

OPTN KPD Blood Type Policy Alignments and Donor Re-Evaluation Efficiency Requirements

OPTN Kidney Transplantation Committee

Purpose of Proposal

Increase the number of transplants by:

- Requiring annual donor re-evaluation, which will:
 - Increase the efficiency of the OPTN KPD program
 - Improve the quality of OPTN KPD matches and so increase the likelihood of match success
- Aligning OPTN KPD blood type A, non-A1 and AB, non-A1B matching eligibility requirements with those in OPTN kidney policy
 - Increased efficiency and clarity
 - Expand the donor pool for some blood type O and blood type B candidates

Proposal

- This proposal will require programs to annually re-evaluate OPTN KPD paired donors in order to maintain the donor's eligibility to participate in OPTN KPD match runs
- Re-evaluation requirements include:
 - Informed consent requirements
 - Psychosocial re-evaluation requirements
 - Medical and social re-evaluation requirements
 - Reporting requirements

Proposal

- **Informed consent:** programs will need to re-inform the donor per *Policy 13.4.C: Informed Consent for KPD Donors*
 - Programs will be required to obtain a signature confirming that the donor has been re-informed that they may withdraw from participation in the KPD program at any time, for any reason
- *13.4.C: Informed Consent for KPD Donors* will also be updated, to require that donors are informed that they may need to be re-evaluated

Proposal

- **Psychosocial evaluation:** programs will be required to fully re-evaluate the donor's psychosocial health per Living Donor *Policy 14.1: Psychosocial Evaluation Requirements for Living Donors*
- **Medical evaluation:** programs will also be required to re-evaluate the donor's medical and social health, including:
 - General, kidney-specific, and social donor history
 - Physical examination
 - General laboratory and imaging tests
 - Metabolic testing
 - Kidney specific testing
 - Cancer screening
 - Transmissible and endemic disease screening and testing

Proposal

- **Infectious disease testing** will be required, including the following tests:
 - CMV antibody
 - EBV antibody
 - Anti-HIV or HIV Ag/Ab
 - HIV NAT
 - HbsAg
 - Total anti-HBc
 - HBV NAT
 - Anti-HCV
 - HCV NAT
 - Syphilis testing
- Donors who have previously tested positive for CMV will *not* be required to re-test for CMV antibody, and donors who have tested positive for EBV will *not* be required to re-test for EBV antibody
- Programs will be required to re-screen and test donors as appropriate for endemic diseases and tuberculosis

Proposal

- **Reporting requirements:** programs must report to the OPTN any changes to the donor information required for match run eligibility
- This proposal includes new required data collection, to capture the date that the donor's re-evaluation was completed and relevant changes reported to the OPTN
 - This data element will be required to maintain donor eligibility to participate in match runs in the OPTN KPD system

Proposal

- Programs must re-evaluate donors annually, with the donor's re-evaluation date determined by the most recent of the following:
 - The donor's date of registration in the OPTN KPD system
 - The most recently reported date of completed re-evaluation
- Programs will have up to 30 days after the donor's re-evaluation date to report a date of completed re-evaluation
 - Failure to report a date of completed re-evaluation within this window will result in the donor becoming ineligible to participate in OPTN match runs
 - Donor will remain ineligible until their program reports the date of completed re-evaluation
- Programs will be notified of the donor's upcoming re-evaluation date 60 days prior to this date

Proposal

- This proposal will align OPTN KPD blood type A, non-A1 and blood type AB, non-A1B matching eligibility requirements with OPTN Kidney Policy
 - Includes modification to blood type A, non-A1 and AB, non-A1B matching data collection, to align with the OPTN Waitlist system
- Maintain matching rules for eligible blood type B and blood type O candidates:
 - Eligible blood type O candidates may be matched with blood type A, non-A1 kidneys
 - Eligible blood type B candidates may be matched with blood type A, non-A1 kidneys and blood type AB, non-A1B

Proposal

- Proposal will remove the specific IgG antibody titer threshold requirement in OPTN KPD policy
- Instead, programs will need to:
 - Obtain written informed consent from eligible candidates regarding their willingness to accept these kidneys
 - Establish a written policy regarding its program's titer threshold for transplanting blood type A, non-A₁ kidneys into candidates with blood type B or O, and for transplanting blood type AB, non-A₁B kidneys into candidates with blood type B
 - Confirm the candidate's eligibility every 90 days, plus or minus 20 days

Rationale: Donor Re-Evaluation Requirement

- Currently, the OPTN KPD system has no requirement for regular donor-re-evaluation, causing donor information to become outdated
 - Reduces match quality, prolongs time between match offer and transplant, and reduces likelihood of match success
 - 38% of OPTN KPD candidates are highly sensitized, and about 38% of candidate-donor pairs were still waiting after 2 years
- Establishing a requirement for annual donor information will:
 - Ensure donor information utilized in match runs is up to date
 - Ensure that the donor pool participating in KPD match runs are actively able to donate
 - Increase overall efficiency in the OPTN KPD system
 - Improve the likelihood of match success

Rationale: ABO Matching Alignment

- Alignment of OPTN KPD A, non-A1 and AB, non-A1B matching policy with that in OPTN Kidney Policy will
 - Allow programs to establish their own titer thresholds → potentially increasing matching opportunities for some blood type O and blood type B candidates
 - Establish requirement for reconfirmation of candidate eligibility for these offers and written consent from candidates regarding willingness to accept these offers
 - Improve general efficiency in the OPTN KPD system, by allowing programs to consolidate their processes for pursuing candidate eligibility to receive these offers
- Maintaining allowance for eligible type O candidates to receive A, non-A1 offers will continue to encourage reduced inequities across blood type

Member Actions

- Transplant program participants in the OPTN KPDPP will need to:
 - Develop a written policy regarding their program's titer threshold for transplanting blood type A, non-A1 into candidates with blood type B and blood type O, and for transplanting blood type AB, non-A1 kidneys into candidates with blood type B
 - Obtain written consent from each eligible candidate regarding willingness to accept blood type A, non-A1 or blood type AB, non-A1B kidneys
 - Confirm candidates' eligibility to receive blood type A, non-A1 and AB, non-A1B every 90 days (+/-20 days)
 - Coordinate and communication with candidate-donor pairs about the requirement for annual re-evaluation
 - Complete annual re-evaluation requirements, report any changes in donor information to the OPTN, and report date of completed re-evaluation

What do you think?

1. Should the infectious disease retesting exception for previously positive donors apply to other tests that the donor has tested positive for? Which ones?
2. Should the donor's re-evaluation deadline be based on the date the donor was first registered in the OPTN KPDPP system, or the first date that the donor had an active status?
3. Is 60 days prior notice to the donor's re-evaluation date sufficient, or should the notification be sent out earlier?
4. Does 90 days between notification and potential donor ineligibility date provide a sufficient amount of time to complete the donor's re-evaluation? Should this timeframe be shortened or extended?
5. Implementation of the donor re-evaluation requirement will include an initial implementation period in which donor eligibility will not be impacted. How long should this initial implementation period be?