Proposed Histocompatibility Policy Rewrite

Histocompatibility Committee
Lee Ann Baxter-Lowe, PhD Chair
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June 23-24, 2014

Background

Summer 2012

- POC released OPTN 'plain language' rewrite
- UNOS staff flagged policies that needed to be resolved

Fall 2013

- Histo Committee distributed substantive histo policy rewrite for public comment

Problem

- Many policies identified as difficult to monitor, outdated, or more adequately and appropriately monitored by accrediting agencies
- Changes
  - **28** sections deleted or moved to guidance document to be completed at the conclusion of the project
  - Reorganized into 7 sections

Problem

- Current OPTN policy does not adequately address the need for accuracy in HLA typing used for match runs.
- Changes:

  Requirement for HLA typing to be accurately determined and reported

  Deadline for resolving HLA typing discrepancies—within 30 days of notification of the discrepancy (notification occurs in TIEDI®)

  The committee will conduct quarterly reviews of HLA typing discrepancies

Problem

- Current OPTN policy is inconsistent in testing requirements for determining unacceptable antigens
- Change:
  - For antibody screenings, laboratories must use one solid phase immunoassay using purified HLA molecules (current standard for determining UA for kidney)

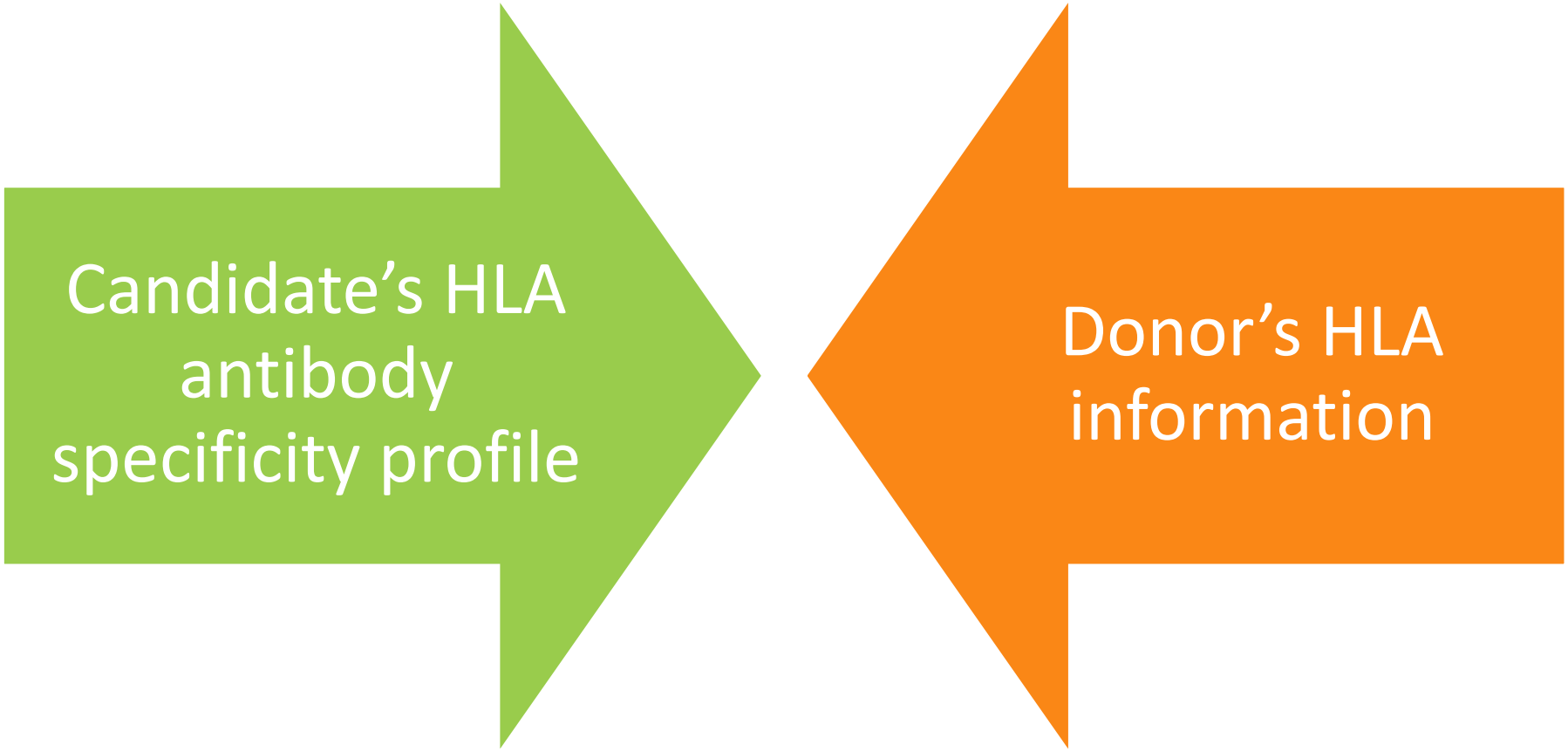
Problem

- Current OPTN policy is inconsistent in storage requirements for excess specimens from donors
- Change
  - Laboratories must preserve excess specimens from deceased donors for at least five years (current standard for 0-ABDR mismatch kidney transplants)

Problem

- OPTN policies are silent on crossmatching requirements for kidney transplantation
- Change
  - Laboratories performing histocompatibility testing for a kidney transplant or multi-organ transplant involving a kidney must perform a final crossmatch and report the results to the transplant program prior to transplant. (Based on Federal regulation CFR §493.1278).

What is a virtual crossmatch?



Overview of public comments

Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	54	30	0	8	16
Regional	11	9	2	0	0
Committee	19	0	0	0	19

Professional Societies Feedback

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Common Themes

- Crossmatching for kidney transplantation: virtual v. physical crossmatch
  - CMS interpretative guidelines do not currently allow for virtual crossmatch
  - Some patient safety concerns expressed with use of virtual crossmatch alone, especially without requirement for HLA-DQA or –DPB to be reported on deceased donors

Committee Decision

No change in policy language:

- Crossmatch method is a local medical decision
- Allow flexibility if CMS interpretation changes
- OPTN Evaluation Plan will specify that virtual crossmatches are permissible under the OPTN
- Policy notes and OPTN histocompatibility guidance document will reference the CMS regulation for laboratories

Common Themes

- Preservation of Excess Specimens
  - ‘any’ excess specimen too broad
  - only a portion or representative sample of the donor material should be saved
  - might be burdensome for labs; increase need for space, equipment, expense

Committee Decision

- Removed the word ‘any’ from the policy language, addressing the majority of the comments

Final Proposal Summary

- **28** sections deleted or moved to guidance document to be completed at the conclusion of the project
- Requirement for HLA typing to be accurately determined and reported
- Deadline for resolving HLA typing discrepancies—within 30 days of notification of the discrepancy (notification occurs in TIEDI®)

Final Proposal Summary

- For antibody screenings, laboratories must use one solid phase immunoassay using purified HLA molecules
- Laboratories must preserve excess specimens from deceased donors for at least five years
- Laboratories performing histocompatibility testing for a kidney transplant or multi-organ transplant involving a kidney must perform a final (physical or virtual) crossmatch and report the results to the transplant program prior to transplant.

OPTN Strategic Plan Alignment

- Promotes transplant safety
  by requiring histocompatibility laboratories to accurately determine and report HLA typing, resolve HLA typing discrepancies in a timely manner, and preserve excess specimens when performing histocompatibility testing that results in transplantation of a deceased donor organ
- Promotes the efficient management of the OPTN
  by simplifying policies for solid organ transplantation and eliminating policies that are outdated or adequately addressed in the standards required by histocompatibility accrediting agencies

RESOLUTION 12

RESOLVED, that Policies 4.1 through 4.15 are stricken in their entirety and replaced with new Policies 4.1 (HLA Typing), 4.2 (Resolving Discrepant Donor and Recipient HLA Typing Results), 4.3 (Antibody Screening and Reporting), 4.4 (Crossmatching), 4.5 (Blood Type Determination), 4.6 (Preservation of Excess Specimens), and 4.7 (HLA Antigen Values and Split Antigen Equivalences); and that modifications to Policies 2.8.C (Required Information for Deceased Heart Donors), 2.8.D (Required Information for Deceased Lung Donors), and 4.16 (Reference Tables of HLA Antigen Values and Split Equivalences), as set forth in Resolution 12, are hereby approved, effective September 1, 2014.

Page 46 of the Board book