

Proposal to Correct Inadvertent Substantive Changes to OPTN Policies

Sponsoring Committee: Policy Oversight Committee (POC)

Policies Affected: OPTN Policies 1.2, 3.4.D.i, 5.3.B, 5.3.C, 5.3.D, 5.3.E, 8.2.A, 8.4.B, 10.1.E, 14.2.A, and 16.1

Distributed for Public Comment: No

Effective Date: March 7, 2014

Problem Statement

After the release of the rewritten OPTN Policies on February 1, 2014, UNOS staff discovered some inadvertent changes were made that substantively changed the Policies or made them less clear. The corrections approved by the Executive Committee on March 5, 2014 will restore the requirements in the OPTN Policies that existed before the plain language rewrite.

Changes

1. Delete Policy 5.3.B: *Informed Consent for Kidneys Based on KDPI Greater than 85%*. This language is part of the new Kidney Allocation System (KAS) changes and is not yet implemented and should not be included in the rewrite version that shows only approved and implemented language.
2. Reinstatement of old Policy 3.5.3.2 requiring pre-procurement tissue typing for ECD kidney donors. This was mistakenly deleted in the rewrite and is reinstated as *Policy 8.2.A: Tissue Typing Requirements for Expanded Criteria Donors*.
3. Reinstatement of language from old Policy 3.5.11.3 that explains that sensitized candidates with a CPRA of 80% or greater are assigned 4 points. This language was added to 8.4.B: *Time of Waiting Points for Standard Donors*.
4. Reinstatement of language from old Policy 3.8.4 that candidate unacceptable antigens must be reported to receive priority in the allocation of pancreas based on CPRA. This language was added as 3.4.D.i: *Reporting Unacceptable Antigens for Pancreas Candidates*.
5. Reinstate the preposition “in” instead of “at” in section 16.1: *Organs Not Requiring Transport* to retain clarification that the timeout must occur in the operating room rather than directly outside the operating room.
6. Correct the following cross-references:
 - To tables of values used to calculate LAS values in section 10.1.E: *LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*.
 - In section 14.2.A: *ILDA Requirements for Kidney Recovery Hospitals*.
7. Reinstate definitions that were included in the public comment draft and then accidentally deleted.

These changes affect OPTN Policies 1.2, 3.4.D.i, 5.3.B, 5.3.C, 5.3.D, 5.3.E, 8.2.A, 8.4.B, 10.1.E, 14.2.A, and 16.1.

Action Required

The rewritten Policies can be viewed [here](#). Members should familiarize themselves with the rewritten OPTN Policies.

Affected Policy Language:

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

1.2 Definitions

F

Final Rule

42 CFR 121 et seq.

G

Geographical Area

A physical area used to group potential transplant recipients in a classification. OPTN Policy uses the following geographical areas for organ allocation: DSA, region, nation, and zones.

Graft failure

Occurs when an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system.

H

Host Organ Procurement Organization (Host OPO)

The OPO responding to a deceased organ donor referral from a hospital.

3.4.D.i Reporting Unacceptable Antigens for Pancreas Candidates

To receive priority in the allocation of pancreas based on the candidate's CPRA, unacceptable antigens sufficient to yield a CPRA greater than or equal to 80% must be reported to the OPTN Contractor. Pancreas from donors with antigens included among the unacceptable antigens for the candidate will not be offered to the candidate.

5.3.B Informed Consent for Kidneys Based on KDPI Greater than 85%

Prior to receiving an offer for a kidney with a Kidney Donor Profile Index (KDPI) score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category.

5.3.CB Liver Acceptance Criteria

The responsible transplant surgeon must determine the acceptable deceased donor weight for each of its liver candidates, and the determined acceptable weight must be reported to the OPTN Contractor.

Liver transplant programs may also specify additional liver acceptance criteria, including *any* of the following:

1. The maximum number of mismatched antigens it will accept for any of its liver candidates
2. Minimal acceptance criteria for livers
3. If a blood type O candidate will accept a liver from a deceased donor with non-A₁ blood type
4. For status 1A or 1B candidates, if they will accept a liver from a deceased donor with any blood type
5. If a candidate with a Model for End-Stage Liver Disease (MELD) or Pediatric End Stage Liver Disease (PELD) score of at least 30 will accept a liver from a deceased donor with any blood type
6. If a candidate will accept a liver for other methods of hepatic support
7. If a candidate is willing to accept a segmental graft

5.3.DC Pediatric Heart Acceptance Criteria

A transplant hospital may specify whether a candidate is willing to accept a heart from any blood type deceased donor. The candidate will be eligible for heart offers from deceased donors of any blood type if the candidate meets at least *one* of the following conditions:

1. Candidate is *in utero*
2. Candidate is less than one year old, and meets *both* of the following:
 - a. Is registered as status 1A or 1B.
 - b. Has reported current isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.
3. Candidate is at least one year old, and meets *all* of the following:
 - a. Is registered prior to turning two years old.
 - b. Is assigned status 1A or 1B.
 - c. Has reported current isohemagglutinin titer levels less than or equal to 1:4 for A or B blood type antigens to the OPTN Contractor within the last 30 days.
 - d. Has *not* received treatments within the last 30 days that may have reduced titer values to 1:4 or less.

If a transplant hospital indicates that a pediatric candidate is willing to accept a heart from any blood type deceased donor, and the candidate meets at least one of the eligibility conditions, anti-A or anti-B titers must be reported as follows:

- At the time of registration (except *in utero* candidates).
- Every 30 days after registration (except *in utero* candidates).
- At transplant (all candidates).
- If graft loss or death occurs within one year of the transplant (all candidates transplanted with an incompatible blood type heart).

5.3.ED Pancreas Candidates after Kidney Transplant Acceptance Criteria

When listing a candidate for a pancreas after a kidney transplant, the transplant program may enter the candidate's prior deceased or living kidney donor's antigens, which will then be considered self antigens in pancreas match runs. If a candidate's prior kidney donor's antigens are entered, the pancreas match run will take into account the candidate's antigens and all of the kidney donor's mismatched antigens that are reported to the OPTN Contractor.

Antigens that are common to a candidate's prior deceased or living kidney donor and a subsequent deceased pancreas donor are considered as matches and the candidate will appear on the match run for all deceased pancreas donors who meet these mismatch criteria. Use of these modified mismatch criteria is optional.

8.2.A Tissue Typing Requirements for Expanded Criteria Donors

Pre-procurement tissue typing is expected in allocating expanded criteria donor kidneys. In the absence of pre-procurement tissue typing, allocation of expanded criteria donor kidneys will proceed according to Policy 8.4.A: Time of Waiting Points for Expanded Criteria Donor Kidney Allocation and candidate waiting time. If pre-procurement tissue typing is not initiated, the Host OPO must provide a written explanation of the reasons to the OPTN contractor.

8.4.B Time of Waiting Points for Standard Donors

Once the minimum criteria listed above are met and waiting time begins to accrue, one point will be assigned to the candidate waiting for the longest period with fractions of points being assigned proportionately to all other candidates, according to their relative waiting time. For each full year of waiting time a candidate accrues, an additional 1 point will be assigned to that candidate. The calculation of points is conducted separately for each geographic (local, regional and national) level of kidney allocation. The local points calculation includes only candidates on the local waiting list. The regional points calculation includes only candidates on the regional list, without the local candidates. The national points calculation includes all candidates on the national list excluding all candidates listed on the host OPO's local and regional lists.

Sensitized candidates with defined unacceptable HLA antigens that yield a CPRA of 80% or greater will be assigned 4 points.

10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, transplant programs must report to the OPTN Contractor clinical data corresponding to the covariates shown in *Table 10-23: Factors Used to Predict Risk of Death* and *Table 10-3-4: Factors that Predict Survival after Lung Transplant*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN Contractor LAS covariate clinical data for every covariate in *Table 10-23* and *Table 10-3-4* for each candidate at least once in every six month period after the date of the candidate's initial registration. The first six-month period begins six months from the date of the candidate's initial registration, with a new six-month period occurring every six months thereafter.

14.2.A ILDA Requirements for Kidney Recovery Hospitals

For any potential living kidney donor who is undergoing evaluation for donation, the living kidney donor recovery hospital must designate and provide each potential living donor with an ILDA who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient. The ILDA may be one person or an independent living donor advocate team with multiple members. An ILDA team must designate one person from the team as the key contact for each potential living donor.

The ILDA must:

1. Function independently from the transplant candidate's team.
2. Advocate for the rights of the potential living donor and the living donor.
3. Fulfill the qualification and training requirements specified in the recovery hospital's protocols regarding knowledge of living organ donation, transplantation, medical ethics, informed consent, and the potential impact of family or other external pressure on the potential living donor's decision about whether to donate. Document that each requirement has been met.
4. Review whether the potential living donor has received information on each of the following areas and assist the potential donor in obtaining additional information from other professionals as needed about the:
 - a. Informed consent process as described in *Policy 14.3* and its subsections
 - b. Evaluation process according to *Policies 14.3.A.ii, 14.4.B and 14.5.A* and its subsections
 - c. Surgical procedure
 - d. Medical risks according to *Policy 14.3.A.ii*
 - e. Psychosocial risks according to *Policy 14.3.A.ii*
 - f. Follow-up requirements, and the benefit and need for participating in follow-up according to *Policies 18.1: Data Submission Requirements, 18.5.A: Reporting Requirements after Donation and 18.5.B: Submission of Living Donor Death and Organ Failure*
5. Document that each topic was reviewed.

16.1 Organs Not Requiring Transport

The transplant hospital and host OPO (if applicable) must develop and follow a protocol to ensure that the correct living or deceased donor organ is transplanted into the correct recipient when *either* of the following occurs:

- Organs are recovered from a deceased donor and remain in the same operating suite as the intended recipient
- Organs are recovered from a living donor and remain in the same facility as the intended recipient

Time outs must occur:

1. Before the organ leaves the deceased or living donor operating room
2. Again when the organ arrives ~~at~~in the potential recipient's operating room, before the transplant occurs

During these time outs ~~and before the transplant occurs~~, the transplant hospital must confirm and document that a member of the transplant team identified the correct organ for the correct potential recipient prior to transplant according to *Policy 5.6: Blood Type Verification upon Receipt*.