modeling showed that adolescents significantly benefitted from either option; however, only "Child Priority" provided a benefit to child candidates over the current system (Exhibit B). However, given the Adolescent Classification Exception that is available to child candidates and the fact that the current allocation system gives priority to adolescents for adolescent donor lungs, the Lung Subcommittee sought input from both the Pediatric Transplantation and Ethics Committees.

The Pediatric Transplantation Committee recommended "Child Priority," acknowledging that adolescents would benefit under either option and that size restriction is a significant barrier to transplantation for younger pediatric candidates. Members also agreed with the Lung Subcommittee that a change in standard allocation to benefit child candidates is preferable to an exception process, which could be inconsistently applied and the outcome of which is uncertain. The Ethics Committee expressed general support for broader sharing and advised that either option was ethically defensible. After considering this feedback, the Lung Subcommittee voted unanimously to recommend the "Child Priority" broader sharing option to the Thoracic Organ Transplantation Committee.

Broader sharing does not improve waiting list mortality rates or transplant rates in infants (Exhibits B-C), so the Lung Subcommittee investigated alternative blood type matching as a way to benefit this most vulnerable population of candidates. Candidates eligible for alternative blood type matching may accept deceased donor lungs of any blood type. Research suggests that children with less mature immune systems, mostly infants, can successfully be transplanted with lungs of any blood type. Alternative blood type heart transplants were performed in Canada beginning in 1996, with demonstrated successful post-transplant outcomes.^{12,13} Since 2001, the OPTN has permitted alternative blood type heart transplants.¹⁴ Researchers in developmental immunology believe alternative blood type lung transplants are also possible.¹⁵ The Lung Subcommittee developed an alternative blood type lung policy that is aligned with the heart policy that the Board passed in June 2014.^{16,17} Members proposed that any Priority 1 candidate less than 1 year old, regardless of isohemagglutinin titers, or a Priority 1 candidate at least 1 year old, but registered prior to turning 2 years old, with isohemagglutinin titers less than or equal to 1:16, can be eligible to receive a deceased donor lung from a donor of any blood type.

¹² Dipchand, A.I., S.M. Pollock BarZiv, C. Manlhiot C, et al. "Equivalent outcomes for pediatric heart transplantation recipients: ABO-blood group incompatible versus ABO-compatible." *Am J Transplant* 10 (2011): 389-397.

¹³ West, L.J., S.M. Pollock-Barziv, A.I. Dipchand, et al. "ABO-incompatible heart transplantation in infants." *New England Journal of Medicine* 344 (2001): 793-800.

¹⁴ Policy 5.3.D: Pediatric Heart Acceptance Criteria, Organ Procurement and Transplantation Network Policies

¹⁵ Urschel, S., G. Visner, "Impact of Developmental Immunology on Outcomes," in *Pediatric Lung Transplantation*, ed. S. Goldfarb, C. Benden, S. Sweet, J.L. Kirklin, vol. 7 of *ISHLT Monograph Series* (University of Alabama at Birmingham, 2013), 18.

¹⁶ Policy 6.5.A: Allocation of Hearts by Blood Type, Organ Procurement and Transplantation Network Policies (not yet implemented).

¹⁷ Policy 6.5.B: Eligibility for Heart Offers from Deceased Donors of Any Blood Type, Organ Procurement and Transplantation Network Policies (not yet implemented).

On May 21, 2015, the Lung Subcommittee voted unanimously to recommend broader sharing with “Child Priority” and present eligibility criteria for alternative blood type matching of lung candidates to the Thoracic Organ Transplantation Committee (7-Support, 0-Oppose, 0-Abstain). On June 11, 2015, the full Committee unanimously voted to accept the Lung Subcommittee’s recommendations and proceed to public comment with this proposal (16-Support, 0-Oppose, 0-Abstain).

How well does this proposal address the problem statement?

Although projected rates must be interpreted with caution in such a small population, modeling suggests an improvement in transplant rates for both child and adolescent candidates over the current allocation system (Exhibit B). There is no evidence to suggest that this proposed policy change would negatively impact adult candidates. Waiting list mortality and post-transplant survival rates for all age groups remain similar to the current system (Exhibits C-D).

Although few have been performed internationally, Canadian case studies suggest that recipients of alternative blood type lungs experience outcomes similar to those who receive identical or compatible blood type lungs.¹⁸ Infants have a higher waiting list mortality than any other candidate age group, mostly due to the scarcity of appropriate-sized donor lungs. In light of this, the Committee believes there is a strong ethical justification for making more donor lungs available to infants, whose developing immune systems theoretically can safely accept them, even in the absence of unequivocal data.

Which populations are impacted by this proposal?

This proposal improves access to transplantation for all pediatric lung candidates, including infants, children, and adolescents (approximately 2,260 candidates added to the waiting list each year).¹⁹ It accomplishes this without adversely affecting waiting list mortality rates, transplant rates, or post-transplant survival rates for adults.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* This proposal will increase the number of transplants by permitting candidates registered before two years old (approximately 12-14 candidates each year) to accept alternative blood type lungs. Some of these deceased donor lungs may have otherwise been discarded due to unavailability of an appropriate blood type match candidate. In fact, OPTN data showed that the percentage of donors recovered between January 1, 2008 and May 31, 2013, for whom there were no candidates on the match run, was substantially higher for donors 0-2 years old than any other age group (N=286, 23.6%).

¹⁸ Grasemann, H., M. de Perrot, G.N. Bendiak, et al. “ABO-Incompatible Lung Transplantation in an Infant.” *Am J Transplant* 12 (2012): 779-781.

¹⁹ Average yearly waiting list additions in candidates less than 18 years old, 2010-2014. Based on OPTN data as of July 17, 2015. Available at: <http://optn.transplant.hrsa.gov/converge/latestData/viewDataReports.asp>.

Table 2. Lung match information for deceased donors recovered between January 1, 2008 and May 31, 2013*

Donor age (yrs)	All donors		No lung match was run		Lung match was run									
					No candidates on match run		Candidates on the match run, but no electronic offers were made		Electronic offers were made, but neither lung was accepted		At least one lung was accepted but neither transplanted		At least one lung was transplanted	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
All	38,225	100.0	15,421	40.3	334	0.9	4,229	11.1	9,538	25.0	200	0.5	8,449	22.1
0-2	1,211	100.0	297	24.5	286	23.6	179	14.8	401	33.1	0	0.0	48	4.0
3-11	1,090	100.0	334	30.6	39	3.6	159	14.6	428	39.3	1	0.1	129	11.8
12-17	1,869	100.0	418	22.4	1	0.1	172	9.2	469	25.1	16	0.9	793	42.4
18-35	10,680	100.0	2,776	26.0	0	0.0	1,126	10.5	2,819	26.4	84	0.8	3,875	36.3
36-65	20,345	100.0	9,112	44.8	6	0.0	2,395	11.8	5,151	25.3	98	0.5	3,583	17.6
66+	3,030	100.0	2,484	82.0	2	0.1	198	6.5	270	8.9	1	0.0	75	2.5

*Analysis limited to Donation after Brain Death (DBD) donors

2. *Improve equity in access to transplants:* The proposed allocation changes will increase equity in access to transplants for both child and adolescent candidates without decreasing the transplant rate for adults. This proposal also seeks to improve access to transplantation for infants by permitting eligible candidates to receive a donor organ of any blood type.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Increasing the availability of deceased donor organs will decrease the waiting list mortality rate for infants.
4. *Promote living donor and transplant recipient safety:* No expected impact on this goal
5. *Promote the efficient management of the OPTN:* No expected impact on this goal

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Thoracic Organ Transplantation and Pediatric Transplantation Committees will review waiting list and transplant data for all ages to ensure that this change in allocation serves its intended purpose without negatively affecting pre- or post-transplant outcomes for adults. Since external factors and other changes in transplant policy can have an influence on the period following policy implementation, interpreting the apparent impact of this policy change based on “before vs. after” analysis must be done with caution.

Questions that will need to be answered for policy evaluation:

The following questions, and any others subsequently requested by the Committees, will guide the evaluation of the proposal after implementation.

ABO alternative blood type matching:

- How many candidates were eligible for ABO-alternative offers?
- How many of these candidates received alternative blood type lung or heart-lung transplants?

- Have death rates for pediatric lung and heart-lung waiting list candidates decreased? (Limited to those meeting age and priority eligibility criteria for ABO alternative blood type matching)
- Is post-transplant survival of pediatric alternative blood type lung or heart-lung transplant recipients comparable to that of pediatric ABO-identical or compatible lung or heart-lung transplant recipients?

Broader sharing

- Have transplant rates for pediatric lung and heart-lung waiting list candidates increased?
- Have death rates for pediatric lung and heart-lung waiting list candidates decreased?
- Has post-transplant survival for pediatric lung and heart-lung transplant recipients changed?

Data used to evaluate the proposal (Policy Performance Measures):

The following metrics, and any others subsequently requested by the Committees, will be used to evaluate the proposal. *Note:* Outcome measures will be provided only when sufficient data are available.

ABO alternative blood type matching:

The following data will be analyzed by policy period (before and after the policy change, as applicable):

- Waiting list additions and snapshot by age at listing and willingness to accept a donor lung of any blood type
- Waiting list death rates for candidates meeting age and priority eligibility criteria for alternative blood type matching
- Lung and heart-lung transplants by age at listing, age at transplant, and ABO-compatibility of the transplant
 - Percentage of transplant recipients eligible for any ABO who received an alternative blood type lung transplant
- Pre- and post-transplant titer information for pediatric recipients of alternative blood type transplants
- Post-transplant outcomes (after sufficient follow-up information becomes available)
 - Patient survival for pediatric recipients of alternative blood type transplants, and comparably aged pediatric recipients of ABO-identical or compatible transplants.
 - Causes of death and titer information for pediatric recipients of alternative blood type transplants who have a graft failure or die within one year of transplant

Broader sharing:

The following data will be analyzed by policy period (before and after the policy change, as applicable):

- Waiting list additions by age group (<12 years, 12-17 years, 18+ years)
- Waiting list death rates by age group
- Waiting list transplant rates by age group
- Transplants by:
 - Recipient age group and geographic zone (DSA, Zone A, Zone B, Zone C, Zone D and Zone E)
 - Recipient and donor age group, and geographic zone
- Post-transplant patient survival (after sufficient follow-up information becomes available) by:
 - Recipient age group and geographic zone (DSA, Zone A, Zone B, Zone C, Zone D and Zone E)
 - Recipient and donor age group, and geographic zone

Timeline for evaluation:

The initial data analysis will be performed after the policy has been in place for approximately 6 months. Data will be evaluated no more frequently than every 6 months for the first two years, and annually thereafter until 5 years post-implementation. Timeline is subject to change based on the results and the needs of the Committees.

How will the OPTN implement this proposal?

This proposal will require programming in UNetSM. The OPTN will follow established protocols inform members and educate them on any policy changes through Policy Notices. This proposal will also be monitored for potential instructional opportunities, in order to give members, professionals and the transplant community an avenue to gain information, ask questions, and modify process, if necessary. This proposal will continue to be monitored for instructional resources needs.

UNOS IT provides cost estimates for each public comment proposal that will require programming to implement. The estimates can be small (108-419 hrs.), medium (420-749 hrs.), large (750-1,649 hrs.), very large (1,650-3,999), or enterprise (4,000-8,000). The IT estimate for this proposal is very large.

How will members implement this proposal?

Programs should consider the appropriateness of registering patients meeting the following criteria as eligible to accept a blood type alternative lung:

- Priority 1, less than 1 year old
- Priority 1, at least 1 year old but registered prior to turning 2 years old, with isohemagglutinin titers less than or equal to 1:16.

Organ Procurement Organizations (OPOs) will need to educate their staff on the new allocation algorithm.

Will this proposal require members to submit additional data?

If a candidate is less than 2 years old at time of registration on the waiting list, a program must report whether they are willing to accept an offer of any blood type for that candidate. If yes, then the program must submit isohemagglutinin titers upon initially reporting that a candidate is willing to accept a blood type alternative lung and update these titers every 30 days. For a recipient of a blood type alternative lung, a program must submit isohemagglutinin titers from a blood sample taken within 24 hours prior to transplant and from a recent sample if graft loss or death occurs within one year post-transplant.

The principle of data collection used to support collection of titer data is “Develop transplant, donation, and allocation policies.” The titer data will be reviewed to determine if revisions are needed to the titer level eligibility criteria for ABO-alternative allocation.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine site surveys of OPTN members. Any data entered in UNetSM may be subject to OPTN review, and members are required to provide documentation as requested. OPTN contractor staff will continue to review deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements.

Policy or Bylaw Language

Proposed new language is underlined and (example) and language that is proposed for removal is struck through (example).

10.4 Lung Allocation Classifications and Rankings

10.4.A Sorting Within Each Classification

Lung candidates at least 12 years old are sorted in the following order:

1. LAS (highest to lowest)
2. Total active waiting time (longest to shortest)
3. LAS variable update date and time (earliest to most recent approval)
4. LAS exception date (earliest to most recent approval)

Lung candidates less than 12 years old are sorted in the following order:

1. Pediatric priority waiting time (longest to shortest)
2. Total waiting time (longest to shortest)

10.4.B Allocation of Lungs by Blood Type

~~A candidate whose blood type is identical to the donor's will receive the single or double lung offer before a candidate whose blood type is compatible but not identical with the donor's. A~~
deceased donor's blood type compatibility with a lung candidate is defined in *Table 10-5* below.

Table 10-5: Deceased Donor Blood Type Compatibility with a Lung Candidate

<u>Deceased Donor's Blood Type</u>	<u>Candidate's Blood Type</u>			
	<u>O</u>	<u>A</u>	<u>B</u>	<u>AB</u>
<u>O</u>	<u>Identical</u>	<u>Compatible</u>	<u>Compatible</u>	<u>Compatible</u>
<u>A</u>	<u>Screened*</u>	<u>Identical</u>	<u>Screened*</u>	<u>Compatible</u>
<u>B</u>	<u>Screened*</u>	<u>Screened*</u>	<u>Identical</u>	<u>Compatible</u>
<u>AB</u>	<u>Screened*</u>	<u>Screened*</u>	<u>Screened*</u>	<u>Identical</u>

*Screened from match run, unless eligible for alternative blood type matching according to *Policy 10.4.B.i*

10.4.B.i Eligibility for Alternative Blood Type Matching

Candidates will be eligible for alternative blood type matching if they meet the requirements according to *Table 10-6* below.

Table 10-6: Eligibility for Alternative Blood Type Matching for Deceased Donor Lungs

<u>If the candidate is:</u>	<u>And meets <i>all</i> of the following:</u>
<u>Less than one year old at the time of the match run</u>	<ol style="list-style-type: none">1. <u>Is priority 1.</u>2. <u>Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.</u>

<u>If the candidate is:</u>	<u>And meets all of the following:</u>
<u>At least one year old at the time of the match run</u>	<ol style="list-style-type: none"> <u>Is registered prior to turning two years old.</u> <u>Is priority 1.</u> <u>Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.</u>

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10.4.B.ii Isohemagglutinin Titer Reporting Requirements for Alternative Blood Type Patients

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN Contractor.

Accurate isohemagglutinin titers must be reported for candidates eligible for alternative blood type matching, according to Table 10-7 below, at all of the following times:

- Upon initially reporting that a candidate is willing to accept an alternative blood type match lung.
- Every 30 days after initially reporting that a candidate is willing to accept an alternative blood type match lung.

Table 10-7: Isohemagglutinin Titer Reporting Requirements for a Candidate Who is Willing to Receive an Alternative Blood Type Match Lung

<u>If the candidate's blood type is:</u>	<u>Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:</u>
<u>A</u>	<u>Anti-B</u>
<u>B</u>	<u>Anti-A</u>
<u>O</u>	<u>Anti-A and Anti-B</u>

Accurate isohemagglutinin titers must be reported for recipients of an alternative blood type match lung, according to Table 10-8, as follows:

- At transplant, from a blood sample taken within 24 hours prior to transplant.
- If graft loss occurs within one year after transplant from the most recent sample, if available.
- If recipient death occurs within one year after transplant from the most recent blood sample, if available.

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Table 10-8: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Alternative Blood Type Lung

<u>If the deceased donor's blood type is:</u>	<u>And the recipient's blood type is:</u>	<u>Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:</u>
<u>A</u>	<u>B or O</u>	<u>Anti-A</u>
<u>B</u>	<u>A or O</u>	<u>Anti-B</u>
<u>AB</u>	<u>A</u>	<u>Anti-B</u>
<u>AB</u>	<u>B</u>	<u>Anti-A</u>
<u>AB</u>	<u>O</u>	<u>Anti-A and Anti-B</u>

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10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-59* below.

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Table 10-59: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA	At least 12 years old, blood type identical to the donor
2	OPO's DSA	At least 12 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1, blood type identical to the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
4	OPO's DSA	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	Zone A	At least 12 years old, blood type identical to the donor
8	Zone A	At least 12 years old, blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
9	Zone A	<p>Priority 1, blood type identical to the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
10	Zone A	<p>Priority 1, blood type compatible with the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
11	Zone A	Priority 2, blood type identical to the donor
12	Zone A	Priority 2, blood type compatible with the donor
13	Zone B	At least 12 years old, blood type identical to the donor
14	Zone B	At least 12 years old, blood type compatible with the donor
15	Zone B	<p>Priority 1, blood type identical to the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
16	Zone B	<p>Priority 1, blood type compatible with the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
17	Zone B	Priority 2, blood type identical to the donor
18	Zone B	Priority 2, blood type compatible with the donor
19	Zone C	At least 12 years old, blood type identical to the donor
20	Zone C	At least 12 years old, blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
21	Zone C	<p>Priority 1, blood type identical to the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
22	Zone C	<p>Priority 1, blood type compatible with the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
23	Zone C	Priority 2, blood type identical to the donor
24	Zone C	Priority 2, blood type compatible with the donor
25	Zone D	At least 12 years old, blood type identical to the donor
26	Zone D	At least 12 years old, blood type compatible with the donor
27	Zone D	<p>Priority 1, blood type identical to the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
28	Zone D	<p>Priority 1, blood type compatible with the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
29	Zone D	Priority 2, blood type identical to the donor
30	Zone D	Priority 2, blood type compatible with the donor
31	Zone E	At least 12 years old, blood type identical to the donor
32	Zone E	At least 12 years old, blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
33	Zone E	Priority 1, blood type identical to the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
34	Zone E	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
35	Zone E	Priority 2, blood type identical to the donor
36	Zone E	Priority 2, blood type compatible with the donor

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10.4.D Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old

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Single and double lungs from deceased donors at least 12 years old to less than 18 years old are allocated according to *Table 10-6* below.

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Table 10-6: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old

Classification	Includes Candidates that are within the:	And are:
1	OPO's DSA	12 to less than 18 years old, blood type identical to the donor
2	OPO's DSA	12 to less than 18 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1, blood type identical to the donor
4	OPO's DSA	Priority 1, blood type compatible with the donor
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	OPO's DSA	At least 18 years old, blood type identical to the donor
8	OPO's DSA	At least 18 years old, blood type compatible with the donor
9	Zone A	12 to less than 18 years old, blood type identical to the donor

Classification	Includes Candidates that are within the:	And are:
40	Zone A	12 to less than 18 years old, blood type compatible with the donor
41	Zone A	Priority 1, blood type identical to the donor
42	Zone A	Priority 1, blood type compatible with the donor
43	Zone A	Priority 2, blood type identical to the donor
44	Zone A	Priority 2, blood type compatible with the donor
45	Zone A	At least 18 years old, blood type identical to the donor
46	Zone A	At least 18 years old, blood type compatible with the donor
47	Zone B	12 to less than 18 years old, blood type identical to the donor
48	Zone B	12 to less than 18 years old, blood type compatible with the donor
49	Zone B	Priority 1, blood type identical to the donor
20	Zone B	Priority 1, blood type compatible with the donor
24	Zone B	Priority 2, blood type identical to the donor
22	Zone B	Priority 2, blood type compatible with the donor
23	Zone B	At least 18 years old, blood type identical to the donor
24	Zone B	At least 18 years old, blood type compatible with the donor
25	Zone C	12 to less than 18 years old, blood type identical to the donor
26	Zone C	12 to less than 18 years old, blood type compatible with the donor
27	Zone C	Priority 1, blood type identical to the donor
28	Zone C	Priority 1, blood type compatible with the donor
29	Zone C	Priority 2, blood type identical to the donor
30	Zone C	Priority 2, blood type compatible with the donor
31	Zone C	At least 18 years old, blood type identical to the donor
32	Zone C	At least 18 years old, compatible with the donor
33	Zone D	12 to less than 18 years old, blood type identical to the donor

Classification	Includes Candidates that are within the:	And are:
34	Zone D	12 to less than 18 years old, blood type compatible with the donor
35	Zone D	Priority 1, blood type identical to the donor
36	Zone D	Priority 1, blood type compatible with the donor
37	Zone D	Priority 2, blood type identical to the donor
38	Zone D	Priority 2, blood type compatible with the donor
39	Zone D	At least 18 years old, blood type identical to the donor
40	Zone D	At least 18 years old, blood type compatible with the donor
41	Zone E	12 to less than 18 years old, blood type identical to the donor
42	Zone E	12 to less than 18 years old, blood type compatible with the donor
43	Zone E	Priority 1, blood type identical to the donor
44	Zone E	Priority 1, blood type compatible with the donor
45	Zone E	Priority 2, blood type identical to the donor
46	Zone E	Priority 2, blood type compatible with the donor
47	Zone E	At least 18 years old, blood type identical to the donor
48	Zone E	At least 18 years old, blood type compatible with the donor

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10.4.ED Allocation of Lungs from Deceased Donors Less than 4218 Years Old

Single and double lungs from deceased donors less than 4218 years old are allocated according to *Table 10-710* below.

Table 10-710: Allocation of Lungs from Deceased Donors Less than 4218 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA, Zone A, or Zone B	<p>Priority 1, blood type identical to the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for alternative blood type matching

Classification	Candidates that are included within the:	And are:
2	OPO's DSA, Zone A, or Zone B	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
3	OPO's DSA, Zone A, or Zone B	Priority 2, blood type identical to the donor
4	OPO's DSA, Zone A, or Zone B	Priority 2, blood type compatible with the donor
5	OPO's DSA, or Zone A, or Zone B	12 to less than 18 years old, blood type identical to the donor
6	OPO's DSA, or Zone A, or Zone B	12 to less than 18 years old, blood type compatible with the donor
7	OPO's DSA	At least 18 years, blood type identical to the donor
8	OPO's DSA	At least 18 years, blood type compatible with the donor
9	Zone A	At least 18 years old, blood type identical to the donor
10	Zone A	At least 18 years old, blood type compatible with the donor
11	Zone B	12 to less than 18 years old, blood type identical to the donor
12	Zone B	12 to less than 18 years old, blood type compatible with the donor
1311	Zone B	At least 18 years old, blood type identical to the donor
1412	Zone B	At least 18 years old, blood type compatible with the donor
1513	Zone C	Priority 1, blood type identical to the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>

Classification	Candidates that are included within the:	And are:
<u>1614</u>	Zone C	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
<u>1715</u>	Zone C	Priority 2, blood type identical to the donor
<u>1816</u>	Zone C	Priority 2, blood type compatible with the donor
<u>1917</u>	Zone C	12 to less than 18 years old, blood type identical to the donor
<u>2018</u>	Zone C	12 to less than 18 years old, blood type compatible with the donor
<u>2119</u>	Zone C	At least 18 years old, blood type identical to the donor
<u>2220</u>	Zone C	At least 18 years old, blood type compatible with the donor
<u>2321</u>	Zone D	Priority 1, blood type identical to the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
<u>2422</u>	Zone D	Priority 1, blood type compatible with the donor Priority 1 and <i>one</i> of the following: <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
<u>2523</u>	Zone D	Priority 2, blood type identical to the donor
<u>2624</u>	Zone D	Priority 2, blood type compatible with the donor
<u>2725</u>	Zone D	12 to less than 18 years old, blood type identical to the donor
<u>2826</u>	Zone D	12 to less than 18 years old, blood type compatible with the donor
<u>2927</u>	Zone D	At least 18 years old, blood type identical to the donor
<u>3028</u>	Zone D	At least 18 years old, blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
<u>3129</u>	Zone E	<p>Priority 1, blood type identical to the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>Less than 12 years old and blood type identical to the donor</u> • <u>Less than 1 year old and blood type compatible with the donor</u> • <u>Less than 1 year old and eligible for alternative blood type matching</u>
<u>3230</u>	Zone E	<p>Priority 1, blood type compatible with the donor</p> <p>Priority 1 and <i>one</i> of the following:</p> <ul style="list-style-type: none"> • <u>At least 1 year old and blood type compatible with the donor</u> • <u>At least 1 year old and eligible for alternative blood type matching</u>
<u>3331</u>	Zone E	Priority 2, blood type identical to the donor
<u>3432</u>	Zone E	Priority 2, blood type compatible with the donor
<u>3533</u>	Zone E	12 to less than 18 years old, blood type identical to the donor
<u>3634</u>	Zone E	12 to less than 18 years old, blood type compatible with the donor
<u>3735</u>	Zone E	At least 18 years old, blood type identical to the donor
<u>3836</u>	Zone E	At least 18 years old, blood type compatible with the donor

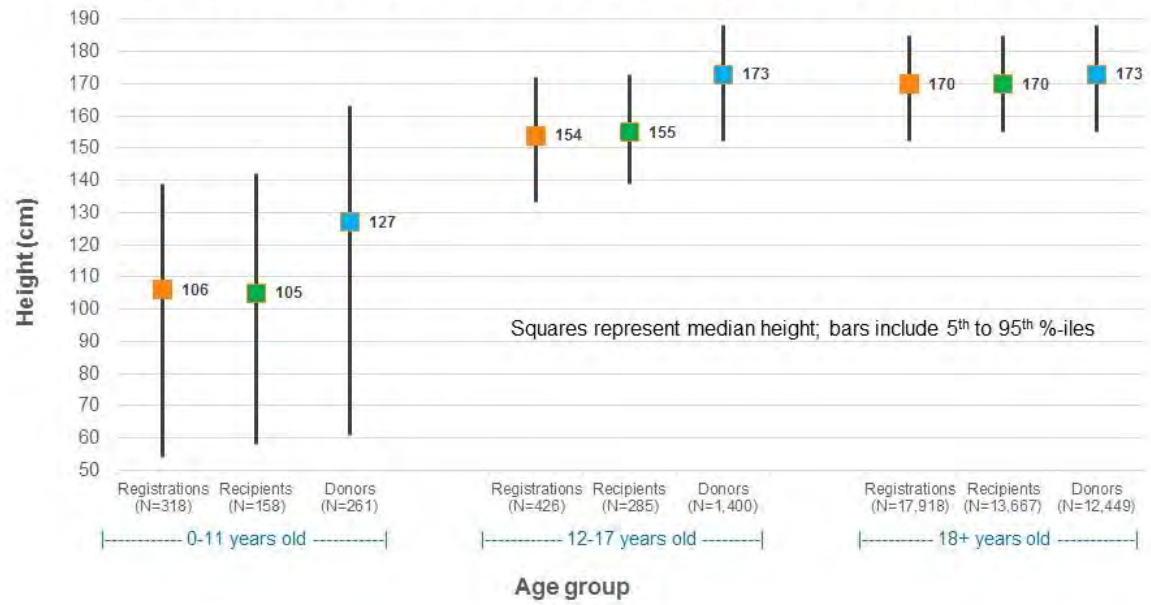
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[Subsequent tables will be renumbered as necessary.]

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Height of lung waiting list registrations, recipients and transplant donors

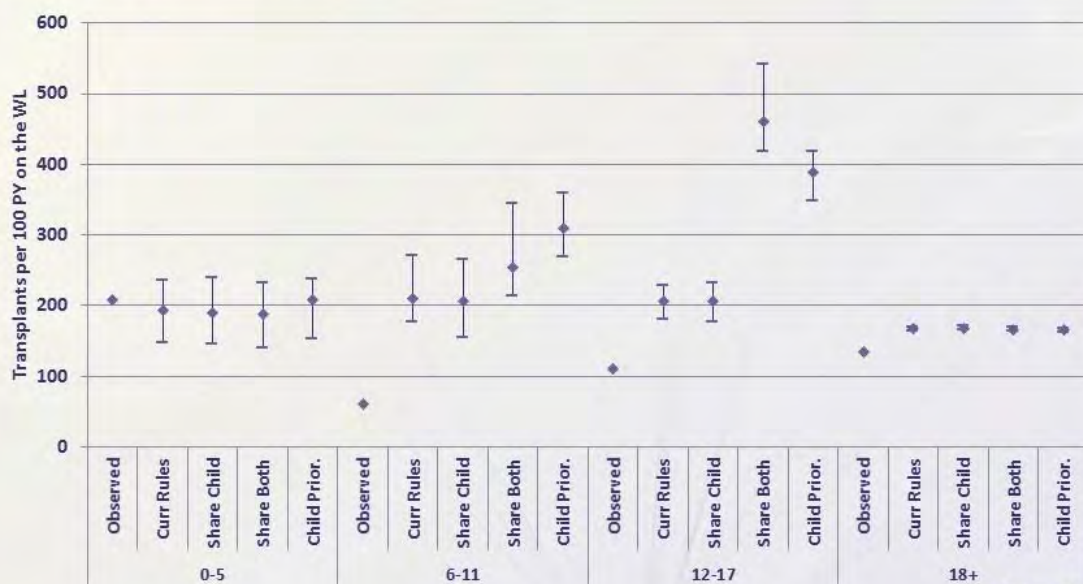
Waiting list registrations and transplants 5/4/05-11/30/13



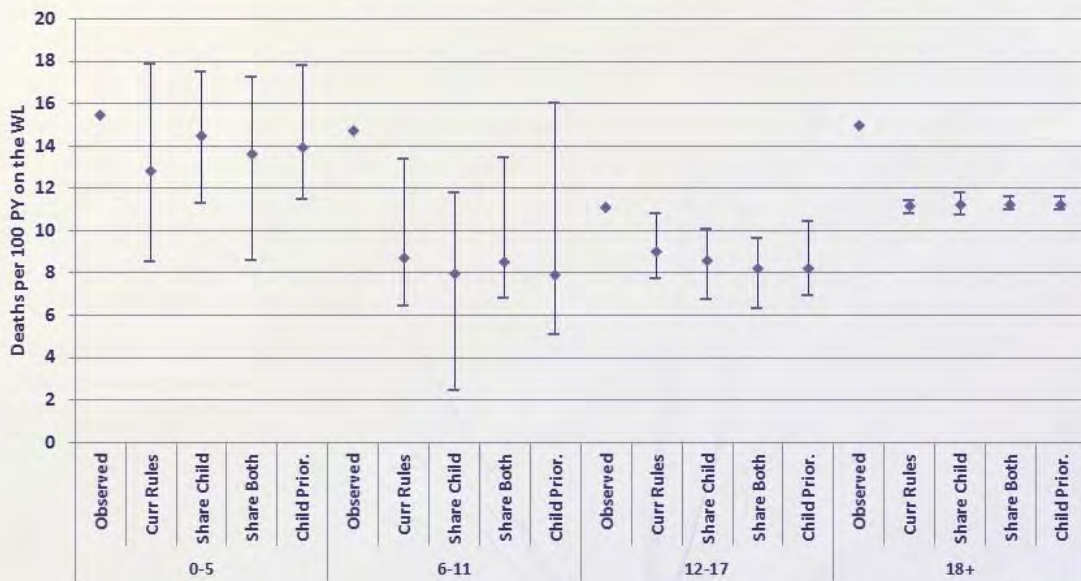
NOTE: Further details, including tabulations by year, are provided in the written report.



Transplant rates by candidate age, observed and by simulation



Waitlist mortality rates by candidate age, observed and by simulation



One-year post-transplant mortality rates, by candidate age, observed and by simulation

